

学術研究 ABS ツールキット  
IV-A

遺伝資源利用研究のアクセスと利益  
配分契約見本

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## 内容

はじめに .....	4
研究契約の種類と利用場面 .....	5
生物多様性条約の相互に合意する条件に基づく契約に含めるべき最低条件.....	7
遺伝資源提供国が提供する標準契約案 .....	9
「マニラ宣言における」バイオ探索研究の契約ガイド .....	9
アセアン生物資源および遺伝資源へのアクセスに関するフレームワーク契約書..	14
フィリピン標準研究契約申請 .....	21
スリランカ大学と企業との間の商用薬草抽出契約 .....	26
ガイアナ協同共和国研究許可申請書 .....	30
キューバ植物園とスウェーデンウプサラ大学生物多様性民族植物学のためのアクセ ス同意書見本 .....	35
アルゼンチン標準共同研究契約モデル 2 .....	38
遺伝資源商用開発ライセンス契約見本 (Gollin) .....	41
インド商用研究のためのアクセス標準契約 .....	55
インド熱帯植物園研究所薬草ノウハウ商用移転契約 .....	63
アフリカユニオン個別レベル秘密保持契約 .....	75
アフリカユニオン研究所レベル秘密保持契約.....	78
アフリカユニオン遺伝資源伝統的知識利益配分契約 .....	85
エチオピア遺伝資源 Teff 商用開発のためのアクセスと利益配分契約見本 .....	91
オーストラリア国際農業研究所 (ACIAR) 共同研究標準契約 .....	101
GEF プロジェクト中央アジア生息域内プロジェクト内情報共有契約 .....	163
遺伝資源利用国が提供する契約見本.....	173
スウェーデン Uppsala 大学とラオス大学の教育・訓練同意書見本.....	173
スウェーデンラオス研究素材収集同意書.....	175
スウェーデン・ラオス遺伝資源探索と伝統的知識に関するアクセスと利益配分確認書 .....	177
スイス科学アカデミーの標準非商用研究用アクセスと利益配分契約.....	179
英国王立植物園 Kew 標準共同研究覚書.....	208
英国王立植物園 Kew とオーストラリア北部準州アクセス利益配分契約 .....	230
カナダ農業食品省植物生殖質ライセンス契約.....	248
欧州 MicroB3 プロジェクト海洋微生物標準アクセスと利益配分契約 .....	269
米国機関のアクセスと利益配分契約案 .....	291
米国 NIH の標準秘密保持契約 .....	291

米国国立衛生研究所癌研究所治療開発プログラムと提供国機関の覚書 .....	295
米国癌研究所遺伝資源収集合意書 .....	310
カリフォルニア大学バークレー校サモアバイオ探索研究利益配分覚書 .....	321
米国国立公園生物資源標準アクセスと利益配分契約 .....	335
米国国立癌研究所 <b>Maxygen</b> 共同研究開発契約 .....	343
米国ハーバード大学商用専有実施権ライセンス契約 .....	395

## はじめに

生物多様性条約第 15 条第 4 項には「取得の機会を提供する場合には、相互に合意する条件で、かつ、この条の規定に従ってこれを提供する。」と定められており、提供国の遺伝資源にアクセスする場合「相互に合意する条件 (MAT)」に従った契約を当事者間で結ぶことが必要である。更に、第 15 条第 7 項には、遺伝資源利用の成果を当事者間で利益配分する際にも「相互に合意する条件 (MAT)」に従った契約が必要である。したがって、「相互に合意する条件 (MAT)」に従った契約は、アクセスと利益配分に関する当事者間の合意が含まれていなければならない。

MAT は当事者間の自由意思による契約が基本である。契約内容は当事者間で決めることができるし、相互に合意すればどのような条件であっても問題ないはずである。しかし、生物多様性条約の基本原則である「公正で衡平な利益配分」の精神に反するような契約を結ぶことは社会的責任から誠実な態度とはいえない。提供国は大抵低開発国あるいは開発途上国であるため、先進国で発達した契約概念に不慣れである。したがって、「公正で衡平な利益配分」を実行するためには、一方の当事者である利用者がその意味を正確に理解し、誠実に交渉を行う必要がある。

本書は、利用者である研究者が契約の概念と実際を正しく理解し、実践できるようにしたものである。具体的には、実際の契約の原文を集め、分類している。現実の契約の各条項の考え方、基本を理解し、実際の研究計画の場合に必要な条項を選ぶことができるようにした。一つの契約ではすべての研究計画を網羅することはできず、それぞれの異なった想定事態に対応して、多くの契約見本から最適な条項を選択できるようにした。

大部分の契約原文は、公開され自由に利用できるものであるが、一部未公開のものもある。できるだけそのまま転載しているが、個人情報に関する部分、特に利益配分に関するロイヤリティ率等は省かれている契約が多い。一部重要と思われる契約やモデル契約は理解のため日本語訳を付した。したがって本契約見本は参考であって、本見本の利用あるいは日本語訳に関して一切の責任を負うものではない。

## 研究契約の種類と利用場面

契約とは、研究を実施するに当たり予想される事態に対応したものであり、判断の方向性、基準について合意したものである。したがって、契約には、できるだけ多くの予想される事態に対応した条項を定める必要がある。金銭的利益配分などは学術研究では予想が困難であるが、困難である。

遺伝資源を利用する研究は千差万別であり、同じものはない。したがって、研究の実行にあたって想定される事態も千差万別と言わざるを得ない。起こりうる事態を想定した契約条項をそろえることは不可能である。ここでは、比較的頻繁に起こりうると思われる事態に対処する条項を中心にまとめている。

契約は研究計画に応じて使い分けが必要である。単に研究素材を送ってもらう場合には簡単な素材移転契約で済む場合がある。研究所間の長年に亘る大がかりな共同研究を実施するためには、覚書と共同研究契約など複数の契約が必要になる場合もある。したがって、契約を結ぶ場合にはできるだけ詳細な計画を作成し、予想される行動、作業等を明確にしておかなければならない。

一般的に研究活動に頻繁に用いられる契約の種類は下記のものがある。これらの契約単独ですべてが網羅されない場合もあり、研究の進展によっても契約を変更する場合もあるので、いくつかの契約書タイプを使い分けすることも必要である。例えば、研究所間の共同プロジェクトでは、最初覚書でプロジェクト概略を決定し、個々の研究活動はそれぞれ個別に共同研究契約を締結するのが一般的である。

表 1 契約書の種類

契約書の種類	概略
覚書(Memorandum of Understanding: MOU、Letter of Intent: LOI)	契約書としての効力はあるが、内容は簡単な場合が多く、権利関係や責任の所在が不明な場合が多いため効力は弱い。概略を決めた契約書の補完的役割として覚書を用いることもできる。
秘密保持契約 (Non-disclosure Agreement: NDA)	未公開データやノウハウの開示に際して、秘密開示の範囲、秘密事項の利用、秘密保持方法等について定めた契約書。
研究許可契約 (Research Permit)	主に研究機関等で研究を実施する際に結ぶ契約。研究機関等の規則の遵守が主な内容となる。
研究あるいは研究開発契約	提供国で実施する研究に用いられる契約。遺伝資

(Research or R&D Agreement)	源の取り扱い、素材や成果移転、利益配分などが決められる。
共同研究契約 (Research Collaboration Agreement)	研究所間などで長期に共同実施するプロジェクト等に用いられる契約。当事者の役割、目標を明確にしたものが多い。また、教育・訓練等幅広い利益配分を決める場合も多い。
ライセンス契約 (Licensing Agreement)	提供国の研究成果を実施するための実施権契約。開発ステージのものが多い。当事者の役割と責任、金銭的利益配分を明確にすることが重要。

## 生物多様性条約の相互に合意する条件に基づく契約に含めるべき最低条件

MAT 契約は当事者間の合意があればよいが、生物多様性条約の原則を外れることはできず、基本的条項は必ず含んでいなければならない。提供国では、法律・規則等で MAT 契約に含めるべき項目が決められている場合もある。したがって、MAT 契約において、特に契約規定のない提供国であって、必要ならば列記されている項目について合意することが必要と思われる。合意の上必要ないと判断された項目については、覚書等でその旨を記載しておくことも有用である。

下記に列記した項目は非商用研究の MAT 契約で出現するアクセスと利益配分関連の標準基本条項である。多くの場合、提供国の許可条件として利益配分条項が入っていることが多いので、これらの条項を契約に入れない場合は、その理由を覚書として別途記載したものを作るのがよい。

表 2 アクセスと利益配分関連の標準基本条項

最低必要条項	内容
研究目的と研究実施予定項目	利用する遺伝資源の種類、量、期間、地域など
非商用目的であること	金銭的利益の有無
遺伝資源に関係する伝統的知識利用	伝統的知識が関与する場合は、先住民・地域社会の許可と契約が必要になる
実施予定の研究における提供国の研究機関と研究者の研究に対する役割	提供国の共同研究機関、共同研究者情報と役割
実施予定の研究から予想される金銭的あるいは非金銭的利益とその配分	提供国の生物多様性研究能力開発への貢献 研究成果へのアクセス、利用方法、論文共著、 特許出願の扱い、提供国の貢献度 金銭的利益配分の扱い
実施予定の研究に使用される方法、技術	方法、技術の詳細と技術移転の可能性
研究結果や制限された収集試料の取り扱い	持ち出し禁止措置のある場合の遺伝資源の取り扱い、保存場所等
遺伝資源やその他の素材の返還・廃棄、あるいはその後のアクセス利用制限	研究終了後の遺伝資源やその派生物の取り扱い
収集試料の第三者移転の条件	収集保管している試料やその派生物の第三者への移転可否、制限条件
非商用研究から商用研究への	商用転換の場合の再契約

転換	
報告義務	年次報告、結果報告、報告会、ワークショップ等



## MANILA DECLARATION

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### Introduction

Scientists in the Asian region have long recognized that exploitation of their biological resources, notably medicinal plants, has rarely been of direct benefit to either Asian scientists or the economic development of the region.

One of the resolutions of the Symposium on the Development of Drugs from Plants, 26-28 October 1989, in Manila, was that the natural plant heritage of each country should be respected and explored for the benefit of that country. In addition, it was resolved that collaboration with foreign scientists should be conducted on a mutually acceptable basis and where possible, training of local scientists should be included.

The Seventh Meeting of the Asian Coordinating Group for Chemistry [ACGC VII] held in Xiamen, People's Republic of China, 5-7 February 1990, discussed Asian concerns over the exploitation of biological materials. This theme, concerning the collection of plant specimens and the role of Herbaria, was further discussed at the UNESCO-sponsored Botany 2000 Herbarium Curation Workshop held in Perth, Australia, 15-19 October in the same year. A code of Ethics for Foreign Plant Collectors developed at the meeting has now been modified to cover all biological materials, including marine organisms.

The exploitation of biological resources has also been dealt with in the Summary of the Workshop on Drug Development, Biological Diversity, and Economic Growth by J. Schweitzer et al. (1991) in *Journal of the National Cancer Institute*, Vol. 83:1294-98.

The Seventh Asian Symposium on Medical Plants, Spices and Other Natural Products (ASOMPS VII) held in Manila, Philippines 2-7 February 1992, concluded with an Open Forum on the Ethical Utilization of Biological Resources.

The open Forum has resulted in the following Manila Declaration, together with its appended Code of Ethics for Foreign Collectors of Biological Samples and Contract Guidelines.

Concerning

The Ethical Utilization of Asian biological resources

Developed at the Seventh Asian Symposium on Medicinal Plants, Spices and Other Natural Products (ASOMPS VII) which was held in Manila, Philippines from 2 to 7 February 1992 and was attended by 283 scientists from 31 countries.

Given that:

1. the maintenance of biological and cultural diversity is of global concern
2. developing countries are major centers of biological and cultural diversity
3. there is increased interest in biological material with medicinal and/or other economic value
4. indigenous peoples frequently possess knowledge that provides a key to natural products of economic value.

Recognizing that:

5. all national governments have sovereignty over their biological resources.
6. current practices of exploitation of biological resources and indigenous knowledge are frequently inequitable, favoring technologically advanced organizations and/or developed countries, to the disadvantage of both conservation and development in the country or region of origin.
7. there is need for further investment in training and technology in developing countries and for equitable partnerships with developed countries in order to obtain new products from biological material.
8. there has been insufficient acknowledgement of the essential role that indigenous knowledge (i.e. intellectual property) plays in identifying important natural products.

Thus, it is recommended that:

9. national governments, with advice from appropriate professional organizations within the region, develop adequate legislation to exercise control over the collection and export of biological material
10. as a high priority, governments, international agencies, multinational corporations and academic institutions, through training, laboratory construction and technology transfer, should support the development of human and material resources needed for all aspects of local biological evaluation of indigenous materials for conservation and for managed

development

11. for all collecting, the authorizing agreement(s) should include provision for any subsequent commercial development that may eventually arise
12. internationally recognized professional societies develop a code of ethics that facilitates the formation of equitable partnerships in the development of new products from biological material.
13. mandatory royalty or license agreements be established to ensure fair and equitable distribution of benefits to the region of origin
14. supply agreements should only be made by the appropriate country organization and not with individuals in that country
15. in order to avoid over exploitation of promising species, the country organization should adopt methods to protect the identity and provenance of its biological material
16. specific regulations be established to ensure that the collection and export of biological material is adequately monitored and controlled in the interest of the country supplying the material. These should include the requirements that;

16.1 collections are made together with local counterparts appointed by the country organization involved

16.2 adequately annotated, preserved voucher specimens of biological material are lodged in appropriate national institutions

16.3 sufficient funds are provided by the external organization to cover the support costs which may be incurred

16.4 if there is a threat of destructive harvesting, provision must be made for sustainable harvesting or development of alternative supplies

16.5 the traditional knowledge of local participants contributing to development of new natural products must be recognized as significant intellectual property.

## Code of Ethics for Foreign Collectors of Biological Samples

[ Appendix 1 ]

The reference document was developed at the Botany 2000 Herbarium Curation Workshop held in Perth, Western Australia, 15 to 19 October 1990. It was modified in April 1992 to cover other biological material.

The foreign collector should:

- arrange to work with a local scientist(s) and institute(s) respect regulations of the country visited; for example, by entering on a research/collecting visitor visa, not a tourist visa, and by observing regulations for export of biological

- specimens, quarantine, CITES, etc.
- obtain official permission for all collections in National Parks or protected areas.
- ascertain whether items used in scientific work and which are difficult to obtain can be contributed.
- when applying for a travel study grant, include equal travel expenses for local counterpart(s) and an amount to cover the cost of processing museum specimens or other costs of the visit to the host institute
- leave a complete set of adequately labelled duplicates with the institute before departing the country.
- ensure that Types of species described as a result of the research are deposited in the National Museum or Herbarium of the country of origin.
- inform the institute in the country of origin where duplicate specimens are to be deposited.
- not exploit the natural resources of the host country by removing high value biological products through collecting wild specimens, for example plants with potential horticultural, medicinal, cultural or other economic value, without prior permission.
- obtain a list of rare and endangered species of the country visited and not collect these species without permission.
- collect no more material than is strictly necessary; for live plant specimens, collect cuttings or seeds rather than uprooting whole plants; for marine specimens, wherever possible, collect subsections rather than whole organisms.
- leave copies of photographs/slides for the host institute(s)
- inform the host institute/appropriate organization of new localities of rare/endangered species found
- remember to send copies of research reports and publications to collaborator(s) and host institute(s)
- acknowledge collaborator(s) and host institute(s) in research reports and publications
- collect identified reference voucher specimens for all biological products to be exported.

## CONTRACT GUIDELINES

[ APPENDIX 2 ]

ASOMPS s VII recognizes that there is considerable variation in the levels of technical expertise for the development of new natural products in the region. There is also recognition that every effort should be made to reduce dependency by developing countries on technology held by developed countries. However, in the short-term, efficient development of new natural products may involve sharing of biological resources and technology between developed countries and

the countries of origin.

In order to avoid contracts which do not achieve equity in partnerships between developed countries and the country of origin, there are suggested minimum standards which should be used:

- The amount of material collected for initial screening should not normally exceed 100-500 grams (dry weight) unless specific permission is obtained.
- Payment should include all handling expenses and infrastructure costs.
- Where screening of extracts is carried out with the aid of a partner organization in the developed world, a minimum of 60% of any income arising from the supply of extracts to commercial organizations should be returned to the appropriate country organization.
- The country organization should receive a minimum of 51% of any royalties arising from external collaboration that results in marketable products. Since a fair royalty would be of the order of 3-5%, the appropriate country organization should receive a minimum royalty of 1.5-2.5%.
- The country organization should not sign agreements that give indefinite exclusive rights to any external party. Exclusivity should be limited to no more than a two-year period.
- Complete evaluation of results of any screening should be reported to the supplying country organization within a reasonable specified period.
- If there is a threat of destructive harvesting, costs of sustainable harvesting or development of alternative supplies must be borne by the external organization.
- The contribution of research participants should be recognized through co-authorship of publications.
- Initial preparation of extracts and screening should be done in the country of origin and assistance to develop this expertise should be provided wherever practicable.

アセアン生物資源および遺伝資源へのアクセスに関するフレームワーク契約書

アセアン生物資源および遺伝資源へのアクセスに関するフレームワーク契約書

## **THE ASEAN FRAMEWORK AGREEMENT ON ACCESS TO BIOLOGICAL AND GENETIC RESOURCES**

Draft Text, 24 February 2000

The Member States of the Association of South East Asian Nations (ASEAN):

**CONSCIOUS** of the fact that the Member States of the Association of South East Asian Nations possess ecosystems considered as among the most diverse in the world in which the ASEAN have a common interest;

**REALIZING** the value of biological and genetic resources in the development of products, compounds and substances that have medicinal, industrial, agricultural and related applications;

**RECOGNIZING** that access to biological and genetic resources are currently unregulated, thus the urgent need to protect ASEAN interests in these biological and genetic resources from biopiracy;

**NOTING** the provisions of the Convention on Biological Diversity on the sovereignty of States over their genetic resources and the need to promote the conservation and sustainable use of these resources as well as the fair and equitable sharing of benefits arising from its utilization;

**RECALLING** the numerous decisions of the Conference of the Parties of the Convention on Biological Diversity promoting and encouraging regional approaches to access and benefit-sharing arrangements;

**RESPECTING** the sovereignty of each Member State over their biological and genetic resources;

**AWARE** of the fundamental principle that the prior informed consent of the Member State and its indigenous peoples and local communities embodying traditional lifestyles would have to be secured before access can take place;

**ACKNOWLEDGING** the need to ensure the uniformity and consistency of access regulations in the ASEAN region by setting minimum requirements for national implementation and maximize opportunities for the conservation and sustainable use of biological and genetic resources.

Have agreed as follows:

Article 1 - Declaration of Principles

The Association of South East Asian Nations (ASEAN) adheres to the following principles with regards to access to biological and genetic resources:

That the Member States have sovereignty over biological and genetic resources within their territories in accordance with the provisions of the Convention on Biological Diversity;

That the Member States shall recognize, respect, preserve and maintain the knowledge, innovations and practices of indigenous peoples and local communities embodying traditional lifestyles to their natural resources, including genetic resources;

That the Member States shall ensure the conservation and sustainable utilization of the biological diversity in the ASEAN region;

That the Member States shall ensure fair and equitable sharing of benefits arising from the utilization of biological and genetic resources at the community, national and regional levels;

That the Member States regard biological and genetic resources as a sacred heritage for all humankind and reject the application of the patent system thereon; and

That the Member States recognize the importance of ensuring that food security in the region is enhanced and recognize the importance of the exchange and utilization of food crop germplasm already widely dispersed and utilized.

#### Article 2 - Objectives

The Framework Agreement shall have the following objectives:

To ensure the conservation and sustainable use of biological and genetic resources and equitable sharing of benefits arising from access to those resources, consistent with the principle of prior informed consent;

To accord recognition and protection to traditional knowledge of indigenous peoples and local communities, and to facilitate fair and equitable sharing of benefits with the said communities where traditional knowledge is utilized;

To ensure that the peoples of ASEAN derive maximum and fairly shared benefits from the development and uses of biological and genetic resources within their territories;

To promote cooperation among ASEAN Member States in the utilization of, and providing access to biological and genetic resources and encourage the sharing of resources;

To ensure that access regulations within the ASEAN region are uniform and consistent in accordance with identified minimum requirements as set out in this Framework Agreement;

To set minimum standards in regulating access to biological and genetic resources and strengthen national initiatives towards this objective; and

To promote technology transfer and capacity building at the regional, national and community levels.

To establish effective and participatory measures for the grant of prior informed consent up to the local level taking into account national perspectives and priorities.

#### Article 3 - Definition of Terms

Under this Framework Agreement, the following terms shall mean:

*Access to Biological and Genetic Resources* - the acquisition and use of biological and genetic resources as well as the derivatives thereof or, as applicable, intangible components, for purposes of research, bioprospecting, conservation, industrial application or commercial use, among others.

*Biological and Genetic Resources* - includes genetic materials, organisms and parts thereof,

population, or any other biotic component of ecosystems with actual or potential use or value for humanity.

*Bioprospecting* - the search for wild species with genes that produce better crops and medicines, or the exploration of biodiversity for commercially valuable genetic and biological resources.

*Resource Providers* - shall include federal, state governments, local authorities, land owners, land users, indigenous and local communities.

*Indigenous Peoples and Local Communities* - shall be defined according to ILO 169 with the following elements: identity, territory, culture, tradition and knowledge

*Traditional Knowledge* - knowledge, innovations and practices of indigenous and local communities relating to the use, properties, values and processes of any biological and genetic resource or any part thereof.

*Derivatives* - something extracted from biological and genetic resources such as blood, oils, resins, genes, seeds, spores, pollen and the like as well as the products derived from, patterned on, or incorporating manipulated compounds and/or genes.

#### Article 4 - Scope and Coverage

The Framework Agreement shall cover all biological and genetic resources including the traditional knowledge associated therein. However, access to biological and genetic resources shall not automatically mean access to the traditional knowledge associated with the resource. Access to such traditional knowledge shall be explicitly indicated in the application for access.

The ASEAN Member States shall consider *ex-situ* materials originating from the ASEAN region collected prior to the adoption of the Convention on Biological Diversity as held in trust for the benefit of humankind where the application of intellectual property rights shall not be allowed.

The ASEAN Member States shall not allow the patenting of plants, animals, microorganisms or any parts thereof, and traditional and indigenous knowledge.

The Framework Agreement shall not allow the prospecting as well as the application of intellectual property rights on genetic materials of human origin. Furthermore, the Member States strongly urge the establishment of a multilateral process to effectively regulate the access, use, and commercialization of human genetic materials.

The Framework Agreement shall not apply to the traditional uses of biological and genetic resources by indigenous and local communities in accordance with their customary practices and traditions. All other individuals, agencies and institutions shall comply with the access regulations that may be established by the Member States.

#### Article 5 - Access Instrument

The nature of the access instrument shall be determined by each Member State based on their respective national policies and legislation in accordance with the minimum terms and conditions laid down by this Framework Agreement.

#### Article 6 - Implementation of the Framework Agreement

The implementation of the Framework Agreement shall be effected by an entity to be identified from existing ASEAN bodies that may fulfill a clearing house function to attain the



objectives of this Agreement. Whenever it becomes necessary, the ASEAN Member States shall make a decision on whether a separate body within the ASEAN may be created to attain the objectives of the Framework Agreement.

There shall be established an interim clearing house mechanism the functions of which may be initially performed by the ASEAN Regional Centre For Biodiversity Conservation (ARCBC) until such time when a permanent body shall have been designated by the ASEAN. To this end, the ARCBC shall establish and maintain a database on the status of biological and genetic resources, as well as access agreements and applications.

#### Article 7 – Regional Clearing House Mechanism

The regional clearing house mechanism shall be responsible for:

Providing relevant information to resource users and the competent national authorities.

Provided that some information received by the clearing house mechanism may not be shared to parties other than the resource providers and shall be subject to appropriate security precautions;

Serving as an information node to which Member States that allowed access to genetic resources shall report such access and to disseminate such information to the other Member States;

Providing technical and legal support to competent national authorities;

Reporting to the Standing Committee the status of implementation of the Framework Agreement;

Monitoring the implementation of national access legislation;

Adopting a system of warning other Member States on applications that have been denied by a Member State including a dissemination of the reasons and circumstances for such a refusal or rejection;

#### Article 8 – Competent National Authority

The Member States shall have the obligation to designate their respective competent national authorities which shall be responsible for:

Formulating and implementing the national legislation on access;

Establishing procedures for the granting of prior informed consent at the national and local levels with the direct involvement of resource providers;

Disseminating information on the access regulation;

Establishing links with the ARCBC in the interim period and with the regional clearing house mechanism once it has been established;

Providing information to the regional clearing house mechanism which they view to be of regional importance

A Standing Committee composed of competent national authorities shall be established and shall be responsible for:

Reviewing the Framework Agreement;

Assisting Member States in the establishment of competent national authorities;

Settling disputes between and among the Member States

## Article 9 – Settlement of Disputes

In cases of dispute between Member States, between a Member State and communities, or between communities regarding access, such cases shall be settled among the concerned parties through dialogue. Dispute between a resource user and a Member-State shall be settled at the national level following the provisions of the national access regulation. Disputes among Member-States shall be settled through an arbitration process in a manner similar to what has been laid down in applicable international treaties.

## Article 10 - Prior Informed Consent and Participation of Key Stakeholders

The prior informed consent of the Member State providing the biological and genetic resources is necessary before access to genetic resources can take place. The competent national authority designated by Member States shall establish legally-binding procedures for the determination of prior informed consent up to the local level.

The procedures leading to the grant of prior informed consent at the local level shall provide for the active involvement of indigenous peoples and local communities embodying traditional lifestyles. The prior informed consent process shall respect and comply with the customary laws, practices and protocols of indigenous peoples and local communities and the disclosure of any information pertaining to the access shall be in a language understandable to the local communities.

The Member States shall provide in their access regulations that each application for prior informed consent shall be accompanied by a full disclosure of the following information:

name of the researcher, collector or collaborator;

specific area and location of the bioprospecting activity;

the defined period when the collection activities will take place;

the specific purposes, objectives, resources to be used, activities and methodologies, expected outputs and other related information;

information on the local collaborator;

information on the potential environmental and ecological impact of the bioprospecting activity; and

potential benefits to the country

If a Member State decides to deny access to a particular application, the regional clearing house mechanism shall disseminate the appropriate information to Member-States for their reference and appropriate action.

## Article 11 - Fair and Equitable Sharing of Benefits

All resource providers, particularly indigenous peoples and local communities embodying traditional lifestyles, shall be actively included in the negotiation of benefits on the basis of a full disclosure of potential benefits and risks arising from the use of the resource. Any benefit sharing arrangements that may be entered into shall not negatively interfere with traditional knowledge systems and practices of indigenous peoples and local communities.

The ASEAN Member States shall recognize the indigenous peoples and local communities as the legitimate users and custodians of biological and genetic resources, and creators of traditional knowledge. In this connection, the ASEAN Member States shall establish legal processes to ensure fair and equitable sharing of benefits arising from the use of such

knowledge and resources.

The negotiation of any benefit sharing arrangements that may come in the form of technology transfer, capacity building, monetary and non-monetary benefits arising from the utilization of a Member State's biological and genetic resources shall be left to its own initiative and discretion based on a minimum set of requirements which shall include the following:

- The participation of nationals in research activities;
- The sharing of research results, including all discoveries;
- A complete set of all voucher specimens left in national institutions;
- Access by nationals to all national specimens deposited in international *ex situ*-collections;
- The receipt by resource providers, without payment of a royalty, of all technologies developed from research on provided materials;
- Fees, royalties and financial benefits; and
- The donation to national institutions of equipment used as part of research.

For the guidance of the Member States, the Framework Agreement shall provide an Annex that will illustrate options and guidelines for appropriate benefit-sharing arrangements particularly those that have been discussed and noted by any *ad-hoc* body or Experts Panel created by the Conference of the Parties to the Convention on Biological Diversity for the purpose. Other options for benefit-sharing shall be determined by the Member States at the national level or whatever they may be able to negotiate in every application for access.

The Member States shall provide for renegotiations of whatever benefit-sharing arrangements that may have been entered into and such renegotiations shall be done with the originally identified resource providers on the terms of benefit-sharing during the development and when new uses are discovered for those biological and genetic resources that have been collected.

#### Article 12 - Common Fund for Biodiversity Conservation

There is hereby created, at the level of the ASEAN, a Common Fund specifically and only for biodiversity conservation. Contributions to this Fund shall be sourced from a share in the revenues derived from any commercialization of the use of common and shared resources among the Member States. The ASEAN Working Group on Nature Conservation and Biodiversity (AWGNCB) shall make the appropriate recommendations on the implementation mechanisms for the said Fund.

The Common Fund shall also be sourced from a portion of whatever the Member States shall impose as the appropriate charges and fees on each access application submitted to their respective competent national authorities. Additional support to the Common Fund shall also be derived from whatever benefit-sharing arrangements that may be negotiated by each Member State, on a case-to-case basis.

#### Article 13 - Environmental and Social Impact and Biosafety Concerns

In view of its importance in realizing the objectives of biodiversity conservation, this Framework Agreement shall conform with any national, regional and international guidelines on biosafety without prejudice to a separate and distinct framework or protocol on the issue that may be developed by the ASEAN Working Group on Nature Conservation and Biodiversity (AWGNCB) taking into account the work of other relevant ASEAN bodies.

This Framework Agreement shall also take into consideration the various environmental and social impacts of access to genetic resources in conformity with national, regional and international guidelines.

Comments, remarks and suggestions can be forwarded until 31 May 2000 to:

SEARICE

Elipdio V. Peria

Unit 331 Eagle Court Condominium #26 Matalino Street Central District, Diliman Quezon City Philippines

Tel. +63 (2) 433-7182

Fax +63 (2) 921-7453

eMail [searice@philonline.com.ph](mailto:searice@philonline.com.ph)

The draft document together with the comments, remarks and suggestions will be presented in June 2000 to the ASEAN Working Group for Nature Conservation and Biodiversity for decision.

フィリッピン標準研究契約申請

APPLICATION FOR RESEARCH AGREEMENT

\_\_\_\_\_ ARA \_\_\_\_\_ CRA

1.a

Name \_\_\_\_\_

Last Name First Name Middle Name

Nationality \_\_\_\_\_ Degree (Sought/Completed) \_\_\_\_\_

Nature of Employment: Government \_\_\_\_\_

Private \_\_\_\_\_

Present Position/Official Designation \_\_\_\_\_

School/Institution/Agency \_\_\_\_\_

1.b

Company/Organization/Institution/Agency

(To be filled up by Head)

Name of Company/Institution/Organization/Agency:

\_\_\_\_\_

Address \_\_\_\_\_

Head \_\_\_\_\_

Tel. No. \_\_\_\_\_ Fax No. \_\_\_\_\_

2. Species/Specimen kind and number/quantity to be collected (e.g. mammals, birds, flowering plants, signs, etc.)

\_\_\_\_\_

\_\_\_\_\_

3. Purpose of Collection \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

4. Places of Collection \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

5. List of researches (foreign and local counterpart) indicate role in project implementation (attach resume)

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6. List of Foreign researchers/contact person assisting you in the field and institutional affiliations

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7. List of cooperating Filipino researchers and their institutional affiliations

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I certify that the statements made herein are correct and true and I will abide by the decision of the IACBGR on this application.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

SUBSCRIBED AND SWORN BEFORE ME this \_\_\_\_ day, 199\_\_ at \_\_\_\_\_, Philippines, personally appeared with Residence Certificate No. \_\_\_\_\_ issued on \_\_\_\_\_, 199\_\_ at \_\_\_\_\_ known to me to be the same person who executed the foregoing instrument and acknowledge to me that the same is his/her voluntary act and deed.

Notary Public

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Please submit the following documents together with this duly signed application form:

- \_\_\_ 1. Three (3) copies of research proposal following attached format.
- \_\_\_ 2. For 1.a applicants, Letter of endorsement from Head of Institution where applicant is affiliated or Reputable Institution, Museum or

University as may be required.

\_\_\_ 3. For 1.b applicants, Company/Institution/Organization/Agency Profile

\_\_\_ 4. Letter of acceptance from Filipino counterpart(s) authorized by or representing the host institutions to cooperate in your activities in the Philippines.

\_\_\_ 5. Two (2) 2" x 2" ID Picture

\_\_\_ 6. Others

**RESEARCH PROPOSAL FORMAT**

\_\_\_ Academic \_\_\_ Commercial

1. Project Title

\_\_\_\_\_

2. Project/Research Objectives

2.1 \_\_\_\_\_

2.2 \_\_\_\_\_

2.3 \_\_\_\_\_

3. Places of Collection

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Projected date of implementation and reason

\_\_\_\_\_

\_\_\_\_\_

4. Bioresources and quantity (if possible) (indicate live or dead specimen specify if by-products or derivatives)

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

5. Methodology (use separate sheet if necessary)

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

6. Manner data to be gathered (recorded, photographed, video, collected, observed, etc.) and format (notes, specimens, photographs, etc.)

\_\_\_\_\_

\_\_\_\_\_



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7. Anticipated intermediate and final destination of bioresources, etc.

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8. How bioresources obtained are to be used initially (i.e. national collection) subsequently (e.g.) drug exploitation, field guide preparation, etc.)

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9. Description of funding support with budget (use separate sheet if necessary)

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10. Analysis of the research of foreseen impact on biological diversity.

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11. Detailed description of immediate compensation anticipated.

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12. Detailed description of long-term compensation anticipated.

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13. List of in-country entities likely to receive compensation enumerated in # 11 and reasons (logical and legal)

スリランカ大学と企業間の商用薬草抽出契約

スリランカ大学と企業間の商用薬草抽出契約

前提

Agreement for the Testing of Plant Extracts between the Company and the University (Sri Lanka), dated January 1st, 2000

**Subject matter** Plant Genetic Resources.

**Summary of use(s)** Plant extracts shall be tested for possible use in the field of agribusiness (crop protection and animal health). If the results of preliminary biological tests are promising, the Company will carry out further investigations such as isolation, structure elucidation and biologically testing of the biologically active compounds.

**Purpose or background** In return for a fellowship and, in the event of commercialisation, the payment of royalties, the University agrees to carry out a research project with the Company dealing with the selection of 120 plant extracts (2 g per extract) per year, with a view to their possible future utilisation in agribusiness (crop protection and animal health). The University is responsible for acquiring all proper licenses and paperwork to allow the legal transfer of the material to the Company.

**Contact details** Dr. V. Kumar, Senior Professor, Department of Chemistry, University of Peradeniya, Peradeniya, Sri Lanka.

E-mail: vkumar@pdn.ac.lk

Telephone: +94-8-389151 Ext 4278, +94-77-801184

Fax: +94-8-389939, +94-8-389129

## **THE PARTIES AGREE AS FOLLOWS:**

The University agrees to carry out a research project dealing with the selection of plant extracts in view of their possible utilisation in agribusiness (crop protection and animal health), hereinafter referred to as "the Project".

The University shall provide exclusively to the Company 120 plant extracts (2 g per extract) per year for testing in the field of agribusiness (crop protection and animal health). The University is responsible for acquiring all proper licenses and paperwork to allow the legal transfer of the material to the Company.

The Company agrees to grant the University in connection with the Project a fellowship for the period of 3 (three) years from January 1, 2000, until December 31, 2002. The amount of such fellowship covering salary and consumables shall be US Dollars 15'000 (fifteen thousand) for each calendar year to be paid by in advance in January of each year.

The extracts (obtained according to clause 1 and 2) shall be sent to the Company by air mail. The delivery of a lot shall be announced by the University two weeks in advance and the arrival shall be confirmed by the Company.

At the latest of 12 (twelve) months after receipt of the extracts, the Company shall inform the University about the preliminary biological results of the testing and its decision to continue or discontinue the biological programs.

If the results are considered as promising by the Company, the University will at the request of the Company collect 3 kg of plant material and send 20 g of plant extracts of the "Selected Plant" against a compensation of US Dollars 400 (four hundred) for one plant. The Company will carry out further investigations on Selected Plants. Further investigations means isolation, structure elucidation and biologically testing of the biologically active compounds. Extracts/Plants that are either inactive or uninteresting for the Company, shall, upon the Company's declaration thereof, be at the department's free disposal and shall then no longer be covered by this Agreement.

Where the Company and the University agree, the University may also carry out the investigation on some active plants and provide the results exclusively to the Company. The costs for these investigations shall be covered by the fellowship as pointed out in clause 3.

Should a patentable invention result from the Company's or the University's testing and analytical activity, the Company is free to apply for patents with regard to such invention in its name and at its expense as it wishes. Any such patents will be filed by the Company indicating the name(s) of the University, its collaborator(s) and the representative(s) of the company, as the case may be, as inventor(s). To this end, the University agrees to execute such documents and signatures as may legally be required.

If and as soon as the Company expresses interest in commercialising chemical products on the basis of the natural constituent(s), the University shall grant to the Company, an exclusive and world-wide right to manufacture, formulate, use and sell products on the basis of the natural constituent(s), isolated from "Selected Plants".

In consideration for the right to commercialise the Company shall pay the University the following compensation: A running royalty which shall be no more than 1% of the net sales value of chemical products manufactured by the Company on the basis of natural constituent(s) selected within the Project. The royalty rate will be agreed between the parties in consideration of the situation of the market and development costs of said chemical products provided, however, that the total amount of royalties to be paid by the Company will in no case exceed US Dollars 100'000 per year for each single compound during 10 (ten) years after commercialisation and that royalty payments will be limited to such period of time.

If the Company or any of its licensees do not take up the manufacture of chemical products on the basis of the natural constituent(s) selected within the Project within 10 (ten) years after execution of the grant, the exclusive right of commercialisation as defined in clause 7 shall lapse and the respective industrial property rights applied for in the name of the Company will be offered for assignment to the University free of charge.

With the payments according to clause 3 (fellowship) and clause 7 (royalties) all obligations with regard to the Convention on Biological Diversity of June 5, 1992, which was signed by Sri Lanka and the home country of the Company, are met.

Both parties undertake to treat all technical and commercial information which they receive from each other as strictly secret except for the purposes of this

Agreement, The obligation of secrecy shall survive the expiration and/or termination of this Agreement or part of it, for a period of seven (7) years.

This Agreement shall enter into effect on January 1st 2000 and shall remain in force until December 31st 2002. Notwithstanding such termination, the terms of this Agreement shall continue to be applied with respect to any plant and/or extracts which have been handed over to the Company prior to December 31st 2002 and which has not returned to the University by declaration according to clause 5 herein above.

This Agreement shall be governed by the substantive laws of the home country of the Company. All disputes arising in connection with the present Agreement shall be finally settled under the Rules of Conciliation and Arbitration of the home city of the Company.

ガイアナ協同共和国研究許可申請書

ガイアナ協同共和国研究許可申請書

**Research Permit Examples**

**FORM B-001**

ENVIRONMENTAL PROTECTION AGENCY/EPA APPLICATION FOR SCIENTIFIC AND/OR COMMERCIAL RESEARCH ON BIODIVERSITY IN THE COOPERATIVE REPUBLIC OF GUYANA	ガイアナ協同共和国生物多様性の非商用あるいは/および商用研究の環境保護局 (EPA) への申請
The EPA welcomes applications from persons interested in conducting biodiversity research in Guyana.	EPAはガイアナ協同共和国での生物多様性研究に関心のあるものの申請を歓迎する。
NOTES TO THE APPLICANT	申請者への通達
a. A non-refundable fee of US\$75 is required for the processing of each application. The fee, along with the method of payment, can be found online.	a. 申請処理に返却不可な US\$75 の費用がかかる。支払方法はオンラインで見つけられる。
b. All questions must be answered. Separate sheet(s) may be used for answers to any or all questions.	b. 下記質問には必ず答えなければならない。別紙を答えに使用することができる。
c. All applications must be typewritten. Failure to do so will result in a delay in processing the application.	c. 全ての申請書はタイプすること。そうしない場合は、申請処理が遅れる。
d. Two (2) copies of the completed Application Form must be submitted, not later than three (3) months prior to the commencement of the research, to the Environmental Protection Agency for review.	d. 研究活動開始の3か月前までに2通の申請書コピーをつけて申請すること。
e. All current sponsors, employers, collaborating institutions, and affiliations with commercial	e. 全ての研究者に関係し、提案されている研究に関連する、すべてのスポンサー、従業員、共同研究機関、提携企業

entities, relating to any or all of the researchers, and for the proposed research, must be specified (see 11 below).	等は特定されなければならない。
f. Any change in the details of the application (for example, in the membership of the research team, or current sponsors/institutions), which occurs after approval has been given, should be reported to the EPA in writing.	f. 承認後の申請書の内容の変更（例えば、研究チームのメンバーシップ、または、スポンサーや研究機関）はEPAに書面で報告しなければならない。
g. The kinds and quantities of information, samples, and specimens proposed to be collected as part of the research are expected to be justified by the aims and objectives of the research, and quantities of materials to be removed are to be reasonable in relation to the abundance of any particular species (see 5 to 12 below).	g. 研究の一環として収集を希望する情報、サンプル、標本の種類と量は、研究の目的と目標によって決められると考えている。収集する材料の量は、特定の種の生息状況によって合理的に決定される。
h. It is recommended that applications be submitted before funding arrangements for the research are finalized with funding agencies, or, at the latest, prior to the departure of the research team for Guyana.	h. 資金提供機関との間で資金提供の取り決めが決定する前に、あるいは、少なくともガイアナに研究チームが出発する前に、本申請を行うことが望ましい。
i. If you are intending to conduct research as an individual, you must submit a letter of recommendation from a recognized Institution/Body/Society. In the case of student applicants, the name and signature of the supervisor is required.	i. もし、研究者が個人で研究活動を行う場合、よく知られた研究機関/研究所/研究学会から推薦状を提出しなければならない。学生が申請する場合は、指導教官の名前とサインが必要である。
j. The Researcher must ensure that all necessary precautions be taken with regard to the health (vaccinations) of the research team.	j. 研究者は、研究チームの健康（予防接種）に関してすべての必要な予防措置をしなければならない。
k. The researcher/research team must	k. 研究者/研究チームは、生物多様性研究

work in accordance with the approved Guidelines for Biodiversity Research.	に関する承認されたガイドラインに従って研究を行わなければならない。
Please provide the information specified in the items below:	記載項目 下記項目について情報を提供すること。
1. Name of authorized signatory to this application	1. 本申請書に正式署名する研究者の名前
2. Agency/institution on whose behalf the application is being made, if any	2. 必要ならば、本申請を行う政府機関/研究機関
3. Postal address, telephone, fax and e-mail	3. 住所、電話、fax、e-mail
4. Descriptive title of the proposed project	4. 提案された研究プロジェクトのタイトル
5. Summary of the proposed project (please attach a copy of the project proposal)	5. 提案された研究プロジェクトの要約 (プロジェクト提案のコピー添付)
6. Objectives; proposed site(s) of the research (give as precise geographical delineation as possible); description of the proposed research, including methodology(ies):	6. 目的; 研究提案場所 (できる限り正確な地図上の位置); 方法を含む提案研究の内容
7. What kinds of material/information are to be collected/produced/imported? (Please check appropriate boxes) <input type="checkbox"/> Specimen/sample collection (specify nature and numbers) <input type="checkbox"/> Recordings (audio and video) <input type="checkbox"/> Photographs <input type="checkbox"/> Written notes <input type="checkbox"/> Computer entries <input type="checkbox"/> Reports <input type="checkbox"/> Articles and scientific papers <input type="checkbox"/> Other outputs (specify) _____	7. 収集、生産、輸入される材料/情報の種類 (適切な個所にチェックを入れる)  <input type="checkbox"/> Specimen/sample collection (specify nature and numbers) <input type="checkbox"/> Recordings (audio and video) <input type="checkbox"/> Photographs <input type="checkbox"/> Written notes <input type="checkbox"/> Computer entries <input type="checkbox"/> Reports <input type="checkbox"/> Articles and scientific papers <input type="checkbox"/> Other outputs (specify) _____
8. Anticipated intermediate and final destinations of all information/reports and specimens and materials:	8. すべての、情報/報告書、標本、材料の予想される中間及び最終行先



<p>9. Is your project intended for commercial or exclusively academic purposes? Please specify your exact intentions. Commercial purposes here include but are not limited to:</p> <ul style="list-style-type: none"> <li>(i) The use of samples or specimens, photographic and audiovisual materials and illustrations, for commercial purposes</li> <li>(ii) Chemical, pharmacological, and biotechnological study</li> <li>(iii) The use of materials or specimens for propagation or breeding purposes</li> </ul> <p>Academic purposes here refer to only taxonomic, conservation, ecological, and biogeographical investigations</p>	<p>9. 計画プロジェクトは商用目的かそれとも研究目的に限定されるか？どちらかを特定すること。商用目的とは下記のものを含むがこのかぎりではない。</p> <ul style="list-style-type: none"> <li>i. 商用目的で、サンプル、標本、写真やオーディオやイラストを使用すること</li> <li>ii. 化学的、薬理的、バイオテクノロジー的な研究</li> <li>iii. 繁殖または育種目的で材料や標本を使用すること</li> </ul> <p>学術研究目的とは、分類学的、環境保全的、生態学的、バイオ分布学的な研究のこのみを意味する。</p> <p>研究期間（ガイアナ到着/出発日、奥地での滞在日）</p>
<p>10. Time schedule (arrival in/and departure from Guyana, including dates in hinterland)</p>	<p>10. 研究期間（ガイアナ到着/出発日、奥地での滞在日）</p>
<p>11. Composition of research team (attach very brief CVs). Also attach a statement on current sponsors.</p>	<p>11. 研究チームの構成（簡単な履歴書添付）</p>
<p>12. Expected environmental impact of the research (brief statement)</p>	<p>12. 研究による環境への影響（簡単な説明）</p>
<p>13. Expected source of funding (see Notes to the applicant [d]). Please attach the budget proposal that will be or has been submitted to the funding agency, including foreign and (estimated) local costs.</p>	<p>13. 予想される資金提供機関名。海外や地域での費用を含む、資金提供機関へ提出する予算提案書を添付すること。</p>
<p>14. Proposed linkage(s) with local institution(s), if any. (State whether each institution has been formally approached and indicate (very briefly) its response.)</p>	<p>14. もしあるなら、地域研究機関との連携提案。（正式な連携提案をしているかどうかと、ごく簡単な相手の反応を記載すること）</p>
<p>15. Training component for local counterparts</p>	<p>15. 地域対応者への訓練内容。</p>
<p>16. Do you intend to conduct research on lands legally owned or occupied</p>	<p>16. 先住民によって公式に所有され、占有されている土地で研究を行うか？もし</p>

<p>by indigenous or local communities? If so, where?</p>	<p>そうなら、どこで行うか。</p>
<p>17. Give a brief description of how Guyana will benefit from your research, including what compensation you anticipate immediately and in the long term for Guyana (cash, barter, services, specimens, sharing future production possibilities from research, royalties, equipment, or materials).</p>	<p>17. 研究によってガイアナがどのような利益が得られるのか簡潔に説明すること。利益には、ガイアナに対する短期と長期の利益配分、例えば、現金、物々交換、サービス、標本、研究から生じる将来の生産分配、ロイヤリティ、実験機器、材料なども含むこと。</p>
<p>Signature of applicant Signature of supervisor, if applicable Office held in the Agency/Institution Date Environmental Protection Agency IAST Building, U.G. Campus, Turkeyen</p>	<p>申請者署名 申請者管理者署名（必要ならば） 研究機関の住所 日付 ガイアナ協同共和国環境保護機関 署名</p>

キューバ植物園とスウェーデンウプサラ大学生物多様性民族植物学のためのアクセス  
同意書見本

**Prior Informed Consent—Biodiversity and Ethnobotany: *Garcinia*  
*sensu lato* (Clusiaceae) in Cuba**

EXCHANGE CONTRACT FOR ACCESSING BIOLOGICAL RESOURCES  
BETWEEN THE NATIONAL BOTANICAL GARDEN OF CUBA (JBN) AND  
THE INSTITUTE OF EVOLUTION, GENOMICS AND SYSTEMATICS,  
UPPSALA UNIVERSITY, SWEDEN

ON BEHALF OF THE FIRST PART: The National Botanical Garden under  
ownership of Havana University, Ministry of Education, JBN in advance, with  
legal address in Carretera El Rocio Km 3, Calabazar, Boyeros, 19230—Havana,  
Cuba, represented in this document by Dr. Angela T. Leiva Sánchez, as head  
director of the institution.

ON BEHALF OF THE OTHER PART: The Department of Evolution, Genomics  
and Systematics, Uppsala University, Uppsala, Sweden, IEGSU in advance, with  
legal address in Norbyvägen 18D, SE-752 36 Uppsala, Sweden, represented in  
this document by Dr. Britta Ekholm as head of the Ethnobotany group of the  
Department of Systematic Botany at the Institute EGS, Uppsala University,  
Uppsala, Sweden.

Both Parts Manifest:

- that they have mutual interest to establish a bilateral collaboration for  
accessing biological resources, with the specifications, obligations, and  
conditions that figure in the present document
- that both parts have the means and resources needed to get the exchange of  
experiences in the best conditions with the requested quality
- that they commit themselves to observing the strict fulfillment and respect of  
the Convention on Biological Diversity which both parts have signed
- that they acknowledge the mutual benefits that such a collaboration will  
represent for the contracting institutions and both countries

BOTH PARTS: Acknowledging the person and legal entity which they sign on this  
document, agree to subscribe to the present contract following the next  
specifications, obligations and conditions:

FIRST: The objective of the present bilateral contract is to access the Cuban alive  
biological resources for scientific purposes, for taxonomical studies,  
ethnobotanical studies, the investigation of chemical compounds and molecular  
studies on Cuban tropical plants of the genus *Garcinia* L. (Clusiaceae), in

cooperation between JBN and EGS; the biological alive plant resources being accessed will be sent from Cuba to Sweden, as a sample big enough to achieve the above mentioned studies, from the wild harvest or donations of the Botanical Gardens in the National Network of Cuba.

SECOND: The alive plant biological resources of Cuba from wild harvesting or donations of the Botanical Gardens in the National Network of Cuba will always have a herbarium sample that will be kept as part of the herbarium collections HAJB of the National Botanical Garden and UPS under ownership of the Uppsala University Museum of Evolution, and they will not be utilized for commercial purposes or exchange; if new species are described from this material, the holotypes must be deposited at the HAJB herbarium.

THIRD: JBN will manage and pay the expenses for the official permits needed to access the natural areas, the biodiversity, exportation, and plant care.

FOURTH: EGS will pay the expenses in Cuba of the Cuban partner for the supervisor, the driver that will take part in the expeditions and the plant care revision, the customs fee, and the transportation for the plant biological material.

FIFTH: The live Cuban biological resources sent from JBN to EGS, collected from germination and cultivation will not be used for commercial purposes under any circumstances, if either the material's origin is wild collected or is a donation from the Botanical Gardens in the Cuban National Network.

SIXTH: The results derived from the chemical and molecular studies will be for mutual benefit and will be shared by JBN and IECSU, in the way of scientific publications or otherwise, as agreed by the parts.

SEVENTH: The transportation from JBN to IECSU of the living plant biological resources will be done by EGS researchers directly from the International Airport José Martí, Havana, to Stockholm.

EIGHTH: Possible modifications or additions to the present contract should be made through a formal agreement between the parties as included as an appendix to the present Agreement.

NINTH: The present Contract of collaboration between JBN and EGS will be valid for two years from the signature date, extendable by equal periods, provided that no party terminates the agreement early.

TENTH: Any difference or difficulty caused in relation with this Contract interpretation or execution, while in effect, will be resolved by means of friendly negotiations between the parties. In case an agreement cannot be reached, the conflict will be solved in the Arbitration Court of the Chamber of Commerce of the Cuban Republic.

ELEVENTH: The applicable law is the portion of Cuban Law that agrees with the Convention on Biological Diversity, which both parties have signed.

Two exact copies of the Contract will be signed, and both copies will be legally valid and will carry the approval of the Cuban Authority of the Centre for Inspection and Environmental Control. Each party will keep a copy in its possession.

The present document is signed on 3 March of the year 2007.

National Botanical Garden of Cuba Institute of Evolution, Genomics and Systematics

Fdo. Dr. Enrico Chavez Fdo. Dr. Britta Ekholm  
Head Director Head of the Ethnobotany group in the  
Department of Systematic Botany

Vto. Bno. Ing. Tomás Rivera Amarán  
Director del C.I.C.A.  
Science, Technology and Environment Ministry

アルゼンチン標準共同研究契約モデル 2

アルゼンチン標準共同研究契約モデル 2

**Model 2:**

**“-----” Project Research Collaboration Agreement**

This Agreement is entered into in \_\_\_\_, this first day of October of 2010

BY AND BETWEEN

XXXXXXXX, ... professor and researcher at AAAA, on his/her own behalf and in the exercise of his/her authority to define his/her own topic of research,

DNI, Domicile in Argentina

Guarantee of AAAA

AND

YYYYYY, tenured scientist at BBBB, on his/her own behalf and in the exercise of his/her authority to define his/her own topic of research,

DNI-PASSPORT, Domicile in his/her country and in Argentina

Guarantee of BBBB

Both Parties mutually acknowledge their legal capacity to execute this Collaboration Agreement within the framework of their scientific activity;

WHEREAS

Existing scientific information on ..... is very limited;

Both Parties share an interest in furthering the study of .....

Both Parties have collaborated on research in the past;

The Argentine Party does not have sufficient means or sufficient experience to undertake a study with this objective;

Party B both has the means to finance said study for at least one year and has experience with multiple similar studies;

IN WITNESS WHEREOF, both Parties agree to execute this Collaboration Agreement, subject to the following:

#### Terms and Conditions of the Agreement

This ..... Agreement is made and entered into by and between the following Parties: ....., herein represented by its director, (profession) Dr. ....., an Argentine national with DNI N° -----, whose domicile is located at ..... ("PROVIDER"), AND ..... herein represented by its director, (profession) ....., a(n) (nationality) national with identification document N° -----, whose domicile is located at ----- ("RECIPIENT"). The Parties agree as follows:

#### CLAUSES

1. The objective of this Agreement is to lay the foundations for the first year of collaboration on the research project entitled "\_\_\_\_\_".
2. Management of and responsibility for the development of the project shall be shared by both Parties. By mutual consent, the Parties may introduce research collaborators to the project.
3. The country of PROVIDER shall exclusively retain all intellectual property rights related to the material used and its derivatives.
4. The research results published in respect of the material used shall be published jointly by RECIPIENT scientist(s) and PROVIDER scientist(s). RECIPIENT and PROVIDER shall duly acknowledge the source of the material in all publications related to the material used; RECIPIENT and PROVIDER shall send copies of the publications and preliminary reports related to the material used and its modifications to the Argentine Ministry of Environment and Sustainable Development.

5. PROVIDER and RECIPIENT shall take all necessary measures to ensure the respect, preservation, and maintenance of the knowledge, innovations, and practices of the communities of their respective countries; PROVIDER and RECIPIENT shall likewise take all necessary measures to ensure compliance with all the applicable laws, rules, guidelines and regulations of their respective countries.

6. Both Parties constitute special domicile for all judicial and extrajudicial purposes deriving from the provisions of this Agreement, as stated above, and voluntarily submit to the jurisdiction of the Courts of the City of Buenos Aires, Argentina, for approval, application, interpretation, or any other purpose in respect of these presents, and expressly waive any other forum or jurisdiction to which they may have recourse.

7. The Argentine Party

8. The other Party

9. The biological samples shall be cold-preserved and transported to ... for analysis in specialized laboratories. The purpose of such analysis shall be ....

10. Any remainder of the biological samples shall be .....(detail).

11. Research results shall be jointly published to reflect the collaboration described herein.

12. Both Parties shall disseminate the research results as extensively as possible, publishing said results in international periodicals. The Argentine Party shall, moreover, disseminate the results across all spheres of administration, particularly those of public administration, which might consider them useful.

13. This Agreement shall be valid for one year.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement in duplicate at the place and on the date above mentioned.



遺伝資源商用開発ライセンス契約見本 (Gollin)

遺伝資源商用開発ライセンス契約見本 (Gollin)

前提

<b>Subject matter</b>	"Formulations" shall mean a combination of natural products developed by Licensor for the treatment of ****, including any components of and modifications made to such formula for any reason, including, but not limited, to addressing the scarcity of any herbal component in the formulation or any governmental restriction that prohibits the sale of the unmodified formulation for any reason.
<b>Summary of use(s)</b>	The following license is an exclusive, worldwide license under this Agreement to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import the Formulations, identified for all fields of use as well as the right to practice or have practiced the Formulations, as well as methods for making and using the Formulations in all fields of use.
<b>Purpose or background</b>	WHEREAS, *** and *** (collectively, "Licensor") have certain knowledge and materials regarding a certain formulation of *** for the treatment of ****. Licensor shares the interest of *** to bring this formulation to the *** through further research and development and commercialization in order to benefit the public health worldwide. WHEREAS, Licensor and *** enter into this Agreement in order to permit *** to commercialize this formulation with the technical assistance of Licensor. *** wishes to share the credit and financial benefits of commercializing this formulation with the Licensor. WHEREAS, *** and Licensor anticipate the possible need to amend this Agreement or enter into other Agreements in the future that may provide additional terms or conditions in order to commercialize the **** formulation and other such formulations.
<b>Contact details</b>	Michael A. Gollin, VENABLE Attorneys at Law, 1201 New York Avenue, N.W., Suite 1000, Washington, DC 20005-3917, United States of America. E-mail: magollin@venable.com

遺伝資源商用開発ライセンス契約見本本文

<p>WITNESSETH:</p> <p>WHEREAS, *** and *** (collectively, "Licensor") have certain knowledge and materials regarding a certain formulation of **** for the treatment of ****. Licensor shares the interest of *** to bring this formulation to the *** through further research and development and commercialization in order to benefit the public health worldwide.</p>	<p>契約の証</p> <p>A（ライセンサーと称する）はXXX組成物とそれを用いる治療法について伝統的知識と遺伝資源を持っている。ライセンサーAは、XXX組成物とそれを用いる治療法が更なる研究開発によって世界の公衆衛生の利益のためになると考えているライセンシーBの興味を共有している。</p>
<p>WHEREAS, Licensor and *** enter into this Agreement in order to permit *** to commercialize this formulation with the technical assistance of Licensor. *** wishes to share the credit and financial benefits of commercializing this formulation with the Licensor.</p>	<p>そこで、ライセンサーAとライセンシーBは、ライセンサーAの技術援助のもとでXXX組成物を工業化するための許可を得るために本契約に合意した。ライセンシーBはライセンサーAと当該組成物の工業化の保証と経済利益を配分することを希望している。</p>
<p>WHEREAS, *** and Licensor anticipate the possible need to amend this Agreement or enter into other Agreements in the future that may provide additional terms or conditions in order to commercialize the **** formulation and other such formulations.</p>	<p>ライセンシーBとライセンサーAは、XXX組成物やその他の組成物の商用化のために、将来付加的な条項や条件を加える本契約の修正あるいは他の契約締結の必要性を認識している。</p>
<p>NOW WHEREFORE *** AND LICENSOR, IN A SPIRIT OF COOPERATION AND COLLABORATION, AGREE TO THE FOLLOWING TERMS AND</p>	<p>そこで、ライセンシーBとライセンサーAは協力共同関係の精神に基づいて次の条項と条件に合意した。</p>

<p>CONDITIONS:</p>	
<p>1. Under this Agreement and according to these terms, Licensor hereby grants the following license rights to ***, which hereby accepts these license rights. The following license is an exclusive, worldwide license under this Agreement to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import the Formulations, identified for all fields of use as well as the right to practice or have practiced the Formulations, as well as methods for making and using the Formulations in all fields of use:</p>	<p>第一条</p> <p>本契約とその条項に従って、ライセンサーAは以下のライセンス権をライセンシーBに与える。ライセンス権は排他的かつ世界全体を対象にして、XXX組成物を製造し、利用し、販売し、販売依頼し、輸入することができる。利用範囲はすべてであり、XXX組成を処方したりする権利も含まれる。更に、すべての利用領域でXXX組成を利用したり製造したりする方法についても権利を有する。</p>
<p>1. As used hereunder the term "Formulations" shall mean a combination of natural products developed by Licensor for the treatment of ****, including any components of and modifications made to such formula for any reason, including, but not limited, to addressing the scarcity of any herbal component in the formulation or any governmental restriction that prohibits the sale of the unmodified formulation for any reason.</p>	<p>1. 本契約で使われる組成物とは、特定疾患領域の治療のためにライセンサーAが開発した自然製品の混合物であるが、あらゆる理由によってその組成物に加えられた成分や変更物のあらゆる組成物も含まれている。また、組成物中の薬用成分の不足に対処したり、またいかなる理由によって未修飾の組成物の販売を禁止する政府制限に対処したりすることも含まれる。</p>
<p>2. The right by *** to grant sublicenses for all or part of the rights granted hereunder, and</p>	<p>2. ライセンシーBの権利には、すべてあるいは一部の権利のサブライセンス権も含まれる。</p>
<p>3. The right by *** to exercise an option to exclusively license from the Licensor any and all other formulations ("Other Formulations") developed by the Licensor, the option to remain open during the term of this Agreement.</p>	<p>3. ライセンシーBの権利には、その他の組成物の一部あるいは全体についてライセンサーAから排他的ライセンスを受けるオプション権を行使する権利も含まれる。</p>

<p>2. Licensor agrees that *** will have sixty (60) days to confirm in writing to Licensor, ***' exercise of its option to exclusively license Other Formulations not yet identified to *** once such Other Formulations have been identified or brought to the attention of ***. The Licensor is free to license to other parties those Other Formulations that *** does not license under this Agreement.</p>	<p>第2条</p> <p>ライセンサーAは、現在は存在しないがその他の組成物が同定されライセンシーBの注目を浴びたとき、ライセンシーBがその他の組成物の排他的ライセンスを受けるオプション権を、ライセンサーAに60日前の書面通知で行使する権利を持っていることにライセンサーAは同意する。ライセンサーAは、ライセンシーBが本契約に従ってライセンスを受けなかったその他の組成物についてライセンスする自由を持っている。</p>
<p>3. *** and Licensor agree that, under this Agreement, Licensor can continue to use the **** Formulation and Other Formulations to treat its existing and future patients and sell any medicines containing the *** Formulation or Other Formulations to such patients. Licensor, however, cannot (a) sell any medicines containing such Formulation or Other Formulations to any other persons, (b) enter into any arrangements other than this Agreement to commercialize the **** Formulation or Other Formulations, or (c) engage in any activity that would otherwise be in violation of this exclusive license.</p>	<p>第3条</p> <p>本契約に従えば、XXX組成物やその他の組成物を現在あるいは将来の患者の治療のために、あるいはそのような患者にXXX組成物やその他の組成物を含む医薬品をライセンサーAが使うことができることにライセンシーBとライセンサーAは合意する。しかし、ライセンサーAは、(a)他人に、XXX組成物やその他の組成物を含む医薬品を販売することはできない。また、(b)XXX組成物やその他の組成物の商業化のために、本契約以外の契約をすることはできない。また(c)本排他的ライセンス契約に違反するかもしれないあらゆる活動に参加してはならない。</p>
<p>4. *** agrees to pay to Licensor the following monies (in United States Dollars):</p> <p>A. As a base amount:</p> <p>(1) The amount of *** for the **** Formulation.</p>	<p>第4条</p> <p>ライセンシーBはライセンサーAに米国ドルで下記のようなライセンス料を支払うことに合意する。</p> <p>A. 一時金として、</p> <p>(1)XXX組成物について一時金YYY(US\$)。</p>

<p>(2)The amount for each Other Formulation identified in the future shall be negotiated in good faith by the parties to this Agreement.</p>	<p>(2)将来同定されるその他の組成物それぞれについての一時金の額は本契約の両当事者で誠意をもって交渉すること。</p>
<p>(3)*** shall pay to Licensor **** of the Formulation fees under Paragraph 4.A.(1) above when the Company has completed raising additional capital in an amount equal to or in excess of ***, and the remaining *** of such Formulation fee when the first successful pilot plant batch of the **** Formulation is made, as determined by ***.</p>	<p>(3)MMM以上の追加資金調達を達成した時、ライセンシーBは、条項4.A.(1)に従って、ライセンサーAに組成物費用としてZZZを支払う。組成物費用の残りの額は、ライセンシーBの決定したXXX組成物の最初のパイロットバッチが成功した時に支払う。</p>
<p>(4)*** shall pay to Licensor *** of each of the Formulation fees under Paragraph 4.A.(2) above, at such time as Licensor provides each of such Other Formulation to ***, and the remaining One-Half (1/2) of each such Other Formulation fee when the first successful pilot plant batch of that Other Formulation is made.</p>	<p>(4)ライセンシーBは、おのおのの組成物に対して、それぞれの組成物をライセンサーAが供給した時、パラグラフ4.A.(2)に従って費用をライセンサーAに支払う。残りの半分の費用はその他の組成物の最初のパイロットバッチが成功した時に支払う。</p>
<p>B. *** will also pay to Licensor each calendar year, the following:</p>	<p>B.ライセンシーBは更に毎年次の金額をライセンサーAに支払う。</p>
<p>(1) A royalty of **% of Net Sales of the **** Formulation and Other Formulations; "Net Sales" means the total revenues of *** based on gross invoiced sales of the Formulation, excluding sales and similar taxes, discounts, allowances, credits for returns, rebates, import duties and other governmental charges, freight and transportation charges, and insurance. For Formulations sold in combination with other products, Net Sales, for purposes of determining royalty payments on such combination, shall be calculated based on the reasonable portion of the Net Sales price attributable to the Formulation.</p>	<p>(1)XXX組成物やその他の組成物の正味売上のN%のロイヤリティを支払う。ここで、正味売上とは、特定の組成物の全送り状に対する総売り上げから、売上税、割引、賃金、収益のための残高、リベート、関税やその他の税金、輸送費、保険費などを除いたものをいう。特定の組成物が他の製品と混合されて販売された場合、そのような混合物におけるロイヤリティを決定する目的で、正味売上価格の中で特定組成物に振り分けられる合理的な割合で計算する。</p>
<p>(2) If *** develops a synthetic form of</p>	<p>(2)もし、ライセンシーBが、本契約に</p>

<p>a Formulation or any part thereof licensed under this Agreement (a "**** Formulation"), a royalty payment based on the Net Sales of any commercial product or service containing the *** Formulation to be negotiated and reduced below 5% in proportion to the contribution made by *** in making the synthetic form, and which royalty may reduce to as low as 0%.</p>	<p>従ってライセンスされた組成物やその一部の合成物（YYY 組成物という）を開発する場合、YYY 組成物を含む商用製品やサービスの正味売上に基づくロイヤリティ支払は、交渉によって決められ、ライセンシーBの合成物製造への貢献に比例して5%以下にされ、できるだけ0%近くまで下げられる。</p>
<p>(3) If a Formulation is sublicensed, a sublicensing fee of twenty percent (20%) of any royalties paid to *** based on sales by the sublicensee.</p>	<p>(3) もし組成物がサブライセンスされる場合、サブライセンシーの売り上げに基づいてライセンシーBに支払われるあらゆるロイヤリティの20%のサブライセンス料がライセンサーAに支払われる。</p>
<p>(4) Commencing January 1, 2003, the minimum annual royalty payment shall be ***; provided, however, that every three years, Licensor and *** will negotiate future minimum annual royalty payments six (6) months before the end of each third year anniversary period of this Agreement.</p>	<p>(4) Y年M月D日より始めて、最低年間ロイヤリティ料は毎年DDDである。しかし、本契約の各第三年日の6か月前に、ライセンサーAとライセンシーBが3年ごとの将来の年間最低ロイヤリティ額を交渉することができる。</p>
<p><b>C.</b> Amounts due for a particular calendar year under this Paragraph 4.B shall be due and payable on March 31 of the immediately following calendar year. *** shall withhold **% of any gross royalty or up-front fee paid under this Paragraph 4 if required in accordance with the *** Income Tax Treaty, Article 21.</p>	<p><b>C.</b> 本契約第4パラグラフBに従って、毎年3月31日に支払可能にする義務がある。所得税条約第21条に従う場合は、第4パラグラフに従って支払われる総ロイヤリティや一時金からZZ%を差し引いた額が支払われる。</p>
<p><b>D.</b> *** shall keep complete and accurate records in sufficient detail to permit Licensor to confirm the accuracy of calculations of all payments made pursuant to Paragraph 4 of this Agreement. Such records shall be retained by *** for no less than a five (5) year period</p>	<p><b>D.</b> ライセンシーBは、本契約第4パラグラフに関連するすべての支払の計算の正確性をライセンサーAが確認するため、すべての記録を完全かつ正確に保存しなければならない。ライセンシーBは、ライセンス料の支払が発生してから少なくとも5年間これらの記録</p>

<p>following the year in which any such payments were made. Once per calendar year, Licensor shall have the option to engage at its own expense, an independent certified public accountant reasonably acceptable to ***, to examine, in confidence, such records kept by *** as may be necessary to determine, with respect to any calendar year, the correctness of any payment made pursuant to Paragraph 4 of this Agreement. The report of such accountant shall be limited to a certificate verifying any report made or payment submitted by *** during such period but may include, in the event the accountant shall be unable to verify the correctness of any such payment, information relating to why such payment is unverifiable. All information contained in any such certificate shall be deemed to be *** Confidential Information hereunder. If any audit performed under this paragraph shall indicate that any payment due pursuant to Paragraph 4 was underpaid, *** shall pay Licensor the amount of any underpayment promptly.</p>	<p>を保存しなければならない。ライセンサーA は一年に 1 回自己費用でライセンサーB が合意する中立の公認会計士によって、ライセンサーB の保持する記録を必要によって検査し、本ライセンス契約第 4 パラグラフで決められたあらゆる支払の正確性を決定することができる。この公認会計士による報告書は、ライセンサーB によってなされたあらゆる報告や支払を確認するための証明書役割に限定される。しかし、公認会計士があらゆる支払の正確性を確認できなかった場合には、支払の確認不能理由の情報を含むことになる。確認書に含まれるすべての情報は、これ以後ライセンサーB の秘密情報とみなされる。本パラグラフに従って行われた監査が、第 4 パラグラフに従って行われたあらゆる支払が不足している場合は、ライセンサーB はライセンサーA に不足分を支払わなければならない。</p>
<p>5. This Agreement will begin on *** and will terminate on ****, unless and until Licensor and *** agree in writing to modify, extend, or sooner terminate the Agreement; provided, however, this Agreement will terminate and any rights conveyed hereunder will automatically revert to Licensor, if, within six (6) months of the date of this Agreement, *** is unable to raise additional capital in an amount equal to or in excess of ****, or if *** terminates this Agreement at any time upon two (2)</p>	<p><b>第 5 条</b></p> <p>ライセンサーA とライセンサーB が書面にて本契約を改正したり、延長したり、中途解除したりすることに同意しない限り、本契約は YY 年 MM 月 DD 日に発効し、YYY 年 MMM 月 DDD 日に終了する。しかし、もし、本契約の発効後 6 か月間に追加資金として PPP 以上集めることができなかった場合や、本契約は財政的に実行不可能であるとみなされる通知を 2 か月前に提出することによりライセンサーB が本契</p>

<p>months notice that the Agreement has been deemed to be financially unfeasible.</p>	<p>約を終了した場合には、本契約は終了し、ここに記載されているすべての権利はライセンサーAに返還される。</p>
<p>6. Licensor hereby confirms that it holds all legal right, title and interests in and to certain intellectual property rights relating to the **** Formulation and Other Formulations to be identified in the future and licensed under this Agreement, including know-how concerning compositions of matter and methods of use of compositions of such Formulation and Other Formulations for the prevention, diagnosis and treatment of certain human diseases and conditions of health and Licensor further confirms that it holds all legal right, title and interests in and to certain personal property rights in tangible embodiments of these compositions and Formulation and Other Formulations.</p>	<p><b>第 6 条</b></p> <p>ライセンサーAは、YYY組成物や、本契約に従ってライセンスされた将来可能性のあるその他組成物に関するすべての権利、権原、及び利益を保持していることを確認する。その権利には、病気や健康の予防、診断、治療に用いられる YYY 組成物やその他組成物の構成成分、製造法に関するノウハウも含まれる。更に、ライセンサーAは、YYY組成物やその他組成物の実際の具体的成分に対して法的権利や所有権を持っていることを確認する。</p>
<p>7. Licensor hereby agrees to assign to *** all right, title, and interest in and under any patentable invention that Licensor holds or subsequently obtains regarding compositions of matter, methods of use and/or manufacture relating to the **** Formulation.</p>	<p><b>第 7 条</b></p> <p>ライセンサーAはライセンシーBにあらゆる特許性の発明についての権利、権原、及び利益を与えることに同意する。特許性のある発明とは、ライセンサーAが YYY 組成物に関する組成、方法、使用、製造について現在保持しておりあるいはこれから保持する特許性のある発明のことである。</p>
<p>8. Licensor shall obtain patent rights as possible under Paragraph 8 subject to obligation to assign to ***. Licensor further agrees that it will cooperate fully with *** in securing patent rights for any patentable subject matter under Paragraph 8, above, provided *** pays all costs and expenses associated with securing such patent rights.</p>	<p><b>第 8 条</b></p> <p>ライセンサーAは、パラグラフ8に従って特許権を持つことができるが、それにはライセンシーBに権利付与するという条件付きである。ライセンサーAは、パラグラフ8の条件で、あらゆる特許性のある主題について特許権を確保することに、ライセンシーBと一致協力しなければならないことに合意す</p>



	<p>る。しかし、ライセンシーBは特許権確保に付随するすべてのコストを支払わなければならない。</p>
<p>9. Licensor agrees with *** that for this effort to be successful, Licensor and *** need to work together in collaboration and cooperation in their conducting research and development on projects under the scope of this Agreement. In particular, Licensor shall assist and consult with *** upon request on any topic reasonably related to the Formulations, including formulation components, formulating methods, manufacturing methods, plant identification, plant medicinal properties, sourcing of plant materials, information from patients regarding safety, efficacy, and side effects, including anecdotal information, and any information useful in establishing a clinical study.</p>	<p><b>第9条</b></p> <p>この開発努力を成功させるために、ライセンサーAとライセンシーBは、本契約の範囲の中でプロジェクトを研究開発することに共同、協力する必要があることについて合意する。特に、ライセンサーAは、組成物に合理的に関連するトピックについて要求があれば、ライセンシーBを援助し、相談に乗らなければならない。トピックには、組成物の内容物、組成方法、製造方法、原料植物同定方法、原料植物の医学的性質、原料植物の入手先、患者に関する安全性、薬効、副作用に関する情報、特に臨床試験を計画するのに有用な今までの経験、逸話に関する情報が含まれる。</p>
<p>If the assistance and consultation furnished by Licensor at the request of *** exceeds twenty-five (25) days, Licensor may charge a reasonable consulting fee for such assistance and consultation. Licensor represents to *** that to the best of Licensor's knowledge and belief, the Formulation and Other Formulations, the exclusive license rights for which Licensor grants under this Agreement to ***, are safe and effective for the treatment of human patients for the conditions and diseases indicated by Licensor.</p>	<p>もし、ライセンシーBが要求し、ライセンサーAから提供された援助や相談が25日以上にわたる場合、ライセンサーAは、そのような援助や相談に対してコンサルタント料を請求することができる。ライセンサーAの知識と経験に従い、排他的ライセンスした組成物やその他の組成物が、ライセンサーAが示した健康状態や病気の患者を治療するのに安全で効果的であることをライセンサーAがライセンシーBに説明しなければならない。</p>
<p>*** understands that such representations do not constitute guarantees, but an assurance based upon the technical knowledge and expertise that the Licensor has developed through its use of these Formulations and Other</p>	<p>ライセンシーBは、ライセンサーAの説明が技術的知識と経験に基づく、保証ではなく確信であることを理解している。その知識と経験は、ライセンサーAが特別な病気や健康状態にある患者を治療するために作成したある処方</p>

<p>Formulations in its own medical practice as well as from discussions with other using the Formulations and Other Formulations to treat the specified human disease or condition.</p>	<p>やその他の処方を使って、ライセンサーA 自身で治療したり他の関係者との議論を通じて開発したりしたものであることも理解しなければならない。</p>
<p>10. Licensor further agrees that it shall not compete with *** in any commercial or business venture regarding the development and marketing of the **** Formulation and Other Formulations identified under this Agreement, except as may otherwise be provided under Paragraph 3 above.</p>	<p><b>第 10 条</b></p> <p>ライセンサーA は、上記パラグラフ 3 に特定されている場合を除き、YYY 組成物やその他の組成物の製品を開発したり販売したりすることについて商業的ビジネス的にライセンサーB と競合しないことに合意する。</p>
<p>11. Licensor and *** agree that this Agreement will be understood to be in force under the law of the State of California and that no other promise or written agreements will be permitted to change any of the terms of this Agreement, except and only to the extent that such changes result from subsequent written amendments agreed to and signed by Licensor and ***.</p>	<p><b>第 11 条</b></p> <p>ライセンサーA とライセンサーB は、本契約はカリフォルニア州法の基で効力を発揮すること、本契約の条項のいかなる変更を許可する約束や契約は存在しないことに合意した。ただし例外として、そのような変更は、ライセンサーA とライセンサーB が合意してサインした修正契約によってのみ認められる。</p>
<p>In the event of a dispute arising under this Agreement, the Parties agree to meet in good faith to resolve the dispute. If such efforts are unsuccessful, the parties shall submit the dispute to non-binding mediation before a neutral mediator in *** prior to any lawsuit. The Parties consent to jurisdiction in the state and federal district of *** in the event of a lawsuit.</p>	<p>本契約のもとで紛争が起こった場合、当事者は紛争解決に誠意をもって対処する。もし、紛争解決が成功しない場合、紛争を裁判に持ち込む前に、ライセンサーB 側の中立の仲裁人に仲裁を依頼するより先に強制力のない調停に持ち込むべきである。当事者は、裁判になった場合、ライセンサーB の州立あるいは連邦裁判所で行うことに同意する。</p>
<p>12. CONFIDENTIALITY. The Parties agree to treat as confidential any and all Confidential Information obtained from each other and to that end further agree that information disclosed pursuant to this Agreement relating to the Formulations,</p>	<p><b>第 12 条 秘密保持</b></p> <p>当事者は、お互いから得た秘密情報は秘密に取り扱うことに合意する。更に、将来開発される組成物に関して開示された情報は、例えば組成物の商用化努力も含まれるが、本契約に従って秘密</p>

<p>including efforts to commercialize the Formulations, shall be deemed Confidential Information.</p>	<p>とみなされる。</p>
<p>Notwithstanding the foregoing, confidential information may be disclosed to the extent required by any law or regulation of any governmental authority having jurisdiction over any of the Parties, with appropriate efforts made to maintain confidentiality. Both Parties shall maintain Confidential Information in confidence as set forth herein, for a period of five (5) years beyond termination or expiration of this Agreement. Upon request from either Party, the confidentiality of specific Confidential Information may be maintained for a longer time as the Parties may subsequently agree.</p>	<p>しかし、前述の秘密保持にもかかわらず、秘密情報は両当事者を管理する政府当局の設定された法令の範囲の要求に対しては開示される。ここで設定され秘密保持される情報は、本契約が満了または終了してからも5年間は誠意をもって秘密保持される。どちらかの当事者の要求により、両当事者が合意すれば、特別な秘密情報は更に長期間秘密保持される。</p>
<p>There are no obligations of confidentiality as to specific information (a) which is publicly known at the time of disclosure under this Agreement or becomes publicly known at any time other than through disclosure by the recipient of the information; (b) which is demonstrably known to the recipient of the information prior to its receipt from the disclosure; (c) which is disclosed to the recipient by a third party not under an obligation of confidentiality and independently of the studies contemplated by this Agreement; or (d) for which disclosure has been approved by the mutual written consent of the Parties; or (e) independently developed without access to Confidential Information from the discloser.</p>	<p>以下に示す情報は秘密保持の責務はない。(a)本契約に従って開示されたときにすでに公開されていたもの、あるいは情報受領者の公開以外の方法で公開になるもの、(b)秘密情報開示前に明らかに受領者の知ることになった証拠のあるもの、(c)本契約で計画されている研究開発から独立して、秘密保持の義務のない第三者から受領者が得たもの、又は(d)両当事者間の書面による同意によって許可されたもの、又は(e)開示によって得られた秘密情報にアクセスすることなく独立に開発されたもの。</p>
<p><b>13. Adherence to Regional and National Laws. The Parties shall adhere to the 1993 Convention on</b></p>	<p><b>第 13 条</b> 地方あるいは国の法律に従って、両当</p>

<p><b>Biological Diversity (CBD)</b>, the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), and other regional and national laws and policies concerning biodiversity, and will endeavor to minimize environmental impacts of collecting Biological Materials.</p>	<p>事者は 1993 年の生物多様性条約 (CBD)、1973 年の絶滅のおそれのある野生動植物の種の国際取引に関する条約 (CITES)、その他生物多様性に関する地方あるいは国の法律や戦略に従わなければならない。生物資源を収集するにあたり環境への影響を最小限にするよう努力しなければならない。</p>
<p>Relevant provisions of the CBD include: the sovereign rights of states over their biological resources; the concern that biological diversity is being significantly reduced by certain human activities; the need to provide additional scientific information about biological diversity that may contribute to its conservation and sustainable use of biological diversity; the need to promote fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including benefits that arise from traditional knowledge; and the need to respect and maintain the knowledge and practices of indigenous communities that are relevant for the conservation and sustainable use of biological diversity.</p>	<p>生物多様性条約の関係する条項には次の項目が含まれる。生物資源にはその国の主権的権利が及ぶこと、人間の活動により生物多様性が著しく減少していること、生物多様性の保全と持続的利用に貢献する生物多様性に関する科学的情報を提供すること、伝統的知識から生ずる利益も含む遺伝資源の利用から生ずる利益を公正に衡平に配分することを奨励する必要性、生物多様性を保全し持続可能利用するのにふさわしい先住民社会の知識と習慣を尊重する必要性などである。</p>
<p>Licensor hereby warrants that it has good title to all materials, plants, roots, seeds, plant products, extracts, Formulations, or any portion thereof ("Materials"), transferred pursuant to this Agreement and that it has obtained all applicable licenses, permissions, releases, authorizations, and/or certifications necessary to transfer and export Materials and related information from national and local governments, public agencies, indigenous groups, and private third parties ("Approvals").</p>	<p>すべての物質、植物、タネ、薬用植物製品、抽出物、組成物、あらゆる部分 (物質という) に対する権益を持っており、本契約に従ってそれを移転することをライセンサーA は保証する。更に、政府、地方政府、公共機関、先住民集団、民間の第三者から、物質や関連する情報の移転や輸出に関するライセンス、許可、譲渡、許可、認可を得ていることをライセンサーA は保証する。</p>
<p>Licensor hereby agrees to give ***</p>	<p>ライセンサーA は、そのような認可を</p>

<p>documentation evidencing such Approvals. Licensor hereby agrees that if it becomes aware that there are any restrictions on the use of the Materials, or any further Approvals that are necessary, it shall notify ***. Licensor, upon request from ***, shall take all necessary steps to acquire any additional such Approvals as may be required to assure that the transfer of Materials and related information is in all respects consistent with applicable law and regulation, and to effectuate the provisions of this Agreement. These provisions apply to all Materials transferred by Licensor. *** shall be responsible for obtaining the necessary Approvals for any Materials they acquire on their own.</p>	<p>証明する書類をライセンサーBに譲渡することに合意する。更に、ライセンサーAは、もし、物質の使用に関していかなる制限、あるいは更なる認可が必要なことを知った場合、ライセンサーBに通知しなければならないことに合意する。ライセンサーBの要求に応じて、物質と関連情報の移転が適応法令に一致していることを確認し、本契約の条項を実施するために、ライセンサーAはそのような付加的な認可を得るのに必要なステップを取らなければならない。これらの条項はライセンサーAによって移転される物質すべてに適用される。ライセンサーBは、自身が入手した物質すべてについて必要な認可を得る義務がある。</p>
<p>14. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.</p>	<p><b>第 14 条</b></p> <p>本契約は副本でもって執行される。それぞれの副本は原本とみなされるが、すべてがひとつであり同じ法律文書を構成している。</p>
<p>15. This Agreement sets forth the entire agreement between *** and Licensor pertaining to the subject matter hereof and supersedes all negotiations, preliminary agreements, memoranda or letters of proposal or intent, discussions and understandings of *** and Licensor.</p>	<p><b>第 15 条</b></p> <p>全ての事に関連してライセンサーAとライセンサーBの間で、本契約は完全条項を形成している。更に本契約は、全ての交渉、事前の契約、覚書、提案書、ライセンサーBとライセンサーAの間で交わされた議論に代わって有効なものである。</p>
<p>All discussions between *** and Licensor have merged into this Agreement, and neither party shall be bound by any definition, condition, understanding, representation, warranty, covenant or provision other than as expressly stated in or contemplated by this Agreement or as</p>	<p>ライセンサーAとライセンサーBの間のすべての議論は、本契約にまとめられている。本契約で記載されたり熟慮されたりしたこと以外のあらゆる定義、条件、理解、表現、保証、約束、条項に両当事者とも拘束されない。同様に、書面にて設定されライセンサーAとライセンサーBの承認された代表者によ</p>

<p>subsequently shall be set forth in writing and executed by a duly authorized representative of *** and Licensor to be bound thereby.</p>	<p>って行使されることについては拘束を受ける。</p>
<p>No amendment or modification of this Agreement shall be valid or binding upon *** and Licensor, unless agreed upon by both parties, made in writing, and signed on behalf of each of *** and Licensor by their duly and legally authorized representative officers.</p>	<p>両当事者の同意があり、書面にてなされ、ライセンサーA とライセンシーB の法的に承認された代表者によってそれぞれがサインをした場合を除き、本契約の改正あるいは修正は、ライセンサーA とライセンシーB の間で無効であり、拘束を受けない。</p>
<p>IN WITNESS WHEREOF, the undersigned are duly authorized to execute this Agreement on behalf of *** and Licensor, as applicable.</p>	<p>以上の証として、下記の署名者はライセンサーB とライセンシーA のために行使することを承認されている。</p>
<p>On behalf of ***, Inc.</p> <p>By: _____</p> <p>Title: _____</p> <p>Date: _____</p> <p>On behalf of ***</p> <p>By: _____</p> <p>Title: _____</p> <p>Date: _____</p> <p>On behalf of ***</p> <p>_____</p> <p>Date: _____</p>	

インド商用研究のためのアクセス標準契約

**AGREEMENT ON ACCESS TO BIOLOGICAL RESOURCES FOR COMMERCIAL PURPOSES**

This Agreement is entered into as of the ..... day of ....., year..... in accordance with Section 3 of the Biological Diversity Act, 2002 and Rule 14 of the Biological Diversity Rules, 2004.

**Signed Between**

**National Biodiversity Authority** (Hereinafter referred to as "the **NBA**") having its office at 475,9th South Cross Street, Kapaleeswar Nagar, Neelankarai, Chennai – 600041, India (www.nbaindia.org).

And

**XYZ** (which can be a Manufacturer/Company/Institute/ Individual,Trust etc) having its office at..... (Hereinafter referred to as **XYZ**)

Hereinafter, the NBA and XYZ shall collectively be referred to as “the Parties” and individually as “Party”.

**WHEREAS:**

NBA has been established by the Government of India under the powers granted to it by section 8 of the Biological Diversity Act 2002 (Act 18 of 2003). Under the said Act, NBA is the authority to permit access to any biological resources and/or associated knowledge found within the territory of India.

XYZ is a (Manufacturer/Company/Institute/ Individual/Trust etc) .....and having business interests in the manufacturing of products which requires certain biological resources and/or associated knowledge as a raw materials.

XYZ has made an application in Form I, under Rule 14 of the Biological Diversity Rules, 2004 to seek approval from the NBA to access the biological resources and/or associated knowledge for the purposes of Commercial Utilisation of the same.

**The Parties hereto agree as follows:**

**1. Definitions**

In this Agreement, unless the context otherwise requires:

**Act** means the Biological Diversity Act, 2002 (No.18 of 2003) and includes the Rules/Regulations/guidelines/notifications/regulations made under it.

**Biological Resources:** means the biological resources as defined in section 2(c) of the Act and includes any associated knowledge, which XYZ desires to access for the purposes of Commercial Utilisation and which is as described in Schedule A to this Agreement.

**Commercial Utilisation** means any use as described in the Act and limited to the actual use as described in Schedule B to this Agreement.

## **2. Grant of Approval**

2.1 XYZ requests for approval and the NBA hereby grants the approval to access the Biological Resources and the associated knowledge specified in Schedule A for the purposes of Commercial Utilisation subject to the terms and conditions set forth in this Agreement.

2.2 Any activities/use involving the Biological Resources that are not expressly authorized by the provisions of this Agreement and any annexures hereto shall be deemed to be expressly prohibited.

2.3 XYZ hereby agrees that this Agreement shall not in any way constitute or be presumed to constitute a partnership, joint venture or joint enterprise in any way or for any purpose between the Parties hereto or make them in any way liable as partners of or as agents for one another. No Party has the authority to act for or to assume any obligation or responsibility on behalf of the other Party and the relationship between the Parties is that of a person and a statutory authority competent to approve certain actions under the Act.

## **3. Assignment**

3.1 Without the prior written consent of the NBA in each instance, neither this Agreement nor the rights granted hereunder shall be transferred or assigned in whole or in part by XYZ to any person whether voluntarily or involuntarily, by operation of law or otherwise. Failure of XYZ to obtain the prior written consent of the NBA to any such transfer or assignment shall be deemed to be a material breach of this Agreement and result in the immediate termination of this Agreement, without notice in addition to any other actions that may be taken against XYZ for the violation of the Act, along with application of provisions of Section 56 of the Act on penalty for contravention of directions.

3.2 This Agreement is strictly personal to XYZ and will be treated as terminated in the event of any substantial changes in the management or shareholding of XYZ, that alters the control structure of XYZ and includes changes brought by a transfer of business units, merger, demerger or any other kind of corporate restructuring.

## **4. Conditions for Access to Biological Resources**



4.1 XYZ shall have access only to ..... (quantity) of Biological Resources as specified in Schedule A of this Agreement and undertakes to access the same in accordance with the directions given by the NBA (as delegated to SBB or BMC or any other governmental agencies)

4.2 XYZ undertakes that it shall not allow any persons other than its authorized employees under its direct control and supervision to have access to the Biological Resources. XYZ undertakes to protect the Biological resources at least as well as it protects its own valuable tangible personal property and shall take measures to protect the Biological Resources from any claims by third parties including creditors and trustees appointed by the court or other authorities in certain legal proceedings like bankruptcy, winding up etc.

4.3 XYZ undertakes to comply with the existing national laws, regulatory mechanisms and international agreements/treaties.

4.4 The approval given under this agreement is without prejudice to any other approvals that may be required to be taken by XYZ from any other authorities under any other law in force in the territory of India. Failure to do so shall be a material breach of this Agreement resulting in the immediate termination of this Agreement.

4.5 XYZ shall not distribute, transfer or obtain IPR or part with the Biological Resources and/or the associated knowledge accessed under this Agreement in any manner without obtaining the prior written consent of the NBA under the provisions of the Act. Nothing contained in this Agreement shall be construed as an authorization from the NBA for the transfer of Biological Resources or any associated knowledge by XYZ.

4.6. XYZ shall deposit the voucher specimen/Type specimen in the designated repositories of India in accordance with the guidelines and directions given by NBA.

**5. Royalty and other Benefit Sharing** [will change on a case by case basis and will be regulated by the ABS guidelines]

5.1 XYZ shall pay to the National Biodiversity Authority, annually, during the term of this Agreement a royalty of.....% as agreed of the total sales of the Product derived from the use of the Biological Resource accessed.

5.2. NBA shall direct XYZ to share the benefits in all or any of the following manner as per sub section 2 and 3 of Section 21 of the Biological Diversity Act, 2002:

- (a) grant of joint ownership of Intellectual Property Rights to NBA, or where benefit claimers are identified, to such benefit claimers.
- (b) Transfer of technology
- (c) Location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;

- (d) Association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilization;
- (e) Setting up of venture capital fund for aiding the cause of benefit claimers.
- (f) Payment of monetary compensation and non monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit

## **6. Reports and Audit**

6.1 XYZ shall submit to NBA half yearly reports on the following:

- (a) the quantity of Biological Resources and/or associated knowledge accessed.
- (b) the total quantity of the Products produced by the use of the Accessed Biological Resource and/or associated knowledge.
- (c) the total billings of such Products (ex factory)
- (e) any other related information sought by the NBA by a written notice.

6.2 XYZ shall keep accurate records (together with supporting documentation) appropriate to determine all amounts due to NBA. Such records shall be retained for at least three (3) years following the end of the reporting period to which they relate.

6.3 The records mentioned in clause 6.2 should be made available during normal business hours for audit by any person authorised by NBA, for the sole purpose of verifying reports and payments hereunder. In conducting audits pursuant to this clause, such person shall have access to all records which he reasonably believes to be relevant to the calculation of royalties.

6.4 The audit by such authorized person shall be at the expense of NBA, except that if such audit shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then XYZ shall pay the cost of such examination as well as any additional sum that would have been payable to NBA had XYZ reported correctly, plus interest on said sum at the rate of three per cent (3%) more than the then prevailing rate of Interest in a nationalized bank per month from the date of the incorrect reporting.

## **7. Term and Termination**

7.1 This Agreement, unless terminated as provided herein, shall remain in effect for a period of ..... years (case to case basis) from the date on which XYZ made its first access to the Biological Resources under this Agreement.

7.2 NBA may terminate this Agreement by a written notice on the happening of any of the following:

(a) If XYZ does not make a payment due hereunder and fails to cure such non-payment within Thirty (30) days after the date of notice in writing of such non-payment by NBA.

(b) If XYZ becomes insolvent or shall have a petition in bankruptcy, winding up filed for or against it. Such termination shall be effective immediately upon NBA giving written notice to XYZ.

(c) If an audit conducted pursuant to clause 6.3 shows an underreporting or underpayment by XYZ in excess of 20% for any twelve (12) month period.

(d) If XYZ defaults in the performance of any obligations under this Agreement and the default has not been remedied within sixty (60) days after the date of notice in writing of such default by NBA.

(e) If any of the events mentioned in Rule 15 of the Biological Diversity Rules, 2004 occur.

7.3 XYZ may terminate this Agreement by giving sixty (60) days advance written notice of termination. Upon termination, XYZ shall submit a final payment report to NBA and any outstanding payments shall become immediately payable.

7.4 Upon termination of this Agreement, XYZ shall cease all use of the Biological Resources and shall, upon request, return or destroy (at the option of NBA) all Biological Resources under its control or in its possession.

## **8. Notice**

8.1 Wherever in this Agreement, it is required or permitted that a communication, notice or demand be given or served by either Party to or on the other Party, such communication, notice or demand will be in writing and will be validly given or sufficiently communicated if forwarded by Registered mail acknowledgement due, e-mail, telegram, telex or facsimile as follows:

The addresses for delivery are:

To the NBA:

The Chairperson, National Biodiversity Authority, 475, 9<sup>th</sup> South Cross Street, Kapaleeswarar Nagar, Neelangarai, Chennai – 600041

e-mail:..... fax:.....

To XYZ:

.....

8.2 Notice will be deemed to have been delivered:

- (a) if delivered by hand, upon receipt;
- (b) if sent by electronic transmission, 48 hours after the time of transmission, excluding from the calculation weekends and public holidays;
- (c) if sent by certified mail, four (4) days after the mailing thereof, provided that if there is a postal strike or other disruption such notice will be delivered by hand or electronic transmission.

8.3 The Parties may change their respective addresses for delivery by delivering notice of change as provided in this paragraph.

## **9. Arbitration**

9.1 If any controversy, question, dispute or difference (hereinafter referred to as a ‘**Dispute**’) between the Parties hereto arises under this Agreement, any Party may give the other Party a written notice of Dispute adequately identifying and providing details of the Dispute. On receipt of such notice by the other Party, the Parties shall try to settle the Dispute amicably between them by negotiating in good faith within 30 days of the receipt of the notice of Dispute by the other Party.

9.2 If the Dispute is not resolved by such good faith negotiation within the period mentioned, the Parties agree to settle the Dispute through arbitration conducted by the sole arbitrator appointed by the NBA. The arbitration shall be governed by the Arbitration and Conciliation Act, 1996. The place of arbitration shall be Chennai, India. The language to be used in the arbitration proceedings shall be in English or as mutually agreed between the Parties.

9.3 The Parties hereto agree that the award and determination of the arbitrator shall be final and binding on both Parties hereto.

## **10. Governing Law and Jurisdiction**

This Agreement is governed by and is to be construed in accordance with the laws of the Republic of India without regard for conflicts of laws principles. The Parties irrevocably and unconditionally submits to the exclusive jurisdiction of the courts in Chennai, India and any courts which have jurisdiction to hear appeals from any of those courts and waives any right to object to any proceedings being brought in those courts.

## **11. Waiver**

The Waiver by NBA, of any breach of any terms of this Agreement made by XYZ shall not prevent the subsequent enforcement of that term and shall not be deemed a waiver of any subsequent breach.

## **12. Severability**

If any part of this Agreement is declared or held invalid by a court for any reason, the invalidity of that part will not affect the validity of the remainder which will continue in full force and effect and be construed as if the Agreement had been executed without the invalid portion.

## **13. Modification**

No amendment or modification of this Agreement shall be valid or binding upon the Parties, unless agreed upon by both Parties, made in writing, and signed on behalf of each of the Parties by their duly and legally authorized signatories.

## **14. Entire Agreement**

The Parties acknowledge that there are no representations either oral or written, as regards the subject matter of this Agreement, between the NBA and XYZ other than those expressly set out in this Agreement. All previous negotiations, understandings, representations, warranties, memoranda or commitments concerning the subject matter of this Agreement are merged in and superseded by this document and are of no effect. This Agreement constitutes the entire understanding between the parties as to the subject matter of this Agreement. This Agreement sets forth all representations forming part of or in any way affecting or relating to the subject matter of this Agreement.

## **15. Representations**

Either Party represent to each other Party that it has the legal right and power to enter into this Agreement and to perform its obligations under the terms of this Agreement and the execution, delivery and performance of this Agreement by it has been duly and validly authorized by all necessary corporate action or Government action on its part.

The documents attached hereto as Schedules forms an integral part of this Agreement as fully as if it were set forth herein *in extenso*, and consists of:

Schedule A: Details of the Biological Resources

Schedule B: Details of the Commercial Utilisation

Schedule C: Application made by XYZ in Form I

and any other Appendix that may be added subsequently under the provisions of this Agreement.

This Agreement has been executed in Duplicate. Each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

**IN WITNESS WHEREOF** this Agreement has been executed by duly authorized representatives of the Parties on the day and the year first mentioned

For National Biodiversity Authority: For XYZ:

Witness

1. 1.

2. 2.

**Schedule A: Details of the Biological Resources**

[To be filled in by XYZ]

**Schedule B: Details of the Commercial Utilisation**

[To be filled

インド熱帯植物園研究所薬草ノウハウ商用移転契約

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前提

**Know How Licencing Agreement between The Tropical Botanic Garden and Research Institute, Kerala, India (TBGRI) and The Arya Vaidya Pharmacy (Coimbatore) Ltd, Coimbatore, India (the PARTY), dated November 10th, 1995**

**Subject matter** A Know How Licencing Agreement relating to know how (KNOWHOW) developed and owned by TBGRI to manufacture herbal formulations based on "Arogyapacha" and other herbal drugs (Jeevani).

**Summary of use(s)** The license hereby granted to the PARTY by TBGRI for utilization of KNOWHOW for a period of 7 years on an exclusive basis commencing from the date of transfer of KNOWHOW, provided that KNOWHOW is effectively utilized within 4 years from the date of transfer of KNOWHOW.

**Purpose or background** This agreement details the terms and conditions for the grant of licence by TBGRI to the PARTY for utilising the KNOWHOW, the rights and obligations of either party and the financial arrangements between the parties.

**Contact details** The Tropical Botanic Garden & Research Institute, Karimancode, P.O.Pacha-Palode, Thiruvananthapuram, 695 562, Kerala, India.  
E-mail: tbgri12@rediffmail.com, tbgri@sancharnet.in  
Telephone: 91-0472-869622, 869228; Fax: 91-0471-869646.

## **AGREEMENT FOR LICENSING OF KNOW-HOW**

### **A.1 THE AGREEMENT**

A.1.1 THIS AGREEMENT made and entered into this Tenth day of November One Thousand Nine Hundred and Ninety Five between Tropical Botanic Garden & Research Institute, a Society registered under the Travancore Cochin Literary, Scientific and Charitable Societies Registration Act 1955, having its registered office at Tropical Botanic Garden and Research Institute, Karimancode, P.O.Pacha-Palode, Thiruvananthapuram - 695 562 (hereinafter called TBGRI which expression shall where the context so admits, include its successors and permitted assigns) of the one part

AND

A.1.2 The Arya Vaidya Pharmacy (Coimbatore) Ltd., a COMPANY incorporated in India under the Indian Companies Act 1913 (No.61 of 1947 - 48) and having its registered office at 1381 & 1382, Trichy Road, Coimbatore - 641 018 (hereinafter called the PARTY which expression shall where the context so admits include its successors and permitted assigns) of the other part.

### **A.2 PREAMBLE**

A.2.1 WHEREAS TBGRI has developed and is in full possession of and has full intellectual property rights to manufacture herbal formulation based on "Arogyapacha" and a few other herbal drugs (Jeevani) as detailed in Annexure I (hereinafter called the KNOWHOW) for making Herbal Formulation based on "Arogyapacha" and a few other herbal drugs (Jeevani) as per specifications laid down in Annexure II (hereinafter called the PRODUCT).

A.2.2 And whereas TBGRI at the request of the PARTY has agreed to grant licence to the PARTY for utilising the KNOWHOW on terms and conditions hereinafter contained.

### **A.3 SCOPE OF AGREEMENT**



This agreement details the modalities and the terms and conditions for the grant of licence by TBGRI to the PARTY for utilising the said KNOWHOW, the rights and obligations of either party thereto and the financial arrangements between the parties.

#### **A.4 GRANT OF LICENCE**

A.4.1 In consideration of the payment as provided for in Clause 5.1 and performance by PARTY of the covenants herein contained, TBGRI hereby grants to the PARTY the licence to utilise the KNOWHOW to make and sell the PRODUCT directly or through any marketing agency authorised by The Arya Vaidya Pharmacy (Coimbatore) Ltd.

A.4.2 The license hereby granted to the PARTY by TBGRI is for utilisation of KNOWHOW for a period of seven years on exclusive basis commencing from the date of transfer of KNOWHOW provided that the KNOWHOW is effectively utilised within 4 years from the date of transfer of KNOWHOW.

A.4.3 The license shall come into force from Tenth day of November One Thousand Nine Hundred and Ninety Five (hereinafter called the EFFECTIVE DATE) and shall remain valid for a period of seven years thereafter.

A.4.4 The PARTY will produce and market the PRODUCT within 4 years from the date of transfer of KNOWHOW. If PARTY fails to do so TBGRI will have the right to cancel the licence granted to PARTY and the PARTY in turn should surrender the KNOWHOW. In such a circumstance the PARTY will not have any right to claim licence fee already paid to TBGRI.

#### **A.5 FINANCIAL ARRANGEMENTS**

A.5.1 In consideration of the licence hereby granted and the transfer of KNOWHOW by TBGRI to the PARTY, the PARTY shall pay to TBGRI as hereunder:

## **Licence Fee**

### **i. Lump sum**

- a. Rs. 5 Lakhs on signing of the agreement, and
  - b. Rs. 5 Lakhs on the day of transfer of KNOWHOW by TBGRI
- and

### **ii. Royalty**

Royalty at the rate of 2% of the ex-factory sale price of the PRODUCT made by the PARTY for a period of 10 years, computed from the date of commercial production. The terms and conditions governing the payment of royalty shall be as in Annexure III.

## **A.6 RESPONSIBILITIES OF TBGRI**

### **A.6.1 Transfer of KNOWHOW**

#### **i. Transfer of KNOWHOW Documents**

TBGRI shall within 180 days of the EFFECTIVE DATE hand over to the PARTY Technology Transfer Documents (TTD) consisting of specifications of product, process details, quality control procedures and user manuals.

#### **ii. Demonstration**

TBGRI shall demonstrate the KNOWHOW at TBGRI, Palode to the authorised representative of the PARTY within 6 months from the EFFECTIVE DATE for which the PARTY shall pay separately. On completion of the demonstration both parties shall sign a certificate to this effect.

#### **iii. Training**

TBGRI shall arrange for the training of Two or Three of PARTY's personnel having the requisite qualifications for a maximum of 2 months for which the PARTY shall provide inputs/pay separately. The training shall be availed of by the PARTY within a period of 3 months from the date of transfer of KNOWHOW.

A.6.2 The transfer of KNOWHOW shall be deemed as completed on performance by TBGRI the tasks stipulated in clause A.6.1.

#### A.6.3 Assistance

TBGRI may at the request of the PARTY and on its paying charges as specified by TBGRI, depute qualified personnel to render assistance in KNOWHOW implementation. This assistance would be available up to a period of 4 years from the EFFECTIVE DATE.

### **A.7 RESPONSIBILITIES OF PARTY**

A.7.1 The PARTY shall employ its best endeavour to work the KNOWHOW and sell the PRODUCT on a commercial scale. The PARTY shall commercialise the KNOWHOW within a period of 48 months from the date of transfer of KNOWHOW as defined in clause A.6.2.

A.7.2 Fulfilment of all procedural, legal, operational requirements for the commercial implementation of the KNOWHOW shall be the responsibility of the PARTY.

A.7.3 The PARTY acknowledges the absolute ownership of KNOWHOW by TBGRI and shall not dispute the legality, validity or enforceability of the licence granted.

A.7.4 It shall not be open to the PARTY to claim the KNOWHOW in their name on the plea of having effected any improvements/modifications upon the KNOWHOW or upon the PRODUCT. All PRODUCTS manufactured by the PARTY shall be deemed to have been manufactured under the licence hereby granted.

A.7.5 The PARTY shall permit the personnel of TBGRI or its attorneys or duly authorised agents, at all convenient time to enter into and upon any premises of PARTY where PRODUCTS under this licence are manufactured/stocked/sold/used for the purpose of inspecting the same and the manufacture thereof, generally to ascertain that the provisions of this licence are being complied with and quality of the PRODUCT maintained.

A.7.6 The PARTY shall not, at any time, assign, mortgage, charge, grant sub-licence or otherwise deal with possession or control of the licence hereby granted.

A.7.7 The PARTY shall not directly or indirectly and either by itself or by its agents use the KNOWHOW otherwise than in accordance with these presents.

A.7.8 The PARTY shall not file any application for seeking intellectual property rights in its own name or in the name of other person(s) on any matter relating to the information disclosed to it by TBGRI under this agreement, save with the written prior approval of TBGRI.

A.7.9 The PARTY shall not oppose or direct or cause any persons to oppose any application seeking intellectual property rights relating to the PRODUCT and/or KNOWHOW filed by TBGRI.

A.7.10 The PARTY shall treat as strictly confidential all information/knowledge obtained from TBGRI, in connection with or relating to the licence hereby granted.

## **A.8 GENERAL PROVISIONS**

A.8.1 During the currency of the agreement both parties shall promptly disclose to each other in writing, all or any improvements or modifications made on the KNOWHOW / PRODUCT. All such improvements/modifications shall then form an integral part of the KNOWHOW.

A.8.2 These presents shall not be construed as a warranty by TBGRI of the novelty, utility, saleability and workability of the KNOWHOW/PRODUCT.

A.8.3 This agreement shall be the sole repository of the terms and conditions agreed to herein by and between TBGRI and the PARTY and no amendment thereof shall take effect and be binding on either of them except provided for in clause A.16. hereunder.

## **A.9 ACKNOWLEDGEMENT**

A.9.1 The PARTY shall affix in a conspicuous manner upon every PRODUCT and a label or plate bearing the inscription "TBGRI KNOWHOW" in letters of size not less than half the nominal size of the largest size of letter ----- name of the party or its brand name or trademark for the PRODUCT. The PARTY shall not sell [PRODUCT and/or any box or Package containing the PRODUCT] without such label or plate being affixed thereon. Similarly every advertisement, boarding, technical literature, publicity and the like material in respect of or relative to the PRODUCT issued by the PARTY shall include the same inscription as aforesaid in a prominent manner.

#### **A.10 FORCE MAJEURE**

Neither party shall be held responsible for non-fulfilment of their respective obligations under this agreement due to the exigency of one or more of the force majeure events such as but not limited to acts of God, War, Flood, Earthquakes, Strikes, Lockouts, Epidemics, Riots, Civil Commotions etc., provided on the occurrence and cessation of any such event the party affected thereby shall give a notice in writing to the other party within one month of such occurrence or cessation. If the force majeure conditions continue beyond six months, the parties shall jointly decide about the future course of action.

#### **A.11 INDEMNITY**

TBGRI hereby agrees to authorise and to empower the PARTY to institute and prosecute such suits or proceedings as the PARTY may deem expedient, to protect the rights hereby conferred and for the recoveries of damages and penalties for the infringement of such rights and to secure to the PARTY full benefits of this licence and for any such purpose to use the name of TBGRI. The PARTY in its turn shall indemnify TBGRI against damages, costs and expenses occasioned by such proceedings, and TBGRI shall in any such proceedings, at the expense of the PARTY afford to the PARTY all proper and or reasonable assistance in proving and defending its title to the grant of the rights hereby conferred.

#### **A.12 TERMINATION OF AGREEMENT**

A.12.1 This agreement may be terminated by either of the parties forthwith if the other party commits breach of any of the terms hereof and shall have failed to

rectify such breach within sixty days of the notice in this behalf having been served on it by the other party.

A.12.2 In addition to the reasons for termination as set forth above, this agreement may be terminated forthwith if either of the parties voluntarily or involuntarily enters into composition, bankruptcy or similar reorganisation proceedings or if applications invoking such proceedings have been filed.

### **A.13 SETTLEMENTS**

Upon termination of the agreement:

A.13.1 All rights granted to and the obligations undertaken by the parties hereto shall cease to exist forthwith except the obligation of the PARTY to keep KNOWHOW in confidence vide clause A.7.10 herein and pay royalty as per clause A.5.1. (ii) above accrued on or prior to the date of such termination, make written reports and keep records, files and books vide para 6 of Annexure III hereto and the right of TBGRI to inspect the same.

A.13.2 The PARTY or its assigns will not utilise the KNOWHOW to manufacture the PRODUCT and the PARTY shall immediately deposit with TBGRI the original and all copies of TTD, and other documents data related to this licence received from TBGRI.

A.13.3 The PARTY shall immediately pay to TBGRI all amounts of money due from it upto the date of termination. Also all sums of money hereto paid by the PARTY under the terms of this licence shall be forfeited to TBGRI, and the PARTY shall not be entitled to any credit or allowance in respect thereof.

A.13.4 The PARTY will not be debarred from disposing off the PRODUCTS which are already manufactured or in the process thereof by sale or otherwise. Such disposal will however, not be effected unless and until the PARTY remits to TBGRI the entire amount of royalty due, in accordance with Clause 5 above including the PRODUCTS sought to be disposed off.

#### **A.14 NOTICES**

A.14 All notices and other communications required to be served on the PARTY under the terms of this agreement, shall be considered to be duly served if the same shall have been delivered to, left with or posted by registered mail to PARTY at its last known address of business. Similarly, any notice to be given to TBGRI shall be considered as duly served if the same shall have been delivered to, left or posted by registered mail to TBGIR at its registered address in Pacha-Palode, Thiruvananthapuram.

#### **A.15 AMENDMENTS TO THE AGREEMENT**

A.15.1 No amendment or modification of this agreement shall be allowed. The request for the same is made in writing by both the parties or their authorised representatives and specifically stating the same to be an amendment of this agreement. The modifications/changes shall be effective from the date on which they are made/executed unless otherwise agreed to.

#### **A.16 ASSIGNMENT OF THE AGREEMENT**

A.16.1 The rights and/or liabilities arising to any PARTY to this agreement shall not be assigned except with the written consent of the PARTY and subject to such terms and conditions as may be mutually agreed upon.

#### **A.17 ARBITRATION**

Applicable to agreements with private parties in India

A.17.1 Except as hereinbefore provided, any dispute arising out of this Agreement, the same shall be referred to the arbitration of two arbitrators, one to be appointed by each party to the dispute, and in case of difference of opinion between them to an umpire appointed by the said two arbitrators before entering on the reference, and the decision of such arbitrators or umpire, as the case may be, shall be final and binding on both parties. The venue of arbitration shall be at such place as may be fixed by such arbitrators or umpire and the arbitration proceedings shall take place under the Indian Arbitration Act, 1940.

A.17.2 Any legal appeal over the arbitrators' award arising out of or in any way connected with this agreement shall be deemed to have arisen in Thiruvananthapuram and only the courts in Kerala shall have the first jurisdiction to determine such matters.

**SEAL OF PARTIES**

This agreement has been executed in two originals one of these has been retained by TBGRI and the other by the PARTY.

In witness whereof the parities hereto have signed this agreement the Tenth day of November One Thousand Nine Hundred and Ninety Five mentioned hereinbefore.

For and on behalf of TBGRI

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For and on behalf of PARTY

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**ANNEXURE - I**

**KNOWHOW**

The KNOWHOW shall mean [please specify the type of knowhow/ scale of development/ parameters, specifications of its operation / use etc.]

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**ANNEXURE - II**

**PRODUCT**



The PRODUCT shall meet/conform to the following [specifications / parameters etc.]

---

## ANNEXURE - III

### **TERMS & CONDITIONS FOR PAYMENT OF ROYALTY**

1. The royalty shall be payable on net ex-factory sale price of all the PRODUCT manufactures sold and used for as such or to make any other product therefrom, exclusive of all duties and taxes payable to the Government. The ex-factory sale price for the basis of payment of royalty on the PRODUCT used for shall be (i) the highest ex-factory sale price of the PRODUCT sold; (ii) or if no merchant sales have taken place, the price such a PRODUCT would fetch if sold in the market as determined by the DIRECTOR TBGRI.
2. The period 10 years for the payment of royalty shall be computed from the date of the start of the commercial manufacture of the PRODUCT authorised by the PARTY to any agency of the Central or State Government or in the PARTY's Annual Reports and shall survive the period of licence hereinbefore mentioned.
3. The royalty shall become due for payment on the 31<sup>st</sup> March and on 30<sup>th</sup> September in every year and shall be paid by the PARTY on / or before the expiry of 60 days from the above two stipulated dates. In the event of default in the payment of royalty amount as above the PARTY shall pay interest on amount in default at the rate of 18% per annum.
4. The PARTY shall within 60 days of the stipulated dates deliver to TBGRI in a prescribed form, a true and complete statement in writing of PRODUCT manufactured, sold and / or used by PARTY during the preceding half year and all the royalty payable to TBGRI under this agreement.
5. PARTY shall be liable for the payment of royalty on all PRODUCT irrespective of any plea whether the same have been manufactured as per the KNOWHOW licensed by TBGRI or otherwise. All PRODUCT manufactured by the PARTY shall be deemed to have been manufactured under KNOWHOW licensed TBGRI. It will not be open to PARTY to claim any exemption or reduction in the payment or amount of royalty accruing under this agreement on the plea of having used KNOWHOW other than that of TBGRI or having effected any improvements/modifications in the intellectual property licensed by TBGRI.
6. PARTY shall at its place of business, keep accurate records in sufficient details to enable the calculation and determination of royalty payable hereunder and upon TBGRI's request shall permit an authorized representative of TBGRI to have access during its business hours to examine relevant records as may be necessary to (a) determine in respect of any half year as specified above, ending

not more than one year prior to the date of such request, the correctness of any report and / or payment under this agreement and (b) obtain information as to the royalty payable for any such period in case of failure to comply with the terms of the agreement.

アフリカユニオン個別レベル秘密保持契約  
Individual Level Confidentiality Agreement

The parties hereto are:

(Insert names and full addresses as appropriate)

\_\_\_\_\_ (the “Disclosing Party”)  
\_\_\_\_\_ (the “Receiving Party”)

I, the Receiving Party, hereby agree that any confidential scientific, technical, marketing or business information received by myself from any member of, or party associated with the \_\_\_\_\_, will not, unless subject to further written agreement, be disclosed or used by myself or the institution I represent, but that it is provided solely so that I may perform my duties. I agree hereto with respect to any confidential information disclosed to myself and which it is obvious to the Disclosing Party or claimed by the Disclosing Party as confidential (“Confidential Information”). Confidential Information may equally well be written information or information transmitted verbally, visually, electronically or by any other means.

I guarantee therefore that I shall:

a) Use said Confidential Information only for the purpose of furthering the activities of the

\_\_\_\_\_

b) Disclose the Confidential Information only to those other employees, colleagues or \_\_\_\_\_ (who shall have similarly committed in writing to the terms of this Agreement) necessary for the evaluation of the information, and shall in no instance disclose the same to any other party for any purpose without the prior written consent of the party providing the information.

c) Agree to protect the confidentiality of the information in the same manner I would protect the confidentiality of my own or my institution’s own proprietary and confidential information of TK kind, but in any case using reasonable care.

d) Agree that Confidential Information disclosed under this Agreement shall at all times remain the exclusive property of the Disclosing Party. No license or other

rights in or to the material disclosed, is granted by this Agreement, nor is any disclosure of Confidential Information under this Agreement, except as provided herein. All Confidential Information made available under this Agreement, including copies thereof, shall be returned to the Disclosing Party (or, upon such party's request or consent, destroyed) forthwith upon the first to occur of:

- i. Completion of the purpose(s) set forth in this Agreement;
- ii. The reasonable request of the Disclosing Party; or
- iii. The cancellation of this Agreement.

e) Not to copy or reproduce Confidential Information of the other party without first obtaining their written permission. Should authorized copies of the Confidential Information be made, each party undertakes to reproduce in complete and identical form and wording the right of ownership of the Disclosing Party.

f) Have no obligation of confidentiality with respect to information that:

- i. Is in the public domain by use and/or publication at the time of its receipt or enters the public domain thereafter through no fault of myself;
- ii. Was already in my possession prior to receipt as shown by written documentation to be delivered to the Disclosing party within thirty (30) days;
- iii. Was properly obtained from a third party not under a confidentiality obligation to the Disclosing Party; or
- iv. Was previously developed, independently, by myself or my institution, as shown by written documentation to be delivered to the Disclosing Party within thirty (30) days.

g) Recognize that the disclosure of Confidential Information under this Agreement can in no way be interpreted as endowing the Receiving Party with any right whatsoever to intellectual or industrial property, patent or any other right relating to Confidential Information.

The obligations of confidentiality under this Agreement shall be limited to a period of five (5) years from delivery of information.

This Agreement shall be governed and construed in accordance with \_\_\_\_\_ (insert name of country) law.

This Agreement contains my entire understanding with respect to the matters herein contained, and supersedes any previous agreements and undertakings with respect thereto.

IN WITNESS WHEREOF, this Agreement is hereby executed by:

Name: \_\_\_\_\_ Signed: \_\_\_\_\_  
\_\_\_\_\_ Date: \_\_\_\_\_

For and on behalf of \_\_\_\_\_ and  
duly authorized in his/her personal capacity:

Name: \_\_\_\_\_ Position: \_\_\_\_\_ Signed: \_\_\_\_\_  
\_\_\_\_\_ Date: \_\_\_\_\_

アフリカユニオン研究所レベル秘密保持契約

Institutional Level Mutual Non-disclosure Agreement

Between (ensure all relevant institutions are included):

\_\_\_\_\_

a \_\_\_\_\_ (insert profession) residing at \_\_\_\_\_  
\_\_\_\_\_ in his/her capacity as \_\_\_\_\_  
(hereinafter referred to as \_\_\_\_\_)

AND

a statutory body duly established under \_\_\_\_\_ (state the relevant  
legislation and the appropriate programme/unit) herein represented by  
\_\_\_\_\_ in his/her capacity as \_\_\_\_\_ and he/she  
being duly authorized thereto (hereinafter referred to as  
\_\_\_\_\_)

WHEREAS:

The parties have capabilities and expertise in using scientific knowledge and  
technological application to \_\_\_\_\_ .

The parties possess proprietary information, technical knowledge, experience,  
specimens and data of a secret and confidential nature relating to the field as  
specified below, all of which are regarded by them as valuable commercial assets  
of a highly confidential nature.

During the course of business discussions, negotiations, meetings and activities  
including, without limitation, any on-site premises visits or demonstrations,  
between the parties, each party may receive, observe or otherwise have access to  
information, whether inside or outside the field, that (a) relates to the Disclosing  
Party's past, present or future research, development, business activities,  
products, services and technical knowledge and (b) either has been identified in  
writing as confidential or is of such a nature (or has been disclosed in such a way)  
that it is obvious to the other party that it is claimed as confidential ("Confidential  
Information"). Confidential Information may equally well be written information  
or information transmitted verbally, visually, electronically or by any other  
means.

As used herein, the party disclosing Confidential Information is referred to as the  
"Disclosing Party" and the party receiving the Confidential Information is

referred to as the “Recipient”.

The nature of the discussions, meetings or activities prompting this Agreement is to share information, research results, background intellectual property and the wish to exchange more information, including Confidential Information and material in this regard. For the purposes of

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Now, therefore, the parties hereby agree as follows regarding Confidential Information:

## 1. USE OF CONFIDENTIAL INFORMATION

1.1 The Confidential Information of the Disclosing Party may be used by the Recipient only in connection with the purpose(s) set forth in this Agreement. The Parties agree to protect the confidentiality of each other’s Confidential Information in the same manner they protect the confidentiality of their own proprietary and Confidential Information of TK kind, but in any case using reasonable care.

1.2 Except as necessary for the purpose(s) set forth in this Agreement, the Confidential Information of the Disclosing Party may not be copied or reproduced by the Recipient without the Disclosing Party’s prior written consent. Should authorized copies of the Confidential Information be made, each party undertakes to reproduce in complete and identical form and wording the right of ownership of the Disclosing Party.

1.3 Each party shall in all events remain free to use, in the course of its business, its general knowledge, skills and experience incurred before, during or after the activities hereunder. (To this end, it is also recorded that nothing in this Agreement shall be construed as constituting an exclusive arrangement between the parties and both parties shall remain free to explore market opportunities in the field, unless otherwise agreed to in writing in a subsequent agreement.)

1.4 With respect to the purpose(s) set forth in this Agreement, neither party is authorized to use the name, logo or trademarks of the other in connection with any advertising, publicity or marketing or promotional materials or activities without the prior written consent of the other party. The Disclosing Party

provides the Confidential Information “as is”.

1.5 The parties shall:

1.5.1 Treat as strictly confidential any and all Confidential Information given or made known to them arising from this association;

1.5.2 Keep all such Confidential Information obtained secret to third parties and only use it in co-operation with each other for the purpose expressly agreed upon by the Parties and to disclose same to their employees only on a need-to-know basis;

1.5.3 Accept responsibility for the observance of the secrecy agreement by their employees; and

1.5.4 If required, cause all of their employees who are directly or indirectly given access to the said proprietary and Confidential Information to execute secrecy undertakings in a form acceptable to the parties in order to protect the parties against the unauthorized disclosure of such Confidential Information to any third party, and to fully co-operate in the enforcement of such secrecy undertakings.

## 2. OWNERSHIP OF CONFIDENTIAL INFORMATION

2.1 All documents or other material objects containing and/or representing Confidential Information disclosed under this Agreement shall at all times remain the exclusive property of the Disclosing Party. No license or other rights in or to the material disclosed is granted by this Agreement, nor is any disclosure of Confidential Information under this Agreement, except as provided herein. All Confidential Information made available under this Agreement, including copies thereof, shall be returned to the Disclosing Party (or, upon such party’s request or consent, destroyed) forthwith with no further formality upon the first to occur of:

2.1.1 Completion of the purpose(s) set forth in this Agreement;

2.1.2 The reasonable request of the Disclosing Party; or

2.1.3 The cancellation of this Agreement.

2.2 Disclosure of Confidential Information shall not constitute any representation, warranty, assurance, guarantee or inducement by the Disclosing Party with respect to infringement of patents or other rights of third parties. No warranty or



representation as to the accuracy, completeness, or technical or scientific quality of any Confidential Information is provided herein. Without restricting the generality of the foregoing, neither party makes any representation or warranty as to the merchantability or fitness for a particular purpose of any Confidential Information disclosed hereunder.

### 3. EXCLUSIONS

Nothing in this Agreement shall prohibit or limit either party's use of information (including, but not limited to, ideas, concepts, know-how, techniques and methodologies):

3.1 Which at the time of disclosure is published or otherwise generally available to the public;

3.2 Which, after disclosure by the Disclosing Party, is published or becomes generally available to the public, otherwise than through any act or omission on the part of the Recipient;

3.3 Which the parties can show was in their possession at the time of disclosure and which was not acquired directly or indirectly from each other;

3.4 Rightfully acquired from others who did not obtain it under pledge of secrecy to either of the parties;

3.5 Which the Recipient is obliged to disclose in terms of an order of court, subpoena or other legal process.

3.6 In the event of either party receiving a subpoena or other validly issued administrative or judicial process requesting Confidential Information of the other party, the Recipient shall promptly notify the Disclosing Party thereof.

### 4. BREACH

It is acknowledged that the breach of this Agreement by the Recipient would cause the Disclosing Party irreparable injury not compensable in monetary damages alone. Accordingly, in the event of a breach, or a threat of a breach, the Disclosing Party, in addition to its other remedies, is entitled to a restraining order, preliminary injunction or similar relief so as to specifically enforce the

terms of this Agreement or prevent, cure or reduce the adverse effects of the breach.

5. ABSENCE OF LICENCE It is expressly agreed between the parties that the disclosure of Confidential Information under this Agreement can in no way be interpreted as endowing the Recipient with any right whatsoever to intellectual or industrial property, patent or any other right relating to Confidential Information.

## 6. COMMENCEMENT AND DURATION

6.1 This Agreement shall operate as from the date of signature hereof and shall remain binding for a period of \_\_\_\_ (\_\_\_\_\_) years, unless terminated prior thereto by mutual written consent between the parties or superseded by another written agreement between the parties in the field.

6.2 In the event of the cancellation or termination of this Agreement for whatever reason, either prior to or at the time of expiry of the period mentioned in clause 6.1 above, the parties agree that after \_\_\_\_ (\_\_\_\_\_) years from the date of such cancellation, termination or expiry, they shall each be relieved from all obligations under this Agreement and that after such time has expired, they will rely on such patents or other intellectual property as they may then own for the protection of any Confidential Information disclosed to each other pursuant to this Agreement.

## 7. GOVERNING LAW

This Agreement shall be governed by and construed in accordance with the laws of \_\_\_\_\_ (insert full name of country) and any dispute arising there from shall be adjudicated by a competent court in \_\_\_\_\_ (insert full name of country) and for these purposes the parties agree to the exclusive jurisdiction of the \_\_\_\_\_ courts for the adjudication of such disputes.

## 8. ENTIRE AGREEMENT

This Agreement is the only and exclusive agreement between the parties with respect to the subject matter of this Agreement, and it supersedes all prior or contemporaneous representations, promises, inducements, proposals, discussions and other communications.

9. GENERAL PROVISIONS

No furnishing of Confidential Information and no obligation hereunder shall be construed to obligate either party to:

9.1.1 Enter into any further agreement or negotiation with or make any further disclosure to the other party; nor shall it

9.1.2 Prevent either party from entering into any agreement or negotiation with any other third party regarding the same subject matter or any other subject matter; nor shall it

9.1.3 Prevent either party from pursuing its business in whatever manner it elects, even if this involves competing with the other party. Any Confidential Information containing estimates or forecasts shall not constitute binding commitments. Neither party shall directly or indirectly use, in an identical or modified form, any Confidential Information obtained from the other to its or a third party's competitive advantage.

9.2 No public announcement or disclosure beyond those disclosures authorized for Confidential Information hereunder may be made by either party concerning this Agreement without the prior written approval of the other party.

9.3 If any clause or term of this Agreement should be invalid, unenforceable or illegal, then the remaining terms and provisions of this Agreement shall be deemed to be severable therefrom; and

9.4 Shall continue in full force and effect unless such invalidity, unenforceability or illegality goes to the root of this Agreement.

SIGNED at \_\_\_\_\_ this \_\_\_\_\_ day of \_\_\_\_\_. AS  
WITNESSES (as appropriate):

1. \_\_\_\_\_ For  
\_\_\_\_\_

Full names

2. \_\_\_\_\_ Capacity

(duly authorized)

アフリカユニオンプロジェクト情報

## Project Information

(Note: Care must be taken to avoid the indiscriminate use of technical jargon and, where appropriate, the document should be translated into local languages)

Title of Project:

\_\_\_\_\_ Synopsis  
of the Project (Clearly summarize what the project is about, the objectives, the partners, the outcome, benefits etc.)

## Contribution of the Provider

Explain what the Recipient / Researcher expects from the Provider, including any targets that may be envisaged and assurance of authenticity.

Rights of Project Partners Include explanations on:

- a) Withdrawal;
- b) Amendment; and
- c) Renegotiation.

## Additional Information

Invite the Provider to feel free to ask any questions about the project.

Contacts: Include contact details of key project personnel

アフリカユニオン 遺伝資源 伝統的知識 利益配分 契約

Benefit Sharing Agreement

Application for permit if applicant is a juristic body

Name of institution or body: \_\_\_\_\_

Registration number of institution or body: \_\_\_\_\_

Contact details of institution or body (including postal/physical address, phone, fax and e-mail address):

\_\_\_\_\_ Name of

contact person in the institution or body: \_\_\_\_\_

Capacity of contact person: \_\_\_\_\_

Application for a permit if applicant is a natural person

Name of applicant: \_\_\_\_\_

Identity number of applicant: \_\_\_\_\_

Contact details of applicant (including postal/physical address, phone, fax and e-mail address):

\_\_\_\_\_  
\_\_\_\_\_

Provider of access to indigenous biological resources (if applicable)

Name: \_\_\_\_\_

Capacity: \_\_\_\_\_

If entering into agreement in a representative capacity, state name of principal:

\_\_\_\_\_

\_\_\_\_\_ Contact details (includes physical/postal address, telephone, fax and e-mail address):

\_\_\_\_\_  
\_\_\_\_\_

Indigenous community (if applicable)

Description of indigenous community:

\_\_\_\_\_  
\_\_\_\_\_

Name of indigenous community representative who will sign this agreement on

behalf of the indigenous community:

\_\_\_\_\_ Capacity:  
\_\_\_\_\_ Contact details  
(includes physical/postal address, telephone, fax and e-mail address) of the  
indigenous community representative:

\_\_\_\_\_  
\_\_\_\_\_

A resolution adopted by the indigenous community must be attached to this form. The resolution must confirm that the indigenous community representative indicated above has been authorized to enter into this agreement on behalf of the indigenous community; that the indigenous community has full knowledge of the bioprospecting project; and that it consents to entering into this Benefit Sharing Agreement.

**Type and Quantity of Indigenous Biological Resources**

This Agreement concerns the following indigenous biological resources (specify below type of resources, quantity of resources and area or source from which the resources are to be collected or obtained)

Type of organism	Scientific and common names (family, genus or species if possible)	Part of organism to be collected	Quantity (Limitation on the quantity of samples)	Full locality data (GIS readings if possible)

Current uses of indigenous biological resources

The present potential uses of the indigenous biological resources to be collected are the following:

\_\_\_\_\_  
\_\_\_\_\_

Intended use of indigenous biological resources

The manner in which, and the extent to which, the indigenous biological resources are to be used or exploited for purposes of the bioprospecting are (insert details):

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Traditional use or knowledge (if applicable)

The indigenous community that is a party to this Agreement has the following traditional knowledge of the indigenous biological resources or has traditionally used the indigenous biological resources in the following way:

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Sharing in Benefits

Benefits will vary considerably from case to case and in particular, benefits will vary depending on whether the stakeholder is providing access to the indigenous biological resources, or is an indigenous community. The lists below provide examples of monetary and non-monetary benefits that may arise from bioprospecting projects. This first list is more relevant if the stakeholder to this Agreement is providing or giving access to the indigenous biological resources, while the second list is more relevant if the stakeholder to this Agreement is an indigenous community. Tick each block that applies to this agreement and identify below who will be the beneficiary of each benefit and the extent of the benefit (provide supporting documentation where necessary).

To be completed if stakeholder is providing or giving access to the indigenous biological resources

Non-monetary, monetary and “in kind” benefits			
Acknowledgement of parties giving access to resources	<input type="checkbox"/>	Voucher specimens with national institutions	<input type="checkbox"/>
Research results and copies of papers	<input type="checkbox"/>	Participation of South Africans in research	<input type="checkbox"/>
Support for conservation	<input type="checkbox"/>	Access to international collections by South Africans	<input type="checkbox"/>
Species inventories	<input type="checkbox"/>	Recognition and promotion of traditional knowledge /use	<input type="checkbox"/>

Student training and support		Community development projects	
Scientific capacity development		Environmental education	
Technology transfer		Fees	
Joint research		Royalties	
Information		Upfront payments	
Equipment and infrastructure		Milestone payments	
Other (specify)		Other financial benefits (specify)	

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To be completed if stakeholder is an indigenous community

Non-monetary, monetary and “in kind” benefits			
Ongoing communication of bioprospecting objectives, methods and findings, translated into local languages		Copies of proposals, reports and publications	
Simplified and popularized posters, manuals, pamphlets and other documents translated into local languages		Recognition and promotion of traditional knowledge / use	
Co-authorship of publications		Lodging of specimens	
Access to research data		Grants for development and environmental education projects	
Copies of photographs and slides		Fees (e.g. for consultation, assistants, guides, use of facilities and infrastructure)	
Inclusion in the research of local collaborators, assistants, guides and informants		Royalties	
Training of local people as appropriate in relevant scientific, legal and management issues		Upfront payments	
Equipment and infrastructure support		Milestone payments	
Co-ownership of any intellectual property rights		Other financial benefits (specify)	
Other (specify)		Other (specify)	

Payment of Benefits



All money arising out of this Agreement and due to any party to this Agreement must be paid into the Bioprospecting Trust Fund. The Trust Fund will in turn provide details in terms who benefits from the fund, how payments will be calculated and made to the beneficiaries. This information may form part of the Annexure to this Agreement. *Please note that implementation of this Clause will vary from country to country and will be guided by the relevant legislation, where it exists.*

#### Duration of the Agreement

This Agreement shall operate as from the date of signature hereof and shall remain binding for a period of \_\_\_\_ (\_\_\_\_\_) years, unless terminated prior thereto by mutual written consent between the parties or superseded by another written agreement between the parties in the field.

#### Review of the Agreement

This Agreement will be reviewed every \_\_\_\_\_ (insert agreed time frame), with a view to amending the Agreement if necessary. \_\_\_\_\_ (*insert period in days or months*) prior to every review, the permit holder must disclose any new material information with regard to the bioprospecting to all stakeholders to enable stakeholders to participate in the review from an informed basis.

#### Other Matters

Any other matters or conditions which the parties to this Agreement wish to record may be attached to this Agreement as an annexure.

A copy of this Agreement must be lodged with \_\_\_\_\_ (insert authority responsible) within \_\_\_\_\_ (*insert period in days or months*) of the Agreement being concluded.

This Agreement constitutes the entire agreement between the parties with regard to the subject matter of this Agreement and no addition to, variation or cancellation of this Agreement or waiver of any rights under this Agreement will be of any force or effect, unless reduced to writing and signed by the parties to this Agreement.

Signature of applicant for permit: \_\_\_\_\_

Date: \_\_\_\_\_

Capacity of signatory: \_\_\_\_\_

On behalf of: \_\_\_\_\_

Endorsement of a juristic body, (if applicable)

Name of juristic body: \_\_\_\_\_

Signature of duly authorized officer from the juristic body: \_\_\_\_\_

Date: \_\_\_\_\_

Signature of access provider of indigenous biological resource: \_\_\_\_\_

Date: \_\_\_\_\_

Capacity of signatory: \_\_\_\_\_

On behalf of: \_\_\_\_\_

Signature of indigenous community representative: \_\_\_\_\_ Date: \_\_\_\_\_

\_\_\_\_\_

Capacity of signatory: \_\_\_\_\_

On behalf of: \_\_\_\_\_ Approved

by: \_\_\_\_\_ Signature:

\_\_\_\_\_

Date: \_\_\_\_\_

エチオピア遺伝資源 Teff 商用開発のためのアクセスと利益配分契約見本

エチオピア遺伝資源 Teff 商用開発のためのアクセスと利益配分契約

Agreement on access to, and benefit sharing from, Teff genetic resources

*Institute of Biodiversity Conservation,  
Ethiopian Agricultural Research Organization  
Health and Performance Food International bv. (HPFI)*

**Agreement  
on access to, and benefit sharing from, Teff genetic resources**

Signed for the Provider

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Date\_\_\_\_\_

Signed for the Company

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Date\_\_\_\_\_

## Table of contents

1	Table of contents	92
2	Parties	93
3	Preamble	93
4	The scope of access	94
5	Intellectual property ownership	95
6	Transfer to third parties	96
7	Effect of the agreement	96
8	Benefit sharing	96
9	Ownership and confidentiality	98
10	Duration of the agreement	98
11	Penalty	98
12	Termination	98
13	Dispute settlement	99
14	Guarantee	99
15	Applicable laws	99
16	Monitoring and follow-up	100
17	Annexes to the agreement	100

## Parties

This **agreement** is signed between:

The Institute of Biodiversity Conservation, whose address is Yeka Kifle Ketema, Kebele 08, P.O.Box 30726; telephone 251-1-627504/612244, fax: 251-1- 627730/613722; e-mail: ibcar@telecom.net.et or Biod@telecom.net.et, Addis Ababa, Ethiopia, hereafter referred to as the “**Provider**”

The Ethiopian Agricultural Research Organization, whose address is Bole Kifle Ketema, Kebele 12/13, P.O.Box 2003; Tel: 251-1-462270; fax: 251-1-461251; e-mail: dg@earo.org.et; Addis Ababa, Ethiopia, hereafter referred to as “**EARO**”

And

Health and Performance Food International bv. (HPFI), whose registered address is P.O. Box 427, Azieweg 4, 9407 TG Assen, NL-9400, the Netherlands, Tel: +31 (0) 6 53 413847, e.mail j.turkensteen@soilandcrop.com, hereafter referred to as the “**Company**”.

Preamble

Whereas Teff (*Eragrostis tef*) is a crop species of Ethiopian origin and has various attributes of interest to the food industry.

Whereas the **Company** has come up with new applications of Teff and thus wants to have access to Teff varieties to be used for producing Teff-based food and beverage products and to develop new Teff varieties more suitable for producing such products.

Whereas the **Company** acknowledges that the genetic resources of Teff the **Company** has acquired or will acquire irrespective of the source are of Ethiopian origin and thus belongs to Ethiopia, and it agrees to respect this fact.

Whereas the **Provider** is a national institution in Ethiopia with the authority to grant and regulate access to genetic resources of Teff and other

species and is responsible for effecting the sharing of the benefits from those genetic resources.

Whereas the **EARO** is a national research institution responsible for the coordination of national agricultural research on Teff in Ethiopia and has developed various Teff varieties.

Whereas Articles 1 and 15-19 of the 'Convention on Biological Diversity' and the 'Bonn guideline on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilization,' which "are a useful first step of an evolutionary process in the implementation of relevant provisions of the Convention", require that the benefits arising out of the utilization of genetic resources be shared fairly and equitably between the **Provider** and the **Company**; and whereas the access to genetic resources and the fair and equitable sharing of the benefits arising from the utilization thereof is to be determined by terms mutually agreed by the two parties.

Whereas the **Company** wants to use the genetic resources of Teff and is willing to share with the **Provider** the benefits arising out of the use; and whereas the **Provider** has consented to the use of the genetic resources of Teff by the **Company**.

Therefore, in witness thereof, the following **agreement** on access to Teff genetic resources and the fair and equitable sharing of the benefits arising from the access has been concluded by the two parties.

The scope of access

The **Provider** agrees that the **Company** accesses and uses the genetic resources of Teff specified in Annex 1 to this **agreement**.

Under this **agreement**, the **Company** is permitted to use the genetic resources of Teff only for the purpose of developing non-traditional Teff based food and beverage products that are listed in Annex 3 to this **agreement**.

The **Company** cannot use Teff for any other purposes (e.g. chemical, pharmaceutical etc.) whatsoever unless explicit written consent is given by the **Provider**.

The **Provider** shall not grant to other parties access to Teff genetic resources for the purpose of producing the products of the **Company** listed in Annex 3 of this **agreement** unless it secures the consent of the

## **Company.**

The **Company** is not permitted to access the traditional knowledge of Ethiopian communities on the conservation, cultivation and use of Teff. Therefore, the **Company** shall not claim any rights over, nor make commercial benefit out of, such traditional knowledge unless explicit written **agreement** is given to it by the **Provider**.

To avoid possible confusion between the traditional knowledge of Ethiopian local communities and inventions made by the **Company**, the **Provider** shall, upon submission by the **Company** of its research proposals, inform the **Company** of the existing traditional knowledge of relevance to the research areas proposed by the **Company**.

The **Company** acknowledges that the genetic resources of Teff it has acquired or will acquire, irrespective of the source, is of Ethiopian origin and thus belongs to Ethiopia. It agrees to respect this fact.

Should there arise any claim challenging the origin or ownership of Teff, the **Provider** shall take the responsibility to defend the parties against that claim, and the **Company** shall assist the **Provider** in the defence.

The **Company** shall assist in identifying and bringing to court infringers upon the rights of Ethiopia over Teff.

## Intellectual property ownership

The **Company** shall neither claim nor obtain intellectual property rights over the genetic resources of Teff or over any component of the genetic resources. However, plant variety protection may be obtained over Teff varieties.

The plant variety protection rights over new Teff varieties the **Company** will develop shall be co-owned by the **Company** and **EARO**. Such varieties shall be used by **EARO** and the **Company** in such a way as not to damage the business interests of the **Company** in so far as the products listed in Annex 3 or the interests of **EARO** or the **Provider** are concerned.

The Teff varieties that are not developed by the **Company** shall be owned by the **Provider** on behalf of the Teff farming local communities of Ethiopia. If it is found to be in the interest of the **Provider** or the **Company**, such varieties may be registered in the name of **EARO**. The **Company** shall handle and cover the cost of such registration outside of Ethiopia, provided

that it has the finances in the given budget year.

#### Transfer to third parties

The **Company** shall not transfer Teff seed samples or any component of the genetic resources of Teff to third parties without first having explicit written consent from the **Provider**.

#### Effect of the agreement

The **agreement** shall not affect the sovereign rights of Ethiopia over the genetic resources of Teff and the **Provider** shall always retain the authority to grant other parties access to any genetic resources of Teff.

This **agreement** shall not affect whatsoever any traditional products of Teff, be it in Ethiopia or abroad.

This **agreement** shall not affect whatsoever any non-traditional products of Teff, be it in Ethiopia or abroad, except for those the Company has specified in Annex 3 to this agreement.

This **agreement** shall not prohibit the exporting of Teff from Ethiopia to other parties. However, if an importer or anyone who buys Teff from that importer wants to use or uses Teff for making any of the products specified in Annex 3 to this agreement and this fact is brought to the attention of the **Provider**, Ethiopia will refuse to export Teff to that importer.

#### Benefit sharing

The **Company** has agreed to share the benefits that arise out of the utilization of the genetic resources of Teff.

The **Company** agrees to pay to the **Provider** a lump sum equal to the

Gross net income in the years 2007 + 2008 + 2009

10% x

amount

This payment shall be made immediately after the publication of the annual account of the **Company** for the year 2009 (i.e. shortly after publication and shareholder approval in June 2010).

The **Company** agrees to pay to the **Provider** annually a royalty of 30% of the net profit from the sale of basic and certified seeds of the Teff varieties



specified in column 3 of Annex 1 to this **agreement**.

The **Company** agrees to pay to the **Provider** annually a license fee equal to the amount defined in Annex 2.

The **Company** agrees to contribute 5% of its net profit, which shall not be less than 20,000 Euro per year, to the **Financial Resource Support for Teff**, hereafter referred to as **FiRST**. The **FiRST** shall be used for improving the living conditions of local farming communities and for developing Teff business in Ethiopia.

The **FiRST** shall be administered jointly by the **Provider** and the **Company**. The University of van Hall/Larenstein will participate in the administration of the **FiRST**. The role of van Hall/Larenstein University in the administration of the **FiRST** will be to ensure that Dutch scientific knowledge and experience with product innovation are transferred into Ethiopia in the process of using the **FiRST**. Other details of the administration of the **FiRST** shall be specified by another agreement of the parties.

The **Company** agrees to share with the **Provider** and **EARO** the results of research it will undertake on Teff. Accordingly, the **Company** shall share with the **Provider** and **EARO** the knowledge or technologies it may generate using Teff except when it constitutes Undisclosed Information to the **Company** according to Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights of the World Trade Organization.

The **Company** agrees to involve Ethiopian scientists in the research it will undertake. The kinds of research on which Ethiopian scientists will participate and the mode of participation shall be specified by mutual agreement of the parties in the research plan of the **Company**. As appropriate, the **Company** will contract out research to Ethiopian research institutions.

The **Company** will take the **EARO** as the most preferred institution to breed Teff varieties.

By way of contributing to the Ethiopian local economy in connection with the access to Teff genetic resources, the **Company** agrees to establish profitable Teff businesses in Ethiopia, such as establishing Teff farming, cleaning and milling enterprises, bakeries, etc. The **Company** will therefore create joint ventures with Ethiopian counterparts.

Furthermore the **Company** will find funding that will augment the **FiRST** specified in paragraph 0 using the opportunity created by the joint ventures. The **Company** shall acknowledge, in all its publications and application for the registration of Teff varieties and other intellectual property rights over products it will develop from Teff, that Ethiopia is the country of origin of that Teff.

#### Ownership and confidentiality

Results of any joint research conducted on Teff materials shall be owned by both parties and shall be released only upon written consent of both parties. Information that is identified by either party as confidential shall be kept as such by both parties.

#### Duration of the agreement

The **agreement** shall remain in force for a period of 10 years. The parties may renegotiate the **agreement** at the end of that period.

#### Penalty

A party that breaches the terms of this **agreement** shall pay to the aggrieved party a penalty of 50,000 Euro if asked to do so by the aggrieved party.

The penalty that is specified in paragraph 0 is applicable on the **Provider** if it breaches the terms of this **agreement**, particularly those given in paragraphs 0, 0, 0, 0, 0, 0 and 0

The penalty that is specified in paragraph 0 is applicable on the **Company** if it breaches the terms of this **agreement**, particularly those given in paragraphs 0, 0, 0, 0, 0, 0, 0, 0, 0 and 0.

If the **Company** fails to fulfil its financial obligations as specified in part 0 of this **agreement** on 'Benefit sharing', the **Provider** may add a penalty of 5% of the due payment for any delay of between 90 and 180 days, and 25% thereafter.

#### Termination

If the company is in the process of bankruptcy, the **Provider** can immediately terminate the **agreement**.

If one of the parties repeatedly fails to fulfil or repeatedly violates its obligations under this **agreement**, then the aggrieved party may terminate

the **agreement** upon 30 days notice given in writing to the other party.

Termination of this **agreement**, except in the case of bankruptcy, will be done through mutual agreement by both parties.

The termination of this **agreement** shall not affect the rights and obligations that were due to accrue to either party prior to the effective date of termination.

Starting with the day of termination of the agreement, the **Company** shall stop using the genetic resources of Teff. However, the **Company** is entitled to continue the use of co-owned Teff varieties upon payment of royalties to be mutually agreed upon by both parties.

#### Dispute settlement

If any dispute arises in connection with the interpretation or application of this agreement, both parties shall seek solution by negotiation. If the dispute cannot be resolved by negotiation, it shall be submitted to an arbitration body in accordance with the procedure laid down in part I of Annex II of the Convention on Biological Diversity.

For the purpose of Paragraph 13.1, the word "party" in Part I of Annex II of the Convention on Biological Diversity shall mean "**Provider**" or "**Company**".

The decision of the arbitral tribunal shall be final and binding on the parties without appeal.

If either of the parties fails to comply with the award of the arbitral tribunal, the aggrieved party may, in accordance with Paragraph 16 (d) (iv) of the Annex to Section A of Decision VI/24 of the 6<sup>th</sup> Conference of the Parties of the Convention on Biological Diversity, UNEP/CBD/COP/6/20, the Hague, 7-19 April 2002, ask the Government of the Federal Democratic Republic of Ethiopia or the Government of the Netherlands to enforce the award given by the arbitral tribunal.

#### Guarantee

Each year, the **Company** shall pay a sufficient sum of money in advance from which the requests by the provider for payment will be subtracted.

#### Applicable laws

The Convention on Biological Diversity (CBD) and the relevant decisions,

guidelines and laws that emanate from it, including the International Treaty on Plant Genetic Resources for Food and Agriculture, in particular but not restricted to, its Article 9 on Farmers' Rights, the Bonn Guidelines, decisions of the various Conferences of the parties as well as those provisions of the Union for the Protection of New Plant Varieties (UPOV) that are consistent with the CBD and the relevant decisions, guidelines, and laws that emanate from it shall apply to matters not addressed in this agreement.

The CBD and the decisions, guidelines or laws that emanate from it shall prevail over the UPOV in cases on which the two do not agree.

Monitoring and follow-up

The **Company** shall submit to the **Provider** annual research and financial reports.

The **Provider** has the right to review at any moment, through an independent accountant if it so wishes, the bookkeeping as well as the relevant administrative details of the items covered by this **agreement**.

Meetings between the two parties will be held as required to exchange information.

Annexes to the agreement

The following Annexes shall form part of this **agreement**.

Annex 1: Varieties of Teff accessed by S&C. This Annex shows the different varieties of Teff and the authorization of use given by the **Provider** to the **Company**. This Annex may be updated by mutual agreement of the parties as needed.

Annex 2: Annual payments of licence fee per hectare for growing Teff. The annual payment of the licence fee provided for in Paragraph 0 will be determined after each harvest season based on this Annex.

Annex 3: List of products of the **Company**. This Annex shall be updated by mutual agreement of the parties as needed.

オーストラリア国際農業研究所（ACIAR）共同研究標準契約

**Standard Conditions for Project Agreements between the Australian Center for International Agricultural Research (ACIAR) and Commissioned Organization(s)**

背景

**Subject matter** Plant Genetic Resources, Animal Genetic Resources, Microbial Genetic Resources and sometimes uncharacterized Genetic Material transferred inadvertently: for example, microbes or parasites present in samples of plant material.

**Summary of use(s)** Our standard conditions of agreement require partners to enter into formal agreements for germplasm exchange. We also maintain an intellectual property register for all relevant projects, but the information has been provided to us on the basis that it is for in-house use only.

**Purpose or background** ACIAR, as part of the Australian Aid program, is a facilitator and funder of collaborative projects in international agricultural research, rather than an executor of the research projects itself.

It facilitates (i.e. assists with design) and funds two types of projects:  
(a) Bilateral projects, which involve collaborations between Australian research organisations (for example, CSIRO, Universities, State Government departments, sometimes the private sector) and similar organisations in one or more developing countries in the region; and  
(b) Multilateral projects, led by International Agricultural Research centres (these are usually centres within the CGIAR system, but can also include some non-CGIAR centres). The CGIAR centres have their own policies for providing access to germplasm, and also maintain a publicly available database call "SINGER" (<http://singer.cgiar.org>).

ACIAR has entered into about 100 contracts relating to either exchange of genetic resources and/ or biotechnology applications. For further information on the current projects ACIAR supports, please see: <http://www.aciar.gov.au>

## 契約内容

### PROJECT PROFORMA

This proforma should be used in conjunction with ACIAR's Project Development Guidelines and Project Budget Proforma, available on ACIAR's web site <http://www.aciar.gov.au>. The proforma contains instructions for completion of each section. The same proforma is used for small, medium, preliminary large and full large proposals. This cover page and all instructions (in blue font) should be deleted before submission of the proposal to ACIAR. Proposals exceeding 25 pages (excluding budget and appendices) will be returned for editing.

#### SECTION 1. Project Outline Administration

Project title: Title should be descriptive and concise

Proposal stage: Preliminary or Full

Proponent's  
name:

Phone:

Fax:

Email:

Proponent's  
organisation:

Commissioned  
organisation: The Commissioned Organisation is the lead organisation in Australia, or for IARC (International Agricultural Research Centre) projects, lead IARC

Project type: Bilateral or IARC; Small, Medium or Large

% funding to  
IARC

Focus area: To be completed by ACIAR

ACIAR Research  
Program Area:

Project Number: Assigned by ACIAR

Geographic  
Region/s

Country/ies:

### 1.1 Project title and details

### 1.2 Funding Investment requested from ACIAR

(Annual totals and the totals amount for each year the)

<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Year 4</b>	<b>Year 5</b>	<b>Total</b>
---------------	---------------	---------------	---------------	---------------	--------------

**Project**

**Duration**

**Proposed Start Date:** Usually 1 January or 1 July

**Proposed Finish Date:**

**Key Contacts**

All institutions involved in the project should be noted. One scientist per institution is required. These sections should be duplicated as required, e.g. for multiple collaborating organisations.

**Project Leader: Australian Commissioned Organisation /  
Commissioned IARC**

Title and

Name

Position

Organisation

Phone

Fax

Email

Postal Address

Street Address

**Administrative Contact: Australian Commissioned  
Organisation / Commissioned IARC**

Title and  
Name

Position

Organisation

Phone

Fax

Email

Postal Address

Street Address

**Collaborating Scientist: Australian Collaborating  
Organisation / Collaborating IARC**



Title and  
Name

Position

Organisation

Phone

Fax

Email

Postal Address

Street Address

**Project Leader: Partner Country**

Title and  
Name

Position

Organisation

Phone

Fax

Email

Postal Address

Street Address

**Collaborating Scientist: Partner Country Collaborating  
Organisation (if any)**

Title and  
Name

Position

Organisation

Phone

Fax

Email

Postal Address

Street Address

### **Project summary**

A project summary (maximum 600 words) is required for both preliminary and full proposals. The summary must be clear to general scientific readers and contain:

- Background statement (1-2 paragraphs) on the problem, the priority, the approach and objectives, and the proposed collaborators
- A fuller description of the specific objectives and expected outputs, including a realistic assessment of the likely community benefits and impacts (social, economic, environmental) of the project outputs and any significant capacity enhancement. Possible negative impacts, if likely to be significant, should also be mentioned.
- A paragraph on how the project will be undertaken, including methods, personnel and application of project outputs. Specify adoption pathways and approaches for the dissemination of research results.

## **SECTION 2. Project Justification**

### **2.1 Partner Country and Australian research and development issues and priority**

For **preliminary proposals**, emphasise 'what and why' in less than one page.

For **full proposals**, address the following in a maximum of two pages:

- origin of project idea (meeting, visit, previous project, project review, etc.)
- the agricultural or natural resource problem or opportunity targeted by the project, the proposed solution, and why research is an important approach to the problem
- occurrence of the problem (partner developing country, Australia, other developing country)
- why the project is appropriate for the country/countries nominated as opposed to other countries
- the size and value of the production system involved, and quantification of the cost of the problem
- the project's alignment with the priorities of ACIAR, the developing country including, where possible the priority attached to the proposed research in the ACIAR country consultation process. In the case of projects involving an IARC, clarify the priority for the IARC, including fit with the IARC's Strategic Plan. Provide other justification if the project has not been identified as a priority through an ACIAR country consultation.
- the priority of the problem for the countries and commodities involved relative to other related commodities, and to
- for the particular commodity, for example, livestock or crop breeding versus nutrition
- the potential beneficiaries of the project outputs, and whether farmers have been involved in setting the priorities

### **2.2 Project strategy and context (relationship to previous ACIAR research and other research)**

For **preliminary proposals**, outline in one page maximum:

- proposed research strategy.
- whether and why this is the most appropriate approach
- how the research approach was developed
- whether the proposal builds upon previous projects

For **full proposals**, within a limit of three pages, outline:

- the proposed research approaches; why these approaches are preferred over other possible approaches to the chosen problem; whether these approaches have been tried before;
- the balance between research (strategic, applied, adaptive), development activities (for example, working directly with farmers) and capacity building (for example, training of researchers, enhancing building infrastructure; why this balance is appropriate to the problem and countries involved; how the research fits with existing and previous related research on the problem, including previous or current ACIAR projects; chance of research success;
- previous research underpinning the problem, and in the context of the research approach proposed. This should include relevant work not yet published, for example knowledge arising from related ACIAR projects. Up to eight literature references should be included. In certain circumstances, the ACIAR Research Program Manager may request that a fuller literature review on the subject be appended to the proposal;
- a list (agency, project number, project title) of other projects (completed, in progress or likely to commence) that are closely related to the proposed project. These could include projects supported by ACIAR, IARCs, Rural Industry Research and Development Corporations, AusAID or other agencies in Australia or overseas;
- any planned co-funding.

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### SECTION 3: Project Operations

### 3.1 Objectives

For **preliminary proposals**, list planned outputs as dot-points under each Objective (half a page). For **full proposals**, state the objectives. Outputs are addressed more comprehensively in section 3.2.

Objectives may be grouped into subprojects. It is important the research objectives, subprojects and activities be presented in logical order, and wherever possible that that order be maintained when describing outputs, and later, methods. Sometimes a chronological order is the most logical, with one output leading or linking to the next objective or activity and, in turn, to its output. There can be an overall aim or goal of the project, being a long-term outcome at the farm or community level. Objectives should include the application of outputs. Objectives covering communication and dissemination of project results should also be included.

### 3.2 Outputs (full proposals only).

Specify, in one page maximum single outputs table, the project outputs, including those linked within the project, or stand-alone outputs that have potential beyond the project. Training may be listed as an objective in its own right, with its own output, if enhancement of the capacity of partner research organisations is a major component of the project.

Columns in the table should address Subprojects and/or Research Objectives, Outputs, Assumptions and Applications. Assumptions refer to conditions beyond the project's control, which must be fulfilled for each output to be realised.

The following example describes the outputs from a project aiming to improve farmers' incomes through reducing yield losses in wheat from yellow rust. This will be attained through a research strategy involving dissemination of varieties with better resistance to yellow rust. Outputs of the project would comprise knowledge contained in a description of the new resistance genes, and improved germplasm containing resistance genes. The outputs are targeted at wheat breeders in areas prone to yellow rust.

<b>Subprojects</b>	<b>Outputs</b>	<b>Assumptions</b>	<b>Applications</b>
--------------------	----------------	--------------------	---------------------

**and/or Objectives**

1. Location of apparent new yellow rust resistance genes in gene bank material	1.1 Several new sources (wheat lines) of resistance to known races of rust	1. Resistance genes present in material tested >1:1000	1.1 Select best two resistance sources for objectives 2 and 3  1.2 Make new sources of resistance available to other breeders
2. Rust gene incorporation into desirable plant types by backcrossing	1.2 Updated database on resistances  2. Morphologically suitable germplasm containing new rust gene	2. Rust genes not closely linked to undesirable traits	2.1 Pass best lines to regular breeding stream  2.2 Test best lines for varietal release
3. Verification of gene novelty through test crossing	3. Clear evidence that new genes segregate independently of known genes	3. Absence of cross incompatibilities	3.1 Knowledge to facilitate resistance gene pyramiding  3.2 Populations appropriate for molecular mapping.

**3.3 Research methodologies and project travel**

The purpose of this section is to indicate the overall research and development methodology to be used, sufficient to justify the budget and time estimates, and to demonstrate the collaborative nature of the work. The major risks to successful achievement of objectives should also be considered, with attention to how they will be managed.

For **preliminary proposals** outline within one page the activities needed to achieve the outputs. For **full proposals**, in 2-3 pages, follow the order in which the objectives were introduced. Detail is required on:

- the methods to be adopted, noting that these, especially in the latter stages of the project, could be uncertain if they depend on earlier progress in the project or elsewhere; alternatives should be anticipated where possible, though without extensive detail. Sufficient detail is needed to convince expert reviewers that the proponents are adequately skilled;
- resources needed and the geographic deployment of research activities as appropriate for an international partnership. Methods relevant to capacity building should be described;
- in cases where there is co-funding, description and distinction of the components of the work to be handled within other related projects;
- the method(s) to be used to communicate project results and facilitate application and/or adoption of project outputs by other researchers, policy developers, extension groups, farmers or other stakeholders and/or intended beneficiaries as appropriate. For example, workshops or on-farm demonstrations may be planned for non-project audiences; publications or other information outputs for scientific and/or non-scientific audiences may be expected; partnerships may be developed during project life for the purpose of technology transfer; etc.

All planned project activities, including dissemination activities, are required to be covered in budget documentation.

### **3.3.a. Flow Chart (Methodologies)**

In rows, chart the major research or development activities under each of the objectives. Indicate commencement and major, easily verifiable milestones, especially at project termination. Months or quarters at which point when particular activities are programmed should be shown. The following is an example of a compact flow chart.

(PC = partner developing country, A = Australia)

<b>Objective</b>	<b>Activity</b>	<b>Time line</b>	<b>Milestone</b>
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(Yr and m)

1.1 Field screening 2000

1. Resistance lines from gene bank

gene location (PC and A) Yr 1, m1 to m8

1.2 Glasshouse

confirmation of Yr 1, m9 to Best two resistance  
resistance in 300 lines (R) sources in PC and  
(PC and A) Yr 2, m5 in A decided Yr 2, m5

1.3 Enter cleaned

screening data into gene Database updated Yr  
bank database (A) Yr 2, m6 to m7 2, m8.

2.1 Cross each new R

2. R gene source with five elite  
incorporation lines (PC and A) Yr2, m3 to m8

2.2 Screening, selection  
and accelerated

backcrossing, one cycle Yr 2, m9 to  
each 6 months (PC and BC3 F2 produced by  
A) Yr 3 m12 Yr 3, m12

2.3 BC3 selfed twice and  
good R plants selected  
(PC and A) Yr 4

Ten near homozygous  
new R lines ready for  
crossing or  
distribution in PC  
and in A by Yr 4, m12

3.1 Cross two new R  
genes to all 12 known R  
sources (PC) Yr 2, m3 to m8

3. R gene  
verification

3.2 Rapid generation Yr 2, m9 to 24 F5 populations of  
advance to produce >100 100 random lines



random F5 inbred lines Yr 4, m1 each in PC by Yr 4,  
for each cross (PC) m1

3.3 Seedling screening of Report on novelty  
populations and analysis and behaviour of two  
of results Yr 4, m1 to m12 R genes by Yr 4, m12.

**3.3.b. Travel table**

A travel table of all planned international and domestic travel in all directions is required. The travel table forms the essential basis for calculating travel line items in budgets.

- A chronological listing of travel is preferred, and scheduled major project planning meetings and internal mid-project reviews should be included.
- Country and organisation is required to be specified for each traveller.
- The required annual reporting to ACIAR should be considered. All reporting for the project is required to be submitted through the commissioned organisation.
- Large projects may require a final external project review before termination or soon thereafter, and 5-year projects may need a mid-term external review before being approved to proceed to completion. Costs for project staff participating in these meetings or reviews will need to be included in the project budget (ACIAR only covers costs of its staff and any external reviewers). A brief statement should be included on the tentative timing and form of meetings and reviews. A review is often combined with an end-of-project workshop. An example of a travel table follows.

(PC = partner country, A = Australia)

<b>Person(s) or position travelling</b>	<b>Approximate date of travel</b>	<b>From / to</b>	<b>Purpose</b>	<b>Duration (days Travel Allowance)</b>
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Project leader Bloggs (A)	Yr 1, m1	Horsham to PC	Project design	4
Project scientist, breeding (PC)	Yr 1, m3-6	PC to Syd, Horsham	Training, rust screening	75
Project scientist (A)	Yr 1, m3	Horsham to Syd	Accompany visiting scientist	3
Project scientist (A)	Yr 2, m8	Horsham to PC	Training, procedure verification	10
Project scientist, genetics (PC)	Yr 3, m2	PC to Horsham	Crossing, analyses and publication	14
Leader and two scientists (PC)	Yr 4, m9	PC to Horsham	Workshop	7
Collaborator (A)	Yr 4, m9	Syd to Horsham	Workshop	4

### 3.4 Intellectual Property and other regulatory compliance

ACIAR, the commissioned organisation, and the collaborators must fulfil all relevant obligations under international arrangements on intellectual property (IP) and biological resources (for example, the Convention on Biological Diversity) to which Australia is a signatory.

Intellectual property includes the actual or future legal ownership of techniques or information (via patent, materials transfer agreement or copyright) or living germplasm (via patent or plant variety rights or international treaty). ACIAR aims for equitable sharing of new IP between Australia and the partner countries, and between collaborators, and for the free flow of knowledge. In accordance with its mandate, ACIAR especially seeks ready access to new technologies arising from its projects for the

benefit of poor farmers in partner countries. The full details of ACIAR's policy on IP in projects it funds are at [www.aciar.gov.au](http://www.aciar.gov.au) etc. Projects involving IARCs must also fulfil agreed IARC Intellectual Property policies, as determined in consultation with the IARC partner.

For **preliminary proposals**, indicate briefly whether these are likely to be significant IP issues, and how they will be addressed. For **full proposals**, **Appendix A** must be completed and accompany the proposal. In addition to IP matters, a project may have to comply with other legal requirements related to the research and technology. These include regulations for germplasm transfer, quarantine on plant, soil and animal movement, biosafety, recombinant DNA release, and animal rights. If any of these are relevant, details of compliance with applicable regulations should be outlined, and supported by a covering letter from the commissioned organisation. It should be noted that the final ACIAR project agreement requests the research organisations to warrant that in carrying out the project they will comply with any such regulations.

### 3.5 Project personnel

**Preliminary proposals** need only show the names and organisations of major project participants. **Full proposals** require information in three areas in 1-2 pages:

(i) **List of participants involved in the project** (as per the tables below)

*Australian Commissioned and collaborating organisations (or IARC)*

Name	Sex		Agency	Position	Time in project (%)	Funded by
	M/F					

*Partner country (or country research institutions) or collaborating IARC*

<b>Name</b>	<b>Sex M/F</b>	<b>Agency</b>	<b>Position</b>	<b>Time in project (%)</b>	<b>Funded by</b>
-------------	--------------------	---------------	-----------------	--------------------------------	------------------

- It is usual for the commissioned organisation and overseas institution to contribute to the salary of their respective project leaders (usually at least 20% of project leader's time).
- In the partner country, it may be necessary to distinguish between an overall project leader and a 'day-to-day' operational leader.

**(ii) Description of the comparative advantage of the institutions involved**

**(iii) Summary details of the research capacity, skills and role of each participant involved (one paragraph per person**

#### **SECTION 4: Project outcomes and adoption**

The purpose of this section is to identify the community benefits that might be expected from the project if its outputs are achieved, both in the partner country/ies and in Australia. Mutual benefits are an important aspect of the partnership mode by which ACIAR operates. These benefits can be classified as economic, social and environmental impacts. Consideration is required to identifying the primary beneficiaries, particularly in partner countries, but noting also whether any groups will be disadvantaged and considering also whether the expected project outcomes might have a differential gender impact.

In the subsections below, significant social effects and/or environmental impacts, positive and/or negative, should be canvassed, noting particular impacts on scientific capacity in collaborating countries. Projected application of the research outputs within the duration of the project should be outlined, particularly after the project's termination, to achieve the

benefits listed. The stakeholders in the project outcomes , and the extent to which the project will contribute to these outcomes, should be outlined. The expected time frame for adoption, possible constraints to adoption, and the expected rate of adoption, should also be covered in this section.

In **preliminary proposals**, combine 4.1-4.3 to provide no more than a page.

In **full proposals**, address 4.1-4.3 separately in appropriate detail.

#### **4.1 Communication and dissemination strategies**

Note: This subsection refers especially to pathways of application and dissemination not to the anticipated impact of project outputs, which is covered in 4.2-4.4 below.

Document the communication and dissemination strategies that will be used to promote uptake of the results of the research in order to derive economic, social and/or environmental benefits for the partner country/ies and/or Australia from the project outputs.

- The project would usually include some specific communication and dissemination activities and outputs, including publications. Clarify the types of publications envisaged.
- Explain how the chosen dissemination strategies would be expected to lead to uptake and use of the project outputs. For example, how would limited on-farm demonstrations lead to changed farmer practices?
- Clarify how presentations at scientific forums would lead to application of new knowledge, how participation in a workshop would lead to adoption of new technologies, how training activities would help to build organisational capacity or, if the output is new information to assist policy makers, how this would reach the latter.

#### **4.2 Enhancement of research capacity**

Document how the research and development capacity of the scientists in Australian and partner country institutions will be enhanced, and how increased capacity will be sustained after the project is completed.

### 4.3 Economic benefit

Outline the expected economic benefit for the partner country/ies, associated regions and/or Australia from the project. Include any possible negative economic outcomes. Discuss, and if possible, estimate quantitatively for the partner country, associated regions and/or Australia, the impacts of research outputs and subsequent outcomes. Consideration should also be given to economic impact from spillovers to countries not actively involved in the project. Such estimates will require assumptions about adoption patterns in time and space, and about the magnitude of resulting cost savings (or income boosting). Other assumptions regarding important enabling conditions (for example, input supplies, markets) should also be specified.

For full proposals for large projects, and selected other projects, ACIAR may request that a detailed benefit-cost analysis be appended, as follows. As an aid to economic quantification of benefits, a useful step is to make a table with at least three columns. The left hand column would be year number, commencing with the first year of the project down to, for example, 20 years. The second column would be 'project (and other) costs', while the third column would be 'project benefits'. More columns can be added if splitting into subcomponents of benefits or costs is desired.

Costs in the second column for the first several years would usually only consist of project (and related) costs. It would be unusual for a project to result in economic benefits coincident with the conduct of the research. Figures in the benefits column should be derived from project outputs. In many cases, these benefit figures will be 'rubbery'. The justification provided in the text for choosing various numbers is often of more import than the numbers themselves. The key question is whether there is a compelling argument that significant economic benefits will arise from the project.

The annual project costs and benefits may be left in tabular form. Alternatively, some manipulation of them is justified if determining, for example, a benefit:cost ratio, a net present value, or an internal rate of return. ACIAR's Impact Assessment Program (IAP) is able to provide advice as required.

#### **4.4 Social benefit**

Outline the expected social benefit for the partner country/ies, associated regions and/or Australia from the project. Include any possible negative social outcomes. Consider whether there will be any significant equity, cultural, gender, religious, political, ethnic or demographic impacts of the project outputs. Consider which sections of the community stand to benefit, and which may suffer negative effects.

Community needs and aspirations, and cultural practices and customs should be considered in designing the project. Canvass whether there are factors that might inhibit participation in the project or its benefits, for example insecure land tenure, insufficient training, lack of credit availability or labour at key times. If so, indicate how these could be overcome, whether there is a mechanism for feedback from targeted communities during the project, and whether target communities have registered concern about the problem to be researched, and endorsed the likely project outcomes.

#### **4.5 Environmental benefit and possible negative environmental outcomes**

For the partner country/ies, associated regions and/or Australia, describe the likely direct positive and negative effects on the physical, chemical or biological environment where the technology is adopted, or elsewhere (off-site externalities) as a result of adoption of the outputs. Effects can arise through changes such as erosion, pesticide residues, nutrient pollution or biodiversity. Clarify the regulations applying to relevant environmental matters and the likelihood of compliance or steps to ensure compliance. If environment management is the primary focus of the project, indicate whether relevant authorities been consulted, and with what reaction.

Documentation of possible negative environmental outcomes is required to assist ACIAR fulfil its obligations under section 160 of the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act). S160 requires ACIAR to seek the advice of the Minister for the Environment and Heritage, through initial consultation with Environment Australia, on aid projects that are likely to have a significant environmental impact anywhere in the world. Consideration of negative environmental impacts should be in

the context of the Environment Australia document *EPBC Administrative guidelines on significance*, available at [www.ea.gov.au/epbc/assessapprov/referrals/significanceguide.html](http://www.ea.gov.au/epbc/assessapprov/referrals/significanceguide.html).

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## **SECTION 5: Budget**

For **preliminary proposals**, provide an indication of the likely project duration and an indication of the average yearly budget, ie. a budget of a few lines showing expected expenditure from ACIAR funds in Australia and each overseas country in terms of salaries, supplies and services, travel and capital costs.

For **full proposals**, completion of the budget proforma, by reference to its accompanying budget guidelines, is required.

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## **SECTION 6: Additional Documentation**

**(This section applies to full proposals only). The following must be attached:**

- **Letters of support** from each national research institution and/or government planning agency of the partner country/ies, IARCs (if involved in the project) and the Australian institution/s should be attached if possible, although in some cases these are not obtainable until the proposal is approved by ACIAR. Letters of support should include a statement confirming that the project leader will be available for the percentage of his/her time indicated, and will not be absent from the project for significant times (usually greater than 2 months) during the project without prior agreement with ACIAR.
- **Letters of approval for use of Genetically Modified Organisms, and/or Experimental animals** if appropriate. Document procedures required in all countries where such experiments will be undertaken and attach copies of approvals obtained.
- Any letters confirming **compliance with regulations related to germplasm transfer, quarantine on plant, soil and animal**



**movement, biosafety, recombinant DNA release, animal rights,** etc as addressed in subsection 3.4

- Short (half-page) **curricula vitae** (resumes, biodata) of the key project staff for the Australian commissioned organisation, collaborating organisations and the partner country/ies and IARCs (if involved in the project). CV for the leaders and one key researcher from each collaborating institution would usually be sufficient. Publication lists need not be included.

### **Privacy Statement**

ACIAR, as a Commonwealth government agency, is required to comply with the eleven Information Privacy Principles as set out in section 14 of the *Privacy Act 1988* ( [www.privacy.gov.au/publications/ipps.html](http://www.privacy.gov.au/publications/ipps.html) ). These are based on the 1980 OECD guidelines governing the protection of privacy and trans-border flows of personal data. The personal information provided in this project proposal, including CVs, is stored in hard copy and electronic format in ACIAR. The information is reproduced internally for the purpose of meetings to consider project proposals. It is reproduced for restricted external purposes as part of the contractual documentation exchanged with the commissioned organisation, collaborating institution(s) and partner country government(s). Personal information (individuals' contact details) is also stored in ACIAR's project information system. ACIAR endeavours to keep this information as up to date as possible, with the assistance of the individuals whose details are recorded. ACIAR does not divulge personal information to third parties for any other purpose.

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### **Appendix A: Intellectual Property Register**

ACIAR maintains an Intellectual Property Register that contains details of actual or future legal ownership of techniques or information (via patent or copyright) or germplasm, as identified in the attached proforma.

The intent of ACIAR's IP register, is to ensure that developing country partners have the 'Freedom to Operate' in order to utilise the outcomes of ACIAR-funded projects. The register (i) identifies constraints that will affect the application of the results of ACIAR projects especially by developing

countries; (ii) provides triggers to address these constraints in project development (or, in certain cases, at a later stage agreed between the project participants and ACIAR); and (iii) ensures that the ownership of plant germplasm exchanged in projects is identified and tracked.

In completing the IP proforma, the commissioned organisation has a responsibility to discuss its content with any Australian collaborating and overseas collaborating organisations and to provide those organisations with a copy of the appendix. ACIAR requires copies of all Materials (including germplasm) Transfer Agreements and certain other documentation (as specified in ACIAR's *Standard Conditions of Agreement*, which also has important clauses relating to IP.) before the project can commence. This Appendix is intended for ACIAR internal use only, and will not be provided to reviewers of project proposals or form part of the project contractual documentation.

Any information that is classified Commercial-in-Confidence can be provided as a separately annexed document.

Where deemed necessary, a separate agreement signed between collaborators and covering their understanding of access to and the sharing of background and new IP, will need to be seen and accepted by ACIAR before final approval of the project. This agreement comes under, but is separate from, the project agreement between ACIAR and the commissioned organisation

Examples of the major types of IP in projects in each program area include:

**Animal Sciences:** germplasm (forages and sometimes livestock); diagnostics (target DNA/protein sequences and DNA and antibody probes and molecular markers); vaccines (methods of production, target sequences, expression systems); rumen microbes; processes used for livestock feed formulations and modifications; information systems; processing technologies.

**Crop Sciences:** germplasm, transgenic crops (enabling technologies and marker genes), diagnostics (antibody- and DNA-based and molecular

markers), fungal and other species with bio-control properties; insect and weed control techniques; information systems.

**Economics Programs:** decision support systems for water allocation; CGE and other economic models; copyright in reports; confidential information on markets and marketing of particular commodities; databases (e.g. industry price and production data, GIS databases)

**Fisheries:** genetic resources; new technologies for hatchery, grow-out and diet formulation; new technologies for disease management and production enhancement in aquaculture; diagnostic tests

**Forestry:** germplasm (especially of Australian trees); nursery and propagation technologies; processing technologies for wood and non-wood forest products; bio-actives from forestry products; molecular markers; diagnostic tests for diseases; bio-control agents; models, databases and information systems.

**Postharvest Technology:** germplasm; decision support systems; grain storage technologies (controlled atmospheres, grain protectants, fumigants); grain drying equipment designs and protocols; analytical techniques (including antibodies); bio-control methods; natural disease protectants; disinfestation technologies; market information; product processing technologies

**Land and Water Resources:** equipment design for tillage and cropping beds; software for managing irrigation systems; diagnostic keys for nutrient deficiencies; engineering technology for wastewater management; decision support systems; crop simulation models; remote sensing/ GIS data sets and data sets for cropping systems simulation; germplasm/ fermentation/ application technology for rhizobial inoculants and bio-fertilisers.

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## ***ANNEXE 1***

### **STANDARD CONDITIONS FOR PROJECT AGREEMENTS BETWEEN ACIAR AND THE COMMISSIONED ORGANISATION**

***as at 1 January 2000***

#### **TABLE OF CONTENTS**

1. INTERPRETATION
2. SERVICES
3. SUB-CONTRACTING
4. TERM OF PROJECT AGREEMENT
5. PAYMENT
6. NEGATION OF EMPLOYMENT, PARTNERSHIP AND AGENCY
7. PERSONNEL
8. TRAVEL
9. PROJECT EQUIPMENT AND SUPPLIES
10. INTELLECTUAL PROPERTY
11. DISCLOSURE OF INFORMATION
12. COORDINATOR
13. PROJECT COMMITTEE
14. REVIEW AND EVALUATION
15. REPORT
16. TERMINATION
17. INSURANCE
18. INDEMNITY
19. WAIVER
20. APPLICABLE LAW
21. AUTHORITY
22. COOPERATION
23. VARIATION TO THE PROJECT AGREEMENT
24. DISPUTE RESOLUTION

## **SCHEDULES**

1. ACIAR ACQUITTAL 15
2. TRAVEL NOTE 17
3. PREPARATION OF ANNUAL REPORTS 18
4. PREPARATION OF A FINAL REPORT 20

**Standard Conditions for Project Agreements between ACIAR and  
the Commissioned Organisation**

**THE PARTIES AGREE AS FOLLOWS:**

**WHEREAS:**

*A. ACIAR has power to enter into the Project Agreement under sections 5 and 6 of the Act subject to approval by the Minister under paragraph 37(1) (a) of the Act where required.*

*B. ACIAR has requested certain research services to be carried out and the Commissioned Organisation has agreed to provide the services in order to complete the Project on the terms and conditions of the Project Agreement.*

## 1. INTERPRETATION

### 1.1 In these Conditions:

"*Act*" means the Australian Centre for International Agricultural Research Act 1982;

"*Collaborating Country*" means the country with which ACIAR or the Commonwealth has entered into a Memorandum of Understanding;

"*Collaborating Institution*" means the organisation or institution in the Collaborating Country which is nominated by the government of the Collaborating Country to undertake any aspects of the Project which are to be conducted outside Australia in collaboration with the Commissioned Organisation;

"*Commissioned Organisation*" means the person named as the Commissioned Organisation in the Project Agreement Letter who by executing and returning a duplicate of the Project Agreement Letter to ACIAR has undertaken to provide the Services in accordance with the Project Agreement;

"*Commonwealth*" means the Commonwealth of Australia;

"*Conditions*" means the terms and conditions set out in this document from clauses 1 to 24;

"*Confidential Information*" means in relation to a party, information that:

(a) is by its nature confidential;

(b) is designated by that party as confidential; or

(c) the other party knows or ought to know is confidential; but does not include information which: (i) is or becomes public knowledge other than by

breach of the Project Agreement or by any other unlawful means; or (ii) is in the possession of the other party without restriction in relation to disclosure before the date of receipt by that party; or (iii) has been independently developed or acquired by the other party;

"*Exploit*" means to manufacture, sell, hire or otherwise commercialise a product or process, or to provide a service, incorporating the Intellectual Property, or to licence a third party to do any of those things.

"*Financial Year*" means the period from 1 July to 30 June of the following year;

"*Intellectual Property*" includes all copyright and neighbouring rights, all rights in relation to inventions (including patent rights), plant varieties, registered and unregistered trademarks (including service marks), registered designs, Confidential Information (including trade secrets and know how) and circuit layouts, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields;

"*Letter of Intent*" means a letter forwarded by ACIAR to the Commissioned Organisation that states an intention to enter into a Project Agreement;

"*Net Monies Received*" means all monies received by the Commissioned Organisation net of any expenses that are properly paid on an arms-length basis by the Commissioned Organisation in exploiting the Intellectual Property in the Material;

"*Material*" includes documents, equipment, software, goods, information and data stored by any means: (a) brought into existence for the purpose of performing the Services; (b) incorporated in, supplied or required to be supplied along with the Material referred to in (a) above; or (c) copied or derived from Material referred to in (a) or (b) above for the purpose of performing or in connection with the Services;

"*Memorandum of Understanding*" means the memorandum of understanding or similar arrangement entered into between ACIAR or the Commonwealth, as the case may be, and the government of the Collaborating Country in regard to the Project;

"*Minister*" means the Minister responsible for ACIAR;

"*month*" means a calendar month;

"*person*" includes a natural person, a body corporate and an unincorporated association;

"*Project*" means the project described in the Project Document and referred to in the Project Agreement Letter;

"*Project Agreement*" means the Project Document, these Standard Conditions for Project Agreements between ACIAR and the Commissioned Organisation and the Project Agreement Letter;

"*Project Agreement Letter*" means the letter forwarded by ACIAR to the Commissioned Organisation offering to enter into an agreement with the Commissioned Organisation to perform the Services on the terms and conditions set out in the Project Agreement;

"*Project Document*" means the document which was provided to ACIAR by the Commissioned Organisation in relation to the Project and which document has been approved by the Director and Board of Management of ACIAR;

"*Services*" means the tasks to be performed by the Commissioned Organisation as set out in the Project Agreement;

"*Specified Personnel*" means professional, technical, support and administrative staff who have been nominated in the Project Document by the Commissioned Organisation to perform all or part of the Services;

"*The Parties*" means ACIAR and the Commissioned Organisation;

1.2 Words imputing a gender include any other gender.

1.3 Words in the singular number include the plural and words in the plural number include the singular.

1.4 The Schedules (and annexures if any) form part of this Agreement. In the event of a conflict between the terms and conditions contained in the clauses and any part of a Schedule, then the terms and conditions contained in the clauses will take precedence. In the event of a conflict between any part of a Schedule and any part of an annexure, then the Schedule will take precedence.

## 2. SERVICES

2.1 The Commissioned Organisation shall perform the Services in the period specified in clause 4.1. in accordance with the Project Agreement and any timetable specified therein.

2.2 When performing the Services, the Commissioned Organisation shall cooperate fully with the Collaborating Institution for the purpose of ensuring timely completion of the Project.

### 3. SUB-CONTRACTING

3.1 The Commissioned Organisation shall not, without the prior written approval of ACIAR, sub-contract the performance of any part of the Services. In giving written approval ACIAR may impose such terms and conditions as it thinks fit.

3.2 The Commissioned Organisation shall be fully responsible for the performance of the Services notwithstanding that the Commissioned Organisation has sub-contracted the performance of any part of those Services.

3.3 The Commissioned Organisation shall provide a copy of any such sub-contract to ACIAR within 7 days of its signature by the parties.

### 4. TERM OF PROJECT AGREEMENT

4.1 The Project Agreement shall commence on the date specified in the Project Agreement Letter and shall expire at the end of the period stated in the Project Agreement Letter. Any Services performed by the Commissioned Organisation prior to the date of commencement of the Project Agreement may be treated as Services under the Project Agreement if so specified by ACIAR in a Letter of Intent.

4.2 A Project Agreement may be extended where ACIAR determines that sufficient reason exists to do this and the Parties so agree in writing.

### 5. PAYMENT



5.1 The total amount of funds payable by ACIAR to the Commissioned Organisation for the Services is the "financial limitation" specified in the Project Agreement Letter.

5.2 In performing the Services the Commissioned Organisation shall not incur expenditure in any period in excess of the funds payable for that period in accordance with clause 5.4 without the written approval of ACIAR.

5.3 Unless otherwise agreed by the Parties in writing, ACIAR shall in no way be liable for any additional costs incurred for services performed by the Commissioned Organisation outside the scope of the Services.

5.4 Subject to clause 5.1, in consideration of the performance of the Services by the Commissioned Organisation, ACIAR agrees, subject to appropriation being made by the Parliament of the Commonwealth, to pay from the Australian Centre for International Agricultural Research Official Departmental Account to the Commissioned Organisation:

(a) the funds specified in the Project Document; and

(b) any other costs or funds as may from time to time be agreed in writing between the Parties.

5.5 ACIAR shall pay the Commissioned Organisation six monthly in advance during the term of the Project Agreement the funds referred to in clause 5.4 in accordance with the budget for the Project set out in the Project Document with the following conditions:

(a) each payment shall only be made following ACIAR's receipt of:

(i) a satisfactory written report as detailed in clause 5.10, for the previous six month period; and

(ii) a satisfactory Annual Report as detailed in clause 15.1.

(b) any funds that are unexpended by the Commissioned Organisation at the expiration of the six month period for which they were allocated shall be

carried over for expenditure in the following six month period and the advance made for the following six month period by ACIAR to the Commissioned Organisation shall be reduced accordingly, unless ACIAR approves otherwise in writing.

5.6 The Commissioned Organisation may, without reference to ACIAR, transfer funds payable in respect of a particular item in the budget for the Project to another item. The amount transferred may be 10% or \$10,000 of the total of the particular item in the budget from which the funds are being transferred, whichever is the lesser. Transfers involving larger amounts must be referred to ACIAR for written approval.

5.7 Notwithstanding clause 5.6, the Commissioned Organisation shall not transfer funds payable in respect of a particular item in the budget payable outside Australia to another item in the budget payable outside Australia. However, the Collaborating Institution will be able to vary its component of the budget in the same way described in the preceding clause 5.6.

5.8 Transfer of funds between items in excess of the amount referred to in clause 5.6 shall not be made without the prior written approval of ACIAR.

5.9 Where the budget for the Project set out in the Project Document provides for the payment of any funds by the Commissioned Organisation to a Collaborating Institution, the Commissioned Organisation shall pay those funds six monthly in advance within seven days after receipt of payment from ACIAR under clause 5.5 during the term of the Project Agreement. Any funds that are unexpended by the Collaborating Institution at the expiration of the six month period for which they were allocated shall be carried over for expenditure in the following six month period and the advance made for the following six month period by the Commissioned Organisation to the Collaborating Institution shall be reduced proportionately, unless ACIAR approves otherwise in writing.

5.10 No later than 30 days after the expiration of each six month period for which the funds were allocated ("acquittal period"), the Commissioned

Organisation shall provide to ACIAR a written report that includes the following details:

(a) the amount received from ACIAR for that acquittal period and the amounts expended against each item of the budget in the Project Document;

(b) the amount, if any, advanced by the Commissioned Organisation to the Collaborating Institution;

(c) certification by an officer duly authorised by the Commissioned Organisation that the details set out pursuant to paragraph (a) above accurately reflect expenditure which has been incurred against each item for the purposes of the Project.

5.11 The report to be provided pursuant to clause 5.10 must be substantially in the form set out at Schedule 1.

5.12 The Commissioned Organisation acknowledges it is totally responsible for payment of and accounting to ACIAR for all expenses incurred in performing the Services. ACIAR is entitled to audit independently the accounts of the Commissioned Organisation in regard to the Project at any reasonable time upon notice to the Commissioned Organisation.

### **5.13 Goods and Services Tax**

- i. Subject to subclause 5.13.ii, where ACIAR is required to reimburse the Commissioned Organisation for an amount the Commissioned Organisation pays to a third party, the amount payable by ACIAR will be a GST exclusive amount (ie. The amount paid by the Commissioned Organisation less any amounts in respect of GST included in the consideration provided to the third party), whether or not amounts for GST are separately identified by the third party supplier to the Commissioned Organisation.
- ii. Amounts that ACIAR is required to pay under the other terms of this Agreement are calculated on a GST-exclusive basis. Where the Commissioned Organisation becomes liable to remit any amount of GST in respect of any Supply the Commissioned Organisation makes to ACIAR

in accordance with this Agreement ("GST liability"), the amount otherwise payable by ACIAR under this Agreement will be increased by the amount of the GST liability, or any lesser amount required by law. The increased amount will be payable by ACIAR in the same manner and at the same time as other amounts payable under this Agreement.

- iii. Where required, the Commissioned Organisation will provide a tax invoice that may enable ACIAR, if permitted by the GST legislation, to claim a credit or refund, a notional credit or refund, of GST.
- iv. There are some circumstances in which supplies relating to this Agreement are not taxable Supplies under the GST legislation, for example certain Supplies may be "exempt" (input taxed) or GST-free (subject to a zero rate). The Commissioned Organisation will not charge for GST in those circumstances.
- v. As required by any applicable legislation, where identifiable cost savings are realised by virtue of the enactment of the GST legislation and related New Tax System changes, those cost savings will be reflected in the calculations of the charges under this Agreement.
- vi. In this clause:

**"GST Legislation"** means any goods and services tax implemented in Australia pursuant to the *A New Tax System (Goods and Services Tax) Act 1999* introduced by the Federal Government and includes all Acts relating to that Act, together with all amendments made to it, and any subsequent Act of Parliament enacting such Acts, whether or not subject to any amendment, and **"GST"** means the goods and services tax payable pursuant to such GST Legislation.

**"New Tax System changes"** has the meaning given by section 75AT of the *A New Tax System (Trade Practices Amendment) Act 1999*.

**"Supplies"** and other terms used in this annexure which have meanings under the GST Legislation have the meanings implemented pursuant to the GST Legislation.

## 6. NEGATION OF EMPLOYMENT, PARTNERSHIP AND AGENCY

6.1 The Commissioned Organisation shall not by virtue of this Project Agreement be or for any purpose be deemed to be an officer, employee, partner or agent of ACIAR, or as having power or authority to bind or represent ACIAR, and shall not represent itself, and shall ensure that its officers, employees, agents and sub-contractors do not represent themselves, as such.

## 7. PERSONNEL

7.1 The Commissioned Organisation shall provide adequate and competent personnel to perform the Services and shall ensure that they undertake the Services in accordance with the terms and conditions of the Project Agreement.

7.2 Subject to clause 7.6 the Commissioned Organisation shall ensure that the Specified Personnel undertake work in respect of the Services in accordance with the terms of this Agreement. Where Specified Personnel are unable to undertake work in respect of the Services, the Commissioned Organisation shall notify ACIAR immediately. The Commissioned Organisation shall, if so requested by ACIAR, provide replacement personnel acceptable to ACIAR at no additional charge and at the earliest opportunity.

7.3 Personnel of the Commissioned Organisation, including Specified Personnel, who are undertaking Services in the Collaborating Country and who are not citizens of that country shall in no way become involved in the political affairs of the Collaborating Country. If, in the opinion of ACIAR such personnel have become involved in the political affairs of the Collaborating Country, ACIAR may require the Commissioned Organisation, at its own cost, to promptly remove the personnel involved from work in respect of the Services and for their replacement with personnel of equal competence approved in writing by ACIAR prior to their appointment.

7.4 ACIAR may, on reasonable grounds, give notice requiring the Commissioned Organisation to remove personnel (including Specified Personnel) from work in respect of the Services. The Commissioned Organisation shall at its own cost, promptly arrange for the removal of such

personnel from work in respect of the Services and their replacement with personnel acceptable to ACIAR. If the Commissioned Organisation is unable to provide acceptable replacement personnel under this clause 7.4, clause 7.3 or clause 7.2, ACIAR may terminate this Agreement in accordance with the provisions of clause 16.

7.5 The Commissioned Organisation is responsible for arranging travel for and payment of salaries and allowances to its personnel including Specified Personnel from the budget provided for in the Project Document.

7.6 The Commissioned Organisation shall obtain the prior written approval of ACIAR to the appointment of the Specified Personnel or any specialist or scientist to perform the Services, which approval shall not be unreasonably withheld. If ACIAR requests the Commissioned Organisation to provide any of the following information, the Commissioned Organisation shall forthwith provide that information to ACIAR including:

- (a) the full names and date of birth of the proposed person(s);
- (b) a statement which describes the position to be held, the position selection criteria and details of the duration of the proposed appointment; and
- (c) a copy of the curriculum vitae of each of the proposed persons which details relevant employment experience and educational qualifications;
- (d) any other information relating to the proposed appointment necessary for or directly related to the Services.

## 8. TRAVEL

8.1 The Commissioned Organisation shall provide written notice to ACIAR substantially in the form at Schedule 2 detailing all visits scheduled to a Collaborating Country by its personnel including Specified Personnel. Details of any dependants accompanying the personnel shall also be provided in the notice.

8.2 In the event it is advised that officials from the Collaborating Country involved in the Project intend to visit Australia, the Commissioned Organisation shall use its best endeavours to ensure that as much notice as possible is provided to the Australian Embassy, the Australian High Commission or the Australian Consulate, as appropriate, in the Collaborating Country so that it may commence visa and other formalities.

8.3 The Commissioned Organisation shall provide promptly to ACIAR a copy of any such notices to the Australian Embassy, the Australia High Commission or the Australian Consulate.

8.4 At the completion of the travel referred to in clause 8.1, the Commissioned Organisation shall provide to ACIAR a travel report that shall include the travel itinerary and information relevant to the monitoring of the Project.

## 9. PROJECT EQUIPMENT AND SUPPLIES

9.1 The Commissioned Organisation shall arrange, from the funds payable by ACIAR to the Commissioned Organisation for the Services, the procurement and delivery of all equipment and supplies that are specified in the Project Document.

9.2 The Commissioned Organisation shall exercise administrative control of and maintain and keep equipment and supplies referred to in clause 9.1 in good repair.

9.3 The Parties agree that the ownership of equipment and supplies that are procured for the Project for the performance of the Services in Australia shall vest in the Commissioned Organisation from the date of purchase.

9.4 The Parties agree that the ownership of equipment and supplies procured by the Commissioned Organisation for the purposes of the Project in the Collaborating Country shall vest in the government of the Collaborating Country at the completion of the project.

9.5 Unless otherwise agreed in writing, the Commissioned Organisation shall effect with reputable and substantial underwriters and maintain insurance against all loss or damage to the Project equipment referred to in clause 9.1 until the Services are completed.

9.6 Notwithstanding the above, the Commissioned Organisation may undertake self insurance arrangements where ACIAR agrees in writing to such arrangements.

## 10. INTELLECTUAL PROPERTY

10.1 ACIAR and the Commissioned Organisation shall have regard to the provisions of and fulfil all relevant obligations under international arrangements to which Australia is a signatory relating to intellectual property and biological resources including but not limited to:

- the International Undertaking on Plant Genetic Resources;
- the FAO trustee arrangements with international agricultural research centres;
- the Convention on Biological Diversity;
- the Agreement on Trade Related Aspects of Intellectual Property rights;
- and the provisions of the International Union for the Protection of New Varieties of Plant.

Transfer and exchange of germplasm between the Commissioned Organisation and the Collaborating Institution shall be subject to Materials Transfer and Acquisition Agreements and in accordance with the Convention on Biological Diversity. This subclause shall be interpreted such that the relevant obligation is that which was in effect at the time of the action in question.

10.2 The Commissioned Organisation shall, no later than the commencement of the Services under this Agreement, inform ACIAR in writing of all pre-existing Intellectual Property owned by itself or third parties that is proposed to be used in the Services and of any limitation on its



use under this Agreement. Unless otherwise agreed in writing by the Parties, the Project Agreement does not affect the ownership of pre-existing Intellectual Property identified pursuant to this clause.

10.3 The Commissioned Organisation warrants that to the best of its knowledge information and belief intellectual property provided by the Commissioned Organisation pursuant to the Services does not infringe any Intellectual Property rights of any third party in Australia or the rest of the world.

10.4 The Warranty referred to in clause 10.3 shall survive the expiration or termination of the Agreement.

10.5 The Commissioned Organisation shall notify ACIAR of the details of any Intellectual Property created as a result of the performance of the Services. Any notification shall be treated as Confidential Information by ACIAR.

10.6 Recognising that it will be desirable to use or exploit advances or discoveries that may be made in the course of the Project, the Parties agree that ownership of all Intellectual Property in the Material will in Australia, vest in the Commissioned Organisation, and will in the Collaborating Country, vest either in the Collaborating Institution or an authority designated by the Collaborating Institution.

10.7 The Commissioned Organisation agrees that it will enter into equitable arrangements with the Collaborating Institution in relation to the following matters:

(a) the allocation of ownership of Intellectual Property in the Material between the Commissioned Organisation and the Collaborating Institution in countries other than Australia and the Collaborating Country;

(b) the terms of any licences between the Commissioned Organisation and the Collaborating Institution to use or exploit the Intellectual Property referred to in clause 10.3 and paragraph (a);

(c) the terms of any licences of other Intellectual Property owned or licensed by either the Commissioned Organisation or the Collaborating Institution which are necessary for the utilisation of the Material; and

(d) the allocation of costs relating to the application for and maintenance of the Intellectual Property rights between the Commissioned Organisation and the Collaborating Institution.

10.8 The Commissioned Organisation agrees that the arrangements referred to in clause 10.7 will be made taking into account the following factors:

(a) the intellectual contributions of the Commissioned Organisation and the Collaborating Institution;

(b) the financial contributions of the Commissioned Organisation and the Collaborating Institution;

(c) the contribution of pre-existing Intellectual Property, materials, research effort and preparatory work of the Commissioned Organisation and the Collaborating Institution;

(d) the facilities provided by the Commissioned Organisation and the Collaborating Institution; and

(e) such other relevant considerations as the Commissioned Organisation and the Collaborating Institution may mutually determine.

10.9 Where ownership of Intellectual Property in the Material vests in the Commissioned Organisation, the Commissioned Organisation shall grant to ACIAR a permanent, irrevocable royalty-free, non-exclusive licence (including a right of sub-licence) to use, reproduce, adapt and exploit that Intellectual Property in all countries in which it is vested in the Commissioned Organisation.

10.10 Where ownership of Intellectual Property in the Material vests in the Commissioned Organisation, the Commissioned Organisation agrees that it shall pay to ACIAR within 30 days of the expiration of 30 June and 31

December 25%, or such percentage as is otherwise agreed, of Net Monies Received by the Commissioned Organisation by way of licence fees, sale price or royalties in relation to such Intellectual Property, and this obligation of the Commissioned Organisation shall continue for a period of twenty (20) years from the commencement of the Project Agreement.

10.11 The Commissioned Organisation agrees it shall not sub-licence or assign its Intellectual Property in the Material without first obtaining the prior written consent of ACIAR, and in giving any such consent ACIAR may impose any conditions it sees fit.

10.12 The Commissioned Organisation shall maintain proper books of account which evidence receipt of any licence fees, sale price or royalties payable to it in respect of Intellectual Property in the Material and any expenses properly paid in relation thereto and ACIAR shall be granted access to those records at any time upon request. This obligation shall continue for a period of twenty (20) years from the commencement of the Project Agreement.

10.13 Where the Commissioned Organisation intends to publish any article or paper of an academic, scientific or technical nature in regard to the Services or the Project, or to place any advertisement requesting applications from persons to perform any part of the Services, any such publication or advertisement must acknowledge the funding and other support provided by ACIAR in regard to the Project.

10.14 The Commissioned Organisation may report details of the Project in the non-specialist media provided however:

(a) it acknowledges the funding and support provided to the Project by ACIAR; and

(b) in the event that the subject of the proposed media report is potentially controversial the Commissioned Organisation will, prior to publication, request the written consent of ACIAR to the publication of any such report, and ACIAR may in its discretion consent or refuse consent to any such publication.

## 11. DISCLOSURE OF INFORMATION

11.1 The Commissioned Organisation shall not, without prior written approval of ACIAR, disclose to any person other than ACIAR, any Confidential Information of ACIAR. In giving written approval, ACIAR may impose such terms and conditions as it thinks fit.

11.2 ACIAR shall not, without prior written approval of the Commissioned Organisation, disclose to any person other than the Commissioned Organisation, any Confidential Information of the Commissioned Organisation. In giving written approval, the Commissioned Organisation may impose such terms and conditions as it sees fit.

11.3 Either Party may at any time require the other Party to give and arrange for its employees, officers, agents and subcontractors to give written undertakings relating to the non-disclosure of its Confidential Information. The other Party shall promptly arrange for all such undertakings to be given.

11.4 The obligations under this clause shall not be taken to have been breached where the information referred to is legally required to be disclosed.

11.5 This clause shall survive the expiration or termination of the Project Agreement.

## 12. COORDINATOR

12.1 The person designated in the Project Document as the Project Leader, or any person agreed in writing by the Parties to replace that person, shall be responsible for coordinating all the Services to be provided by the Commissioned Organisation and this person shall liaise with ACIAR regularly in regard to the progress of the Project.

## 13. PROJECT COMMITTEE

13.1 ACIAR may establish a Project Committee that shall include a representative of each of the Parties and, where appropriate, Collaborating Institution.

13.2 The Project Committee shall advise the Parties in relation to Project matters, and may call for specialised advice on any matter related to the Project.

#### 14. REVIEW AND EVALUATION

14.1 ACIAR may at any time undertake to review and evaluate the Project.

14.2 To facilitate any review pursuant to clause 14.1 the Commissioned Organisation shall provide any financial, technical or such other information as is required by ACIAR and shall at all reasonable times permit persons authorised by ACIAR to have access to the premises upon which the Services are being performed.

#### 15. REPORT

15.1 The Commissioned Organisation shall provide ACIAR with Annual Reports on the anniversary date of commencement of the Project until the final year. These reports must include the information referred to in Schedule 3. The Annual Report for the final year of the Project should be subsumed into the Final Report.

15.2 Upon the completion of the Project in accordance with the Project Agreement, the Commissioned Organisation shall provide ACIAR with a Final Report that must be prepared in accordance with the guidelines at Schedule 4. The Final Report is due within 6 months of the completion of the Project.

#### 16. TERMINATION

16.1 In the event of acts of God, fire, storm, flood, earthquake, explosion, accident, acts of a public enemy or terrorism, war, rebellion, insurrection, sabotage, epidemic, quarantine restrictions, industrial dispute,

transportation embargo or failure or delay in transportation that render the performance of the Services impracticable or impossible either Party may, upon providing a minimum of three (3) calendar months written notice to the other, terminate the Project Agreement.

16.2 In addition to clause 16.1, ACIAR may at any time by written notice, terminate the Project Agreement, in whole or in part. If the Project Agreement is terminated under clause 16.1 or 16.2, ACIAR shall be liable only for:

- (a) payments under the payment provisions of the Project Agreement for Services rendered before the effective date of termination; and
- (b) subject to clauses 16.3, 16.4 and 16.5 any reasonable costs incurred by the Commissioned Organisation and directly attributable to the termination or partial termination of the Project Agreement.

16.3 Upon receipt of a notice of termination the Commissioned Organisation shall:

- (a) stop work as specified in the notice;
- (b) take all available steps to minimise loss resulting from that termination and protect the Material; and
- (c) continue work on any part of the Services not affected by the notice.

16.4 In the event of a partial termination, ACIAR's liability to provide funds under the Project Agreement shall, in the absence of agreement to the contrary, abate proportionately to the reduction in the Services.

16.5 ACIAR shall not be liable to pay compensation in an amount that would, in addition to any amounts paid or due, or becoming due, to the Commissioned Organisation under the Project Agreement, together exceed the funds set out in the Project Agreement. The Commissioned Organisation shall not be entitled to compensation for loss of prospective profits.

## 17. INSURANCE

17.1 The Commissioned Organisation shall, for so long as any obligations remain in connection with the Project Agreement, effect and maintain with reputable and substantial underwriters the following insurance:

- (a) workers' compensation for an amount required by any relevant legislation;
- (b) in relation to Services performed in Australia, public liability insurance for an amount of not less than \$5,000,000; and
- (c) in relation to work performed outside Australia, adequate insurance against claims by third parties resulting from negligent acts performed by the Commissioned Organisation in carrying out the Services;
- (d) adequate travel and medical insurance for any domestic and international travel undertaken on behalf of the Project by its personnel including Specified Personnel.

17.2 Within 14 days of a written request from ACIAR, the Commissioned Organisation must provide ACIAR with a copy of any insurance policy effected in accordance with this requirement and of all receipts for payments of premiums.

17.3 The requirement of clause 17.1(c) does not apply in relation to work performed in a particular country if ACIAR agrees in writing that such insurance is not available in relation to the performance of the Services in that country.

17.4 Notwithstanding the above, the Commissioned Organisation may undertake self insurance arrangements where ACIAR agrees in writing to such arrangements.

17.5 ACIAR undertakes no responsibility in respect of loss or damage to Project equipment or supplies or in respect of any life, accident, travel or any other insurance coverage that may be necessary or desirable for the

personnel or sub-contractors of the Commissioned Organisation or for the dependants of any such persons as may travel for the purposes of the Services.

## 18. INDEMNITY

18.1 The Commissioned Organisation shall indemnify and hold harmless ACIAR, its officers, employees and agents from and against any loss (including legal costs and expenses on a solicitor/own client basis), or liability, incurred or suffered by any of those indemnified arising from any claim, suit, demand, action or proceeding by any person:

(a) where such loss or liability was caused by any unlawful or negligent act or omission of the Commissioned Organisation, its officers, employees, agents or sub-contractors in connection with the Services; or

(b) in respect of any infringement of Intellectual Property by the Commissioned Organisation, its officers, employees, agents or sub-contractors in connection with the performance of the Services or the use by ACIAR of the Services Material.

18.2 The Commissioned Organisation's liability to indemnify ACIAR under clause 18.1 shall be reduced proportionally to the extent that any act or omission of ACIAR or its officers, employees or agents contributed to the loss or liability.

18.3 The indemnities referred to in clause 18.1 shall survive the expiration or termination of the Services.

## 19. WAIVER

19.1 A waiver by either party in respect of any breach of a condition or provision of the Project Agreement shall not be deemed to be a waiver in respect of any continuing or subsequent breach of that provision, or breach of any other provision. The failure of either party to enforce any of the provisions of this Project Agreement at any time shall in no way be interpreted as a waiver of such provisions.



## 20. APPLICABLE LAW

20.1 The Project Agreement shall be governed by and construed in accordance with the law for the time being in force in the Australian Capital Territory.

20.2 The Commissioned Organisation shall ensure that in carrying out the Services it complies with the laws from time to time in force in the Australian State or Territory or in the country in which the Services, or any part thereof, are to be carried out.

## 21. AUTHORITY

21.1 Any and all rights, powers, authorities and discretions expressed in the Project Agreement or in the specifications to be conferred upon or vested in ACIAR may be exercised by any person designated for that purpose by the Minister.

## 22. COOPERATION

22.1 ACIAR shall provide necessary representation with appropriate officials of the Government of the Collaborating Country to assist in securing cooperation reasonably required for the successful completion of the Project.

## 23. VARIATION TO THE PROJECT AGREEMENT

23.1 Variations to the Project Agreement shall be made by means of a Letter of Variation signed for and on behalf of the Parties to the Project Agreement.

## 24. DISPUTE RESOLUTION

24.1 Subject to clause 24.4, before resorting to external dispute resolution mechanisms, the Parties shall attempt to settle by negotiation any dispute in relation to the Project Agreement including by referring the matter to personnel who may have authority to intervene and direct some form of resolution.

24.2 If a dispute is not settled by the Parties within 10 working days of one Party first sending to the other Party written notice that they are in dispute, the dispute may be the subject of court proceedings or may be submitted to some alternative dispute resolution mechanism as may be agreed in writing between the Parties.

24.3 Notwithstanding the existence of a dispute, each Party shall continue to perform its obligations under the Project Agreement.

24.4 A Party may commence court proceedings relating to any dispute arising from this Project Agreement at any time where that Party seeks urgent interlocutory relief.

24.5 This clause shall survive the expiration or termination of the Project Agreement.

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**ACIAR Acquittal**

Schedule 1

Commissioned

Organisation: .....

Project Number: .....

Title: .....

Period: Half year

ending - .....

Set out below is a statement of receipts and expenditures.

**Receipts:**

Funds brought forward from previous period \$.....

(uncommitted carryover)

Funds brought forward from previous period

(committed carryover) \$.....

Total advance received this period \$.....

(a)\$.....

**TOTAL**

less Expenditures:

	COUNTRY COUNTRY		
	AUSTRALIA*	*	TOTAL
Personnel	.....	.....	.....
Supplies & Services	.....	.....	.....
Travel	.....	.....	.....
Infrastructure Costs	.....	.....	.....
Capital Items			

(b).....

**Totals**

Progress variation (Carryover) carried over \$..... (a - b): of which \$..... is uncommitted and \$..... is committed (attach details).

**OR** if the project is overspent

Progress variation (Carryover) carried over \$..... (a - b).

Plus ..... is committed (attach details). *(Please delete which is not applicable)*

**Comments**.....  
.....  
.....  
.....

I certify that the expenditure shown above has taken place and is correct.

Signed  
and  
dated: .....

(Authorised Officer)

**Post to:** Budget Officer, ACIAR, GPO Box 1571 Canberra ACT 2601

**Acquittals due:** 31st July and 31st January

*Please provide information explaining any variations of expenditure from budget allocations.*

Example:

Travel of 1 January to Los Banos by project leader undertaken in economy class instead of business class - surplus funds spent on extra conference facilities required during the trip.

Signed .....

Project Leader

Dated .....

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**Travel Advice Note**

Schedule 2

Commissioned

Organisation:

Person

Travelling:

Position:

**Proposed Travel:**

**Date**

**From**

**To**

**Reasons for Travel:**

Program:

Project:

Describe purpose of visit(s) and officials and institutions being visited.

Describe assistance required of Australian Embassy/High Commission (e.g. appointments, accommodation, bookings, etc.)

**Note:** This form is used to provide advice to Australian diplomatic missions of a visit by Project personnel. Its completion is essential to the maintenance of harmonious relations between missions and ACIAR and commissioned organisations. Curriculum Vitae must accompany Note on first visit to Indonesia and Thailand. Forward completed form at least six weeks ahead of travel to the relevant Research Program Coordinator at the following address:

**Australian Centre for International Agricultural Research, GPO  
Box 1571, Canberra ACT 2601, Australia**

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## **Guide to ACIAR Research Project Leaders on the Preparation of Annual Reports**

### **Schedule 3**

Annual reports assist research collaborators and ACIAR in project monitoring and research feedback. As a communication device between the research collaborators and ACIAR, they are an opportunity to highlight research results and flag matters such as impending problems and potential opportunities for project supplementation and follow-up activity.

All annual reports must represent the effort of the Australian and the overseas research collaborators. The leader of each research team must sign and take equal responsibility for the preparation and submission of the reports.

Commissioned organisations are asked to follow the format described below for these reports. They have been drafted for ease of monitoring and consistency in data presentation.

### **1. Cover Page**

The annual report should contain a cover page with the following identifying details:

(i) heading, that indicates the period it spans;

(ii) project number and title; and

(iii) names of authors of the report.

The due date for annual reports is measured from the agreed project starting date.

## **2. Executive Summary**

This should be a separate page suitable for presentation to ACIAR's Board of Management.

Prepare a precis of not more than 600 words that briefly states:

(i) purpose and context of the project;

(ii) names of collaborating research and institutions;

(iii) results or expected results and why these are believed to be important/valuable; and

(iv) likely direction of future research activities.

## **3. Progress of Research Work**

### **3.1. Project Objectives**

Recount main objectives as per approved project and note any revisions to the aim of the project and reasons for these changes.

### **3.2. Research**

The following points should be included under the sub-heading "Research":

(i) adherence to timetable/staff engaged (append copies of advertisements);

(ii) description of methodology and principal experiments or analysis conducted. Summary of research results. Where necessary, detailed results or data should be included as an appendix;

(iii) statement of the importance of results (including implications) to date for:

(a) future research plans;

(b) future project budget;

(c) conduct of other research projects (if relevant);

(d) related research grants received or applied for;

(e) development of linkages with collaborating-country organisations;

(f) optimal methods/channels of extension/outreach of results to end-users;

(g) environmental impact (collaborating country/Australia, direct and indirect implications); and

(h) any differential impact on men, women and children in the collaborating country.

(iv) discussion of research problems encountered/overcome/chronic and their importance and implications for future research/extension;

(v) brief overview of principal publications, research reports and other communications activities undertaken (detailed lists of papers in progress, completed, and published, to be appended); and

(vi) assessment by the research leaders of the value (social, economic, fundamental or potential) of the research undertaken and principal beneficiaries.

### 3.3. Travel and Meetings

Summary of visits/study tours undertaken by Australian and overseas scientists in association with the project - who, where, when, how long, purpose, significant findings, etc. Copies of trip reports should be appended.



### 3.4. Budget Discussion

Overview and discussion, especially of any proposed variations from approved budget. Detailed statements should be provided where significant over-expenditure or under-expenditure has occurred.

### 3.5. Conclusions

Overall assessment of progress in context of original objectives.

Future research, including current commitments and any modifications to previous plans.

## **4. Appendices**

In the index to the Appendices (or in the index for the Report as a whole), indicate for each attachment whether it is provided electronically or only in hard copy.

List research results of note.

Research reports, papers and publications list including those:

- (i) in progress - author/title citation;
- (ii) completed - author/title citation; and
- (iii) published - full citation needed.

Attach copies of items listed under (ii) and (iii) above.

Trip reports of Australian and overseas scientists funded under the project, including documentation on professional meetings attended and workshops or seminars held.

Budget expenditure details, including details of advances received and acquitted.

Details of any project publicity undertaken and not covered under 2 or 3 above; include relevant photographs, press releases, advertisements, etc.

## **5. Submission**

Submit **two** copies of the report and appendices (one electronic and one bound) to the relevant Research Program Manager. When part of the material cannot be provided electronically, provide an unbound copy of that material as well as including it in the bound copy.

Address:

ACIAR  
GPO Box 1571  
Canberra ACT 2601

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## **Guidelines for the Preparation of a Final Report**

### Schedule 4

Final reports are an essential part of ACIAR's accountability and forward planning process. They:

- highlight operational difficulties and solutions;
- flag possibilities for future directions of the work; and
- provide ACIAR with an initial assessment of project impact

ACIAR sees the final report as a key source document for project evaluation and to provide feedback into the planning of new projects.

A final report for a project should comprise an executive summary and a detailed report, to which should be appended ancillary documentation such as copies of all publications to date produced during the life of the project. Final reports should be submitted jointly by the Australian and collaborating country project leaders. The format of a final report should follow these guidelines.

**Suggested Executive Summary Format:**

**Final Report on ACIAR Project No. (project number)**

**Project:** (Project title)

**Commissioned organisation:** (Name of commissioned organisation)

**Collaborating institutions:** (Name of collaborating institutions)

**Project leaders:**

(i) Australia: (Name/s)

(ii) Partner country (Name/s)

**Date of commencement:** (Date in project document or alternative agreed date)

**Date of completion:** (Agreed date of completion)

**Aims of project:** Outline briefly (changes to the original objectives should be noted)

**Description of work:** Brief description of the work that has been undertaken over the life of the project to achieve its stated aims (flow-charts and outputs tables should

be used)

Summarise the results of the research work undertaken through this project and the conclusions.

Preliminary evaluation:

Address the issues of operational effectiveness, project impact and possible future directions of the work; a comprehensive treatment is necessary.

**Results, conclusions and assessments:**

List all publications resulting from the project

**Publications:**

Summarise proposed follow-up to the project, including further research planned on the same or similar theme, patents, copyright or other property rights proposed etc.

**Follow-up:**

**Suggested Format for Main Body of Final Report: (15-20 pages max)**

**Final Report on ACIAR Project No (project number)**

Provide the background to the project (one or two paragraphs only).

**Background:**

Recount the main objectives as per approved project document. Revisions to the aim of the

**Objectives:**

project and reasons for changes should be noted.

Describe the lines of inquiry, methods etc. (i.e. how did the research team go about achieving the objectives of the project). Timetables/staff engaged, conduct of other research projects (if relevant), related research grants received or applied for, development of linkages with collaborating-country organisations, conduct of other research projects (if relevant), related research grants received or applied for, development of linkages with collaborating-country organisations, etc., should be noted.

**Description of project:**

1. Progress of research work for the final year

The following points should be included:

- (i) adherence to timetable/staff engaged (append copies of advertisements);
- (ii) description of methodology and principal experiments or analysis conducted. Summary of research results. Where necessary, detailed results or data should be included as an appendix;
- (iii) statement of the importance of results (including implications) to date for:

**Project activities - final year**

- (a) future research plans;

(b) future project budget;

(c) conduct of other research projects (if relevant);

(d) related research grants received or applied for;

(e) development of linkages with collaborating-country organisations;

## 2. Travel and meetings during the final year

Summary of visits/study tours undertaken by Australian and overseas scientists in association with the project - who, where, when, how long, purpose, significant findings, etc. Copies of trip reports should be appended.

## 3. Budget Discussion

Attach budget expenditure details, including advances received and acquittals for the final year.

Overview and discussion, especially of any actual variations from approved budget. Detailed statements should be provided where significant over-expenditure or under-expenditure has occurred

## 4. Conclusions

Overall assessment of progress during the final year, in context of original objectives.

1. Progress of research work for the project's lifetime

(i) statement of the importance of results (including implications) for:

(a) optimal methods/channels of extension/outreach of results to end-users;

(b) environmental impact (collaborating country/Australia, direct and indirect implications); and

(c) any differential socio-economic impact on men, women and children in the collaborating country.

(ii) discussion of research problems encountered/overcome/chronic and their importance and implications for future research/extension;

(iii) brief overview of principal publications, research reports and other communications activities undertaken (detailed lists of papers in progress, completed and published to be appended); and

(iv) assessment by the research leaders of the value (social, economic, fundamental or potential) of the research undertaken and principal beneficiaries.

**Research results and outcomes:**

2. Impact and future directions of the project

Detail the results achieved by the research project in its lifetime with specific mention of

any outstanding results or benefits achieved that were/are relevant to all collaborating countries; contributions made by all research groups participating in the project should be noted. Graphic and tabular information may serve to highlight important aspects of the results. Increases in the cost/benefits of this project should be briefly discussed. Any problems should also be highlighted.

A brief summary on the value of the results achieved by the project to such target groups as were identified in the original project proposal, the value to other potential users, to the industry, to extension workers, etc. Note any intellectual property (new technology or net new scientific knowledge) that was generated by the project and how this has helped to achieve the aims of the project. Copyright, patents or other property rights that have been or will be sought for innovations/insights arising from the project should be specified. Results that will be used to solve the agricultural problems originally identified in the relevant collaborating country (or countries) and their use in Australia should be stated. Implications (both direct and indirect) for the environment, impacts on a collaborating country or Australia, and any differential impact on men, women and children in the collaborating country, etc., should be discussed.

**Use of results:**

**Publications/reports:**

List all publications (including 'extension



type' pamphlets) resulting from the research work undertaken under the project and provide as annexes one copy of each publication listed. Publications that have been translated into the language of the partner country should also be noted. List also all reports generated over the life of the project including external reviews, trip reports of Australian and overseas scientists funded under the project and documentation on professional meetings attended and workshops or seminars held. Also include details of any project publicity undertaken and not covered above; append relevant photographs, press releases, advertisements, etc.

Detail proposed action to ensure results are conveyed to research, policy and extension audiences as appropriate to the project. Include details of further research and analysis of the data that are proposed beyond the formal life of the ACIAR project.

**Follow-up:**

Training and capacity-building resulting from the project should be detailed. Job skills developed through the project and training programs introduced to enhance these skills should be listed (include awards offered under the John Allwright Fellowship Program for Agricultural Research).

**Training and capacity building:**

Provide statistics on gender, cost and method

of training.

**Other activities:**

List outcomes of any other activities resulting from the project.

**Submission:**

Submit **two** copies of the report and appendices (one electronic and one bound) to the relevant Research Program Manager. When part of the material cannot be provided electronically, provide an unbound copy of that material as well as including it in the bound copy.

## GEF プロジェクト中央アジア生息域内プロジェクト内情報共有契約

Information Sharing Agreement as adopted by the In Situ/On Farm Project  
in Central Asia

### INFORMATION SHARING AGREEMENT

This agreement is made between the following parties (hereinafter, the parties):

1. Name and address of the National Executive Agency in Kazakhstan
2. Name and address of the National Executive Agency in Kyrgyzstan
3. Name and address of the National Executive Agency in Tajikistan
4. Name and address of the National Executive Agency in Turkmenistan
5. Name and address of the National Executive Agency in Uzbekistan  
(Hereinafter, these five parties will be referred to as National Executing Agencies.)
6. Bioversity International (“Bioversity”)

### Background

This agreement deals with the collaboration on sharing and dissemination of the information and data generated by the UNEP/GEF Project “In Situ/On Farm Conservation and Use of Agricultural Biodiversity (Horticultural Crops and Wild Fruit Species) in Central Asia”. The main purpose of the Project has been the conservation and sustainable use of horticultural crop and wild fruit species genetic diversity in Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan through addressing the problem of inadequate information, coordination and knowledge, thereby contributing to the elimination of the other major barriers to conserving fruit genetic resources (unsustainable use of wild fruit species and loss of traditional diversitybased farming systems).

As a result, better information and knowledge on wild resources, on the number and quality of horticultural crops and their genetic resources, distribution, conservation, and use has been attained. Therefore, knowledge

about levels and distribution of fruit species genetic diversity, and the value of this diversity for sustainable agriculture and ecosystem health have been enhanced in order for them to be used to strengthen national and regional policies and legislation towards the conservation and sustainable use of agrobiodiversity.

The main features during the implementation of the Project have been the good collaboration and coordination among national partners in sharing knowledge and experience and in strengthening links among scientists and farmers. The present Information Sharing Agreement reflects this desire for continuous collaboration among national partners, so that existing linkages among institutions continue in the future through enabling facilitated access to data, publications and resources that have been developed as a result of the Project and that regional collaboration is increased towards agrobiodiversity conservation.

In consideration of the foregoing, the parties agree as follows:

#### 1. Objectives

The objectives of this Information Sharing Agreement are:

To provide a framework for the provision, storage, sharing and dissemination of the information resulting from the Project.

To set forth the terms and conditions under which Project partners will share information among themselves and with non-Project partners through a website.

#### 2. Use of terms

Project: UNEP/GEF Project “In Situ/On Farm Conservation and Use of Agricultural Biodiversity (Horticultural Crops and Wild Fruit Species) in Central Asia”.

**Project partners:** Individuals who have been involved in the implementation of the Project, either as members of the National Executing Agencies or not, and who will be granted access to all the information stored in the website.

**Website:** Digital database held by the Project Coordinator which stores the information and is available on the internet.

**Information:** All the information generated by the Project that will be included in the website.

**Survey data:** Information collected through focus group discussions, household surveys and interviews during the Project.

**Project Coordinator:** Institution in charge of coordinating the implementation of the Project, i.e. Bioversity.

**National Executing Agencies (hereinafter NEA):** Institutions in charge of implementing the Project at the national level and parties to this agreement.

**National Focal Point (hereinafter NFP):** Person or persons designated by each National Executing Agency with capacity to provide information to be uploaded on the website and take decisions about access and use of the information by third parties.

### 3. Open access information and restricted access information

#### 3.1. Parties agree that there will be three types of information:

**Open Access Information:** Information published on the website and publicly available to Project partners and the general public.

**Restricted Access Information:** Information that will be stored in a restricted area of the website, which will be accessible only to Project partners.

Restricted access information will be made available to non-Project partners upon appropriate permission from the party that provided the information.

Restricted access information will be considered publicly available without limitations or restraints after a period of seven years from the official date of finalization of the Project (December 2011).

Absolute Restricted Access Information: Information that will be stored in a restricted area of the website, which will be accessible only to the representatives of the party that provided the information. Absolute Restricted Access Information will be made available to Project partners and the general public upon appropriate permission from the party that provided the information.

3.2. Parties agree that the following information will be Open Access Information: A list of all the scientific publications (articles, research papers, monographs, etc.) as a result of the project;

Scientific publications (articles, research papers, monographs and other publications) as a result of the project, as long as they are allowed by the publisher;

Publications on technologies related to the cultivation and management of orchards;

Database on Project partners;

Draft laws and regulations;

Project proposals to conserve agrobiodiversity;

Training materials (on technologies for the cultivation and management of orchards, etc.) for education and capacity-building purposes, and under protection of intellectual property rights in case of replication;

Information on training centers;

Number of key nurseries and their agroecological zone;

Farmer and households' code numbers;

Farmers' major specializations;

In relation to location references of households, farms and settlements, only open access to latitude and longitude location references of their District information in degrees and minutes without seconds;

Morphological characterization of varieties and species;

General information related to traditional knowledge and management practices; not know-how;

General information about the importance of plant genetic resources and local diversity of fruit crops and wild species for the regional and global community;

All the information included in the survey data that is not under the consideration of Restricted Access Information or Absolute Restricted Access Information.

3.3. Parties agree that the following Information will be Restricted Access Information:

Full content of unpublished scientific work (articles, research papers, monographs, among others);

Database on demonstration plots;

Database on key nurseries and their locations;

Farmers and households' names;

Evaluation data of varieties and species;

Traditional knowledge and management practices: Restricted access under acknowledgement and copyright protection.

3.4. Parties agree that the following information will be Absolute Restricted Access Information:

Socioeconomic data resulting from household surveys;

Latitude and longitude location references of households, farms and settlements; Settlement names;

Endangered species geographical location (for example, varieties under the Red List and CITES).

#### 4. Obligations

4.1. The National Executing Agencies (NEA) will:

Share with all the parties complete contact details of the individuals that have been designated as National Focal Points (NFP).

Ensure that the NFP will coordinate the execution of the responsibilities under this agreement and act as the main contact point between the NEA and the Project Coordinator.

Through the NFP, regularly provide the information to be uploaded on the website to the Project Coordinator.



When providing the information to be uploaded on the website, confirm its open or restricted nature according to Article 3 of this agreement.

Specify the Project partners who will have access to the Restricted Access Information and communicate their contact details to the Project Coordinator.

Obtain any necessary permissions to make the information available on the website.

4.2. Project Coordinator/Bioversity will:

Design the website.

Upload the information provided by the NFP to the website following the conditions of accessibility specified in Article 3 of this agreement for each type of information.

Provide technical guidance on information quality.

Manage the legal basis for access to and use of the website (disclaimers, copyright notifications, terms of use and acknowledgment, among others) and prominently display them on the website.

Place a copy of this agreement on the restricted access area of the website.

Not alter, modify, or otherwise change, the information in any way if the quality standards are met. Not claim exclusive property rights over any information provided by the NFP.

Not express any opinion on the information when making them publicly available.

Acknowledge that the NEA are the source of the information and encourage website users to acknowledge the website as the source of the information. The “terms of use” and acknowledgements will be prominently displayed on the website.

#### 5. Maintenance of the website

Bioversity commits to maintain the website for the first two years of functioning, from the moment the website is published on the internet; after this period, NEA will take the responsibility for its maintenance. Parties may decide to amend or terminate this agreement or to sign a new agreement regulating the new responsibilities in relation to its maintenance.

After the mentioned period of two years, Bioversity will not have any coordination responsibilities and will not be accountable for the information displayed on the website.

#### 6. Conditions for sharing restricted access information among Project partners and with non-Project partners

All Project partners will have access to the Restricted Access Information provided by all parties. If a Project partner wants to use Restricted Access Information for commercial purposes, such Project partner will ask the permission of the NEA that provided such information.

Each National Executive Agency will be able to reproduce and distribute Restricted Access Information originally provided by the same National Executive Agency, without any need to obtain permission from the other parties.

Parties agree that once the Restricted Access Information is considered to be publicly available without limitations or restraints according to Article 3 of this agreement, parties will be able to use, reproduce and distribute such information for free, without any need to obtain permission from one another.

Non-Project partners' access to Restricted Access Information will require the explicit permission from the NEA that provided such information. In this case, the NEA can impose specific terms and conditions for the use of the information. The contact details of all the NFP will be available on the website for non-Project partners to get in touch with the NFP regarding the access to and use of Restricted Access Information.

#### 7. Dissemination of information and acknowledgement

When disseminating and publishing the information or any research finding based on such information, the parties will recognize the other parties through citation, acknowledge or reference to the source of information as well as UNEP-GEF as financial supporter of the Project.

Parties will publicize the website by including its links in their institutional websites and in scientific publications resulting from the use of the information stored on the website.

Parties will make efforts to ensure that all website users publicly recognize the parties as the authors of the information as well as UNEP-GEF and any other donor as financial supporters of the Project.

#### 8. Intellectual property rights

Neither the receipt of the information nor its publication through website shall affect whatever intellectual property rights the National Executive Agencies may hold with respect to the information.

## 9. Effect, amendment and termination of agreement

This Agreement will enter into force on the date of signature by not less than two parties and will become effective for every party at the moment of signature by each party.

The terms of this agreement can be amended upon written agreement by all the parties.

Any party may unilaterally withdraw from the agreement by giving at least thirty (30) days prior written notice to all the parties of this agreement.

## 10. Settlement of disputes

Any disputes or differences of any kind arising between the parties during the implementation of this Agreement shall be settled amicably upon consultation between all parties in accordance with tenor and intent of this Agreement.

Parties agree that six originals of this agreement are signed in Russian and six originals are signed in English (1 original for each Party) and that all originals have equal validity.

Date and signature

遺伝資源利用国が提供する契約見本

スウェーデン Uppsala 大学とラオス大学の教育・訓練同意書見本

スウェーデン Uppsala 大学とラオス大学の教育・訓練同意書見本

Letters of Intent—Education/Training Situation

<p>The Faculty of Sciences, National University of the PDR (represented by Dr. Sue-Trong) and Department of Systematic Botany, Uppsala University, Sweden (represented by Dr Lisa Svensson), hereby declare their intention to cooperate on an ethnobotany project within the Nam-Nam NBCA, the People's Democratic Republic.</p>	<p>ラオス国立大学科学学部（代表者 Sue-Trong 教授）とスウェーデン国 Uppsala 大学植物分類学部（代表者 Svensson 教授）は、ラオス Nam-Nam NBCA 地域で、民族植物学の研究プロジェクトを共同して行う意図があることを表明する。</p>
<p>From the Faculty of Science, Mr. Mak Naeng MSc and Mr. Mai Moeng MSc will take part as Ph.D. students, with Dr. Lisa Svensson and Prof. Birgitta Eriksson from Uppsala University as supervisors. From Uppsala University, Hugo Brun is financed as a Ph.D. student.</p>	<p>ラオス国立大学科学学部からはMak Naeng氏、Mai Moeng氏が博士課程の大学院生として、スウェーデン国 Uppsala 大学からはSvensson教授、Eriksson教授が教育訓練の指導者として参加する。スウェーデン国Uppsala大学からはHugo Brun氏が博士課程の大学院生として資金援助される。</p>
<p>Financing for Mr. Naeng and Mr. Moeng is from the bilateral program of the Swedish International Development Cooperation Agency (Sida) and NUOL. Financing for Mr. Brun is from a grant from the</p>	<p>ラオス国立大学科学学部のNaeng氏とMoeng氏は、ラオス国とスウェーデン国の二国間教育プログラムから資金援助される。スウェーデン国Uppsala大学のBrun氏は、スウェーデン国Uppsala大学のSvensson教授に提供された研究資</p>

Sida/SAREC to Dr. Lisa Svensson.	金の中から援助される。
	ラオス国首都にて、 日付 ラオス国立大学科学学部 Sue-Trong教授 署名  スウェーデン国Uppsala大学E学部 Lisa Svensson教授 署名

スエーデンラオス研究素材収集同意書

スエーデンラオス研究素材収集同意書

Letters of Intent—Derivatives

<p>The Ministry of Health, the People’s Democratic Republic, represented by Mr./Mrs. _____; and the Department of Systematic Zoology, Uppsala University, represented by Dr. Åke Mattsson, hereby declare their intentions to conduct a cooperative project in biology within the Nam-Nam NBCA that concerns traditional techniques for malaria control and development of vector control.</p>	<p>XXX氏に代表されるラオス国保健省と、Åke Mattsson研究者に代表されるスエーデン国Uppsala大学動物分類学部は、伝統的なマラリア駆除方法とvector制御法の開発に関連する、Nam-Nam NBCA地域の生物について共同研究を行う意志があることを表明する。</p>
<p>Dr. Åke Mattsson, Professor Dr. Thomas Lundberg, and Ph.D. students Nils Svensson, Uppsala University, and Mai Moeng, National University of the Capital, are given a permit to collect plant material and insect samples within the NBCA for documentation.</p>	<p>Mattsson 教授とその同僚研究者、Uppsala 大学学生と、ラオス国国立大学の Moeng 氏は、XXX 地域の植物材料と昆虫サンプルを資料作成のために収集する許可が与えられた。</p>
<p>All specimens are collected in triplicate and processed to be detained in the NU herbarium, in the Uppsala University (UPS), and at the Stockholm Museum of Natural History (S).</p>	<p>すべての標本は、3つ組で収集され、ラオス国国立大学の植物保存館、スエーデン国 Uppsala 大学、スエーデン国自然史博物館の三か所に保存される。</p>
<p>All samples are marked with catalogue number and the text: “This material belongs to the PDR. Any</p>	<p>すべてのサンプルは、カタログ番号と共に次の文章が添付される。「この材料はラオス国の所有物である。第三者へ</p>

<p>distribution of this material to a third party requires a specific permit from the Ministry of Environment of PDR.” Prepared plant extracts are transferred to Uppsala University for analysis. All extracts are marked with catalog number and the text: “This sample belongs to the PDR. Any transfer of material to a third party necessitates a permit from the Ministry of Health, PDR.”</p>	<p>の配布には、ラオス国環境省の許可が必要である。」 植物の抽出物はスウェーデン国 Uppsala 大学に分析のため移転される。すべての抽出物は、カタログ番号とともに次の文書が添付される。「このサンプルはラオス国の所有物である。第三者への配布には、ラオス国環境省の許可が必要である。」</p>
<p>All expenses for the project are to be financed by the Swedish International Development Agency. The project is planned to take place from April 1, 2007 to August 31, 2009, and this letter of intent covers that time period only.</p>	<p>全ての研究資金はスウェーデン国の国際開発庁によって供給される。本プロジェクトの期間は、YYY から ZZZ である。本同意書はこの期間のみ有効である。</p>
<p>The Capital, March 3, 2007</p> <p>The Ministry Åke Mattsson Thomas Lundberg Nils Svensson</p> <p>National University of the Capital Mai Moeng</p>	<p>ラオス首都ビエンチャンにて、日付</p> <p>スウェーデン国Uppsala大学 Åke Mattsson 署名 Thomas Lundberg 署名 Nils Svensson 署名</p> <p>ラオス国国立大学 Mai Moeng 署名</p>



スウェーデン・ラオス遺伝資源探索と伝統的知識に関するアクセスと利益配分確認書

スウェーデン・ラオス遺伝資源探索と伝統的知識に関するアクセスと利益配分確認書

Letters of Intent—Bioprospecting and Traditional Knowledge

<p>The representative of the Council of Village Heads of Nam Rew and Nam Chaa Valleys, representing the people of the villages in the Nam Rew and Nam Chaa Valley, Nakay-Mai District, Nua Province, PDR and the Department of Systematic Botany, Uppsala University, Sweden, represented by Martin Stigberg, hereby declare their intention to cooperate on a project concerning plants used for traditional medicine and mosquito control. The project aim is to improve mosquito and health control for the people in the villages.</p>	<p>ラオス国、Nua 州、Nakay-Mai 地区の Nam Rew と Nam Chaa 溪谷の地域社会の長からなる委員会の代表者と、Martin Stigberg 教授が代表するスウェーデン国 Uppsala 大学植物分類学部、は、伝統医学と蚊駆除に利用されている植物について共同で研究することに合意した。本研究の目的は、本地域の村民の蚊駆除と健康管理を向上させることである。</p>
<p>All field equipment used for this control will be donated to the villages after the project time expires.</p>	<p>本管理に使用されるすべての野外実験機器は研究終了後、村に寄贈される。</p>
<p>All rights to findings, in the form of possible patents and marketable products, and profits from possible commercialization will be divided according to the following schema:          • 5% given to local informants and/or</p>	<p>特許や市場可能性のある製品という形で表現される、研究の発見に対する全ての権利と、商品化から得られる金銭的利益は、次の概要に従って配分される。          • 5%は地域の情報提供者、あるいは/</p>

<p>their families</p> <ul style="list-style-type: none"> <li>• 25% put into a village development fund controlled by the Council of Village Heads of the villages in the Nam Rew and Nam Chaa Valleys</li> <li>• 25% is to be used by the Ministry of Health for active disease control in the PDR</li> <li>• 25% to be used by the Ministry of Environment for preservation of biological biodiversity</li> <li>• 20% of gains are put into a research fund with Dr. Martin Stigberg (Lecturer in Ethnobotany, Uppsala University), Prof. Maria Karlsson (Professor in Medical Entomology, Uppsala University) and Dr. Sue-Trong (Dean of the Faculty of Sciences, National University) are board members. The fund should be used for the education of promising Ph.D. students from the PDR within the field of biology.</li> </ul>	<p>又は、その家族に配分される。</p> <ul style="list-style-type: none"> <li>• 25%は、Nam Rew と Nam Chaa 溪谷地方の村落の長の集まりである委員会の管理下にある開発基金に配分される。</li> <li>• 25%はラオス国の保健省に配分され、健康管理のための活動に使われる。</li> <li>• 25%はラオス国環境省に配分され、生物多様性保全のために使われる。</li> <li>• 20%は、スウェーデン国 Uppsala 大学大学植物分類学部の Martin Stigberg 教授、その共同研究者、大学委員会が管理する研究基金に配分される。この基金は、生物学分野で、博士課程の学生をラオス国から受入れ教育するために使われなければならない。</li> </ul>
<p>The project is planned to be financed by the Swedish International Development Cooperation Agency. Project time July 1, 2007, to June 30, 2011.</p>	<p>本プロジェクトは利用国スウェーデン国の国際開発協力庁の資金によって、XXX 日から YYY 日まで行われる。</p>
<p>February 28, 2007</p> <p>Martin Stigberg Department of Systematic Botany,</p>	<p>日付</p> <p>研究者 スウェーデン国Uppsala大学植物分類学</p>

Uppsala University, Sweden	部
Chief ..... Representative of the Council of Village Heads of Nam Rew and Nam Chaa Valley Nam-Nam NBCA, PDR	Nam RewとNam Chaa溪谷地域社会 代表者 ラオス国、Nua州、Nakay-Mai地方

スイス科学アカデミーの標準非商用研究用アクセスと利益配分契約

スイス科学アカデミーの標準非商用研究用アクセスと利益配分契約  
Agreement on Access and Benefit Sharing for Non-Commercial Research

<b>Introduction</b>	<b>はじめに</b>
This document contains a sample agreement on mutually agreed terms (MAT) for Access to Genetic Resources and Sharing of Benefits, for the use by providers and non-commercial academic researchers. At the same time it provides a sample for the potential of model clauses within a sector specific	この文書は、遺伝資源提供者と非商用で科学的な研究者が使えるように作成された、遺伝資源へのアクセスと利益配分に関する、相互の合意に基づく条項を含んだ合意文書の見本である。同時に、この文書は、学術研究を目的とした、可能なモデル条項のサンプルを含んでいる。全ての当事者のニーズと意図に合致するにふさわしい、透明性のある、かつ

<p>approach; as comprised in Art. 15 of the Draft Protocol on ABS under the CBD.1</p> <p>The agreement aims at creating transparent, and legally secure relations that are appropriate to the needs and intentions of all parties involved. The suggested terms and clauses are intended to meet the needs of both the providers of the genetic resources and the researchers seeking access. The agreement proposes language to ensures fair and equitable sharing of benefits.</p>	<p>合法的に確実な関係を作ることを目的としている。提示された条項は、遺伝資源の提供者とアクセスを求める研究者のニーズを満たすことを意図している。この契約案は、公正かつ衡平な利益配分を保証する表現を提案している。</p>
<p>The agreement may be considered for use in various scenarios of access and benefit sharing, such as inventories of biodiversity; research in systematics, ecology and evolution; identification and isolation of active compounds; and genetic research.</p>	<p>この契約案は、博物学、系統分類学、生態学と進化の研究、活性化合物の分離・同定、遺伝学的研究などのさまざまなアクセスと利益配分のシナリオに対応して考慮される。</p>
<p><b>Concepts</b></p> <p>The Agreement is adapted to the specific situation of non-commercial research sponsored by public funding. Its basic premise is that the Mutually Agreed Terms, as stipulated in CBD Art 15, are a bilateral contract concluded between providers and users, resulting from their fair negotiations on the terms of access and benefit sharing.</p>	<p><b>基本理念</b></p> <p>本契約は、公的資金によって支援される非営利研究の特定の状況に適用される。その基本的な前提は、CBD 第 15 条に規定されている相互に合意した条件は、アクセスと利益配分の条項について公正な交渉の結果、提供者と利用者間で合意した双務的な契約である。</p>

<p>Involved parties are encouraged to take account of each others specific needs and circumstances, reflecting on the type of envisaged research (e.g. ecological vs. phytopharmacological research) and the specifics of the research (e.g. difficulties in identifying taxa, sharing of material). For the provider, this may include means to monitor the use of genetic resources.</p>	<p>当事者は、お互いに特定のニーズと状況を考慮するように促され、構想された研究のタイプ（例えば、生態学的研究か植物薬理学的研究か）を反映し、研究の特徴(分類群の同定困難、素材の共有など)を反映するよう求められる。提供者にとって、遺伝資源の利用をモニターするための手段を含めることができる。</p>
<p>We assumed the following basic scenario:</p> <ul style="list-style-type: none"> <li>• The resources are accessed by a researcher under the lead and responsibility of a research institute.</li> <li>• The research is non-commercial, aiming at providing publicly available results. The results have therefore to be published.</li> <li>• Unexpected research results may trigger reflections towards their utilisation in a commercial context.</li> <li>• Benefits are non-monetary as a rule. They usually accrue during the research process.</li> <li>• Genetic resources might be transferred to third parties under a framework of customary cooperation by research institutes.</li> </ul>	<p>次のような基本的シナリオを想定した。</p> <ul style="list-style-type: none"> <li>• 遺伝子資源は研究者と研究機関の指導と責任よりアクセスされる。</li> <li>• 研究は非営利目的の研究であり、公共が利用可能な結果をめざす。結果は出版される。</li> <li>• 予期せぬ研究結果が、商用目的に利用される方向に向かうきっかけになる。</li> <li>• 利益は、ルールとして非金銭的である。利益は、研究過程の中で発生する。</li> <li>• 遺伝資源は、研究機関間の慣習の枠組みの中で第三者機関に移転することができる。</li> </ul>
<p>The analysis of research types and</p>	<p>研究のタイプとアクセス実態を分析し</p>

<p>access situations carried out by the ABS-team led to the following conclusions:</p>	<p>た結果、下記の結論が導かれた。</p>
<p>1. One of the challenges in implementing the ABS system consists in controlling the flow of the acquired resources throughout the value chain, especially in the user country. At the centre of the problem lies the risk that the resources and related information accessed under the conditions for non-commercial intent enter the R&amp;D sector without corresponding MATs for potential commercial developments.</p>	<p>1. ABS システムを実行する際の課題の1つは、利用国のバリューチェーン全体の流れの中で、取得した遺伝資源の流れを制御することである。問題の中心として、非商用目的という条件の下でアクセスした遺伝資源や関連情報が、潜在的な商用開発に対応する相互合意もなく、研究開発セクターに移されるというリスクがある。</p>
<p>2. Non-commercial researchers depend largely on public funding. For continued financial support the publication of research results is a crucial step and has to happen in a timely manner. Scholarly standards for disclosure of information for scientific transparency and the exchange of material among peers may collide with the need of providers to control the use of genetic resources. In turn, too strict control measures could put research at stake.</p>	<p>2. 非営利研究の研究者は、大部分は公的資金に依存している。継続的な資金援助を得るために、研究成果の出版の重要なステップで、タイムリーに行わなければならない。科学的な透明性のための情報の開示と研究者間の研究材料の交換に対する学術的な基準は、遺伝資源の利用を制御する提供者の必要性和相反するところがある。逆に言えば、あまりにも厳しい規制措置は、研究を危険にさらすことになる。</p>
<p>3. Different fields of research with</p>	<p>3. 遺伝資源を用いる研究のさまざま</p>

<p>genetic resources imply different degrees of probability that the research results flow (intentionally or unintentionally) into the commercial value chain. It is, however, essential to realize that some fields of research show very low probability, for example the elaboration of biodiversity inventories or ecological studies. In such cases the providing country could require less control over the uses and instead request periodic reports on research progress to monitor the user's compliance with the MATs.</p>	<p>な分野には、意図的か意図しないかにかかわらず、研究成果を商業的価値チェーンに流し込む、異なった度合の可能性を含んでいる。しかし、例えば、生物多様性目録または生態学的研究の精緻化の例のように、ある分野の研究は非常に低い可能性であることを認識することが不可欠である。このような場合、提供国は、利用に対して制御を低くする必要があり、代わりに、利用者の相互に合意する条件の遵守を監視するために、研究の進捗状況の定期的な報告を求めるべきである。</p>
<p>The Agreement takes account of various research activities by proposing options for the following conditions:</p> <ol style="list-style-type: none"> <li>1. Different situations (e.g. access to genetic resources vs. access to related traditional knowledge; access to specified taxa vs. the need to identify the samples after collection);</li> <li>2. Different models of research cooperation; and diverse needs to monitor the implementation of the agreement;</li> <li>3. Specific aspects of academic research, such as the need to publish results and the exchange of data, storage and accessibility of samples</li> </ol>	<p>下記の状況に対するオプションを提供することにより、さまざまな研究活動を考慮している。</p> <ol style="list-style-type: none"> <li>1. 遺伝資源へのアクセス、伝統的知識へのアクセス、特定の分類群へのアクセス、収集後にサンプル同定が必要な場合などの異なった状況</li> <li>2. 異なった共同研究形態、契約実施の監視に対する様々なニーズ</li> <li>3. 成果の報告出版の必要性、データ交換の必要性、試料の保存と第三者利用可能性など学術研究の特徴</li> </ol>

etc.	
<p><b>How to use the Agreement</b></p> <p>The Agreement on Access to Genetic Resources and Sharing of Benefits (ABS) for Non-commercial Academic Research containing Model Clauses is based on the conviction that mutually agreed terms are a contract that needs to be negotiated and concluded between the parties, i.e. the providers and the users of genetic resources. The proposed Agreement provides a tool-box for composing a contract on mutually agreed terms tailored to accommodate the needs of the stakeholders. We recommend that both parties possess the full text of the Agreement in order to foster discussions on options and provide solutions to disagreements that might arise.</p>	<p><b>この契約の利用方法</b></p> <p>非営利学術研究の遺伝資源へのアクセスと利益配分は、モデル条項を含んでいる。相互に合意した条件は、遺伝資源の提供者と利用者の中で交渉され合意される必要のある約定であるという確信に基づいている。ここに提案された契約案は、当該当事者のニーズに合わせて作成された相互に合意された条件に基づく契約を作成するためのツールボックスを提供する。両当事者は、オプション条項に対する議論を促進し、生じる可能性のある不一致に解決を与えるために、全ての条項を含んだものを保有することを勧める。</p>
<p>The Agreement consists of different types of clauses:</p> <ol style="list-style-type: none"> <li>1) General clauses, like the preamble, or the definition of the purpose (article 4);</li> <li>2) Clauses on substantive issues (articles 5 to 17);</li> <li>3) Clauses on procedural issues.</li> </ol> <p>Most of the clauses on substantive issues offer a basic clause (marked green in the sample agreement) and</p>	<p>本契約は、異なる種類の条項で構成されている。</p> <ol style="list-style-type: none"> <li>1) 前文や目的（第 4 条）の定義のような一般的な条項</li> <li>2) 本質的な問題に対する条項（第 5 条から第 17 条）</li> <li>3) 手続きに関する条項</li> </ol> <p>本質的な問題に関する条項の大部分について、（サンプル契約の中ではグリーンマーク）基本的な条項を提供す</p>



<p>include options that can be added to the basic clause or used as a stand-alone solution. Other clauses offer only options to choose from as needed.</p>	<p>る。基本的な条項に追加または独立した解決策として使用することができるオプション条項がある。他の条項は、必要に応じて、選択可能なオプションのみを提供している。</p>
<p>In drafting the Agreement, we intended to cover most issues that might arise in the relationship between providers and non-commercial public researchers. The basic clauses by themselves may form a full contract for simple non-commercial research situations. Not all cases will need all clauses; each agreement must be modelled according to the specific needs of the parties engaged in the negotiations. The Agreement is therefore made freely available as Word Document under a Creative Commons Licence that allows for changes in the document.</p>	<p>本契約案を起草するに当たり、提供者と非営利公共研究者間の関係で生じる可能性のあるほとんどの問題をカバーしている。基本的な条項は、簡単な非営利研究状況に対応した完全契約フォームを形成している。すべてのケースで、すべての条項を必要としない。契約交渉に従事している当事者の特定のニーズに応じて、それぞれの契約は作られる必要がある。</p>
<p><b>Preamble</b></p> <p>The purpose of this Agreement is to set out the conditions for the use of genetic resources, any associated Traditional Knowledge (TK) and the sharing of resulting benefits between the parties concerned in accordance with the Convention on Biological Diversity (the CBD), particularly in respect with the principles established under its Articles 1, 8(j),</p>	<p><b>前文</b></p> <p>生物多様性条約 (CBD)、特にその第1条、第8(j)条、第15条と、ボン・ガイドラインのもとで確立された原則に従って、この契約の目的は、遺伝資源、それに付随する伝統的知識 (TK)の利用と、結果として得られる利益の関連する当事者間の配分の条件を設定することある。</p>

15, and the Bonn Guidelines.	
The Agreement contains Mutually Agreed Terms (MAT) according to Article 15.7 CBD.	契約には、生物多様性条約第 15.7 条に従って、相互に合意した条件 (MAT) を含む。
The Agreement is designed to promote non-commercial academic research, such as research in taxonomy, ecology, biochemistry and genetics, and to foster conservation and the environmentally sound and sustainable use of genetic resources.	契約は、分類学、生態学、生化学、遺伝学などの非営利学術研究を推進するようにデザインされ、遺伝資源の保全と、環境上適正かつ持続可能な利用を育成するように考えられている。
Its objective is to provide a sound basis for cooperation, transparency, communication and trust between the parties to the Agreement, taking account of the concerns of both providers and users of genetic resources.	この契約書の目的は、遺伝資源の提供者と利用者双方の懸念を考慮して、当事者間の協力、透明性、意思疎通、信頼に確固たる基盤を与えることである。
<p><b>1. Parties to the Agreement</b></p> <p>The Agreement is entered into on [insert the date] by and between</p> <p>[insert the name and details of the following:</p> <p>..State and Institution (competent ABS national authority)</p> <p>..The contact person responsible for the implementation of the Agreement on behalf of the institution]</p>	<p><b>1. 本契約の合意者</b></p> <p>本契約は「日付」より下記当事者間で有効となる。</p> <p>「名前と詳細」</p> <p>「国名、権威ある当局」</p> <p>「権威ある当局の本契約実施に責任のある者」</p> <p>以後提供者として扱われる。</p> <p>および</p>

<p>together hereinafter referred to as the Provider.</p> <p>and</p> <p>[insert the name and details of</p> <p>..The responsible research institution</p> <p>..The representative of the research institution responsible for the implementation of the Agreement]</p> <p>Represented by the authorized head or member of the research team; authorized researcher [insert the name and details of researcher].</p> <p>together hereinafter referred to as the “User”.</p>	<p>「名前と詳細」</p> <p>責任ある研究機関</p> <p>本契約実施のための研究機関の責任者</p> <p>研究チームの責任者あるいは研究メンバー</p> <p>又は、研究責任者「名前、詳細」</p> <p>以後利用者として取り扱われる。</p>
<p><b>2. Prior Informed Consent</b></p> <p><b>Option 2.1</b></p> <p>The Agreement is based on the Prior Informed Consent (PIC) issued beforehand by the Provider to the User for the access to the genetic resources concerned. The PIC document is attached to this Agreement and is considered an integral part of the Agreement.</p>	<p><b>2. 事前の情報に基づく合意</b></p> <p><b>オプション 2.1</b></p> <p>本契約は、当該遺伝資源へのアクセスについて提供者が利用者に事前に発行された事前の情報に基づく合意（PIC）に基づいている。PIC は本契約に添付され、本契約の不可欠な部分である。</p>
<p><b>Option 2.2</b></p>	<p><b>オプション 2.2</b></p>

<p>The Provider hereby confirms that he/she has been informed on the research project by the User and consents to provide access to genetic resources in situ and/or ex situ necessary to carry out the research in accordance with the research project attached to this Agreement.</p>	<p>提供者は、利用者によって研究プロジェクトの説明を受け、本契約に関連付けられた研究プロジェクトに従って、実施される研究に必要な原生の、あるいは/又は、域外保存の遺伝資源へ利用者がアクセスすることを同意することを確認する。</p>
<p><b>3. The Purpose of the Agreement</b></p> <p>The purpose of this Agreement is to specify the terms for</p> <ol style="list-style-type: none"> <li>1. Accessing genetic resources,</li> <li>2. Their utilization in accordance with the PIC,</li> <li>3. Their possible transfer to third parties, and</li> <li>4. For sharing the benefits resulting from the utilization of genetic resources.</li> </ol>	<p><b>3. 本契約の目的</b></p> <p>この契約の目的は以下の条件を特定することである。</p> <p>遺伝資源へのアクセス PIC に従い遺伝資源を利用 遺伝資源の第三者への分譲の可能性 遺伝資源の利用から生じる利益を配分</p>
<p><b>4. Terminology</b></p> <p>In this Agreement the terms defined in Article 2 CBD shall have the same meaning, unless otherwise defined in this article.</p>	<p><b>4. 用語</b></p> <p>本契約では、生物多様性条約第2条に説明された用語は、本契約で特定しない限り、同じ意味で用いる。</p>
<p><b>4.1 Genetic Resources</b></p> <p>Genetic Resources means genetic material of actual or potential value.</p>	<p><b>4.1 遺伝資源</b></p> <p>遺伝資源とは、現実のあるいは潜在的な価値を有する遺伝的素材である。</p>
<p><b>Option 4.1.1</b></p>	<p><b>オプション 4.1.1</b></p>

Genetic Material means any material of plant, animal, microbial or other origin containing functional units of heredity.	遺伝的素材とは、遺伝機能を有する植物、動物、微生物、その他の生物を意味する。
<b>Option 4.1.2</b>  The term “Genetic Material” includes living and dead resources.	<b>オプション 4.1.2</b>  遺伝素材の用語には、生きているかあるいは死んでいる資源も含まれる。
<b>Option 4.1.3</b>  The term “Genetic Material” includes derivatives as defined below.	<b>オプション 4.1.3</b>  遺伝素材には、4.2 で定義する派生物も含まれる。
<b>4.2. Derivatives</b>  <b>Option 4.2.1</b>  Derivatives means products based on Genetic Resources and generated through techniques such as expression, replication, characterization or digitalization.	<b>4.2. 派生物</b>  <b>オプション 4.2.1</b>  派生物とは、遺伝資源を基礎にするものであり、発現、複製、特徴化、デジタル化などの技術を通じて生じたものである。
<b>Option 4.2.2</b>  Derivatives mean substances created from Genetic Resources that are substantially modified to have new properties.	<b>オプション 4.2.2</b>  派生物とは、遺伝資源から作られ、相当の修飾を受け新たな性質を獲得した物質である。
<b>4.3 Commercialization</b>  Commercialization means the use of the Genetic Resource for the generation of any kind of actual or	<b>4.3 商用化</b>  商用化は、あらゆる種類の現実のまたは潜在的な経済的利益の生成ために遺伝資源を使用することを意味します。

<p>potential economic profit. It means in particular any sale, lease, licensing of the Genetic Resource, and/or Products generated from its use through actions such as filing a patent application, obtaining intellectual property rights or other tangible or intangible rights. It includes any transfer of the Genetic Resource to a for profit organization.</p>	<p>商用化は、特に、遺伝資源、および/又は、特許の出願、知的財産権、またはその他有形、無形の権利の取得などの活動を通じて、遺伝資源の利用から発生した製品の販売、リース、ライセンスを意味する。 商用化は、営利機関への遺伝資源の移転も含まれる。</p>
<p><b>4.4 Mutually Agreed Terms (MAT)</b></p> <p>The Mutually Agreed Terms are an agreement negotiated between the Provider and the User of the Genetic Resources and/or holders of Traditional Knowledge associated to the Genetic Resources according to the national law of the country providing the resources. The MAT regulate conditions for the access to the Genetic Resources and to their associated Traditional Knowledge and the fair and equitable sharing of benefits that result from their use. They are adapted to the specific access situation.</p>	<p><b>4.4 相互に合意する条件(MAT)</b></p> <p>相互に合意する条件とは、遺伝資源提供国の国内法に従い、遺伝資源の提供者と利用者、および/あるいは、遺伝資源に付随する伝統的知識の保持者との間で交渉される合意である。MATは遺伝資源およびそれに付随する伝統的知識へのアクセスを規制している。また、それらの利用から生ずる結果得られる利益の公正かつ衡平な配分も規制している。特定のアクセス状況に適応している。</p>
<p><b>4.5 Traditional Knowledge</b></p> <p><b>Option 4.5.1</b></p> <p>Traditional Knowledge is the</p>	<p><b>4.5 伝統的知識</b></p> <p><b>オプション 4.5.1</b></p> <p>伝統的な知識は、生物資源の保全と持</p>

<p>accumulated knowledge that is vital for the conservation and sustainable use of biological resources and/or which is of socioeconomic value, and which has been developed over the years in indigenous/local communities.</p>	<p>続可能な利用と、そして/または、社会経済的価値を持つものに必須である蓄積された知識である。そして、先住民/地域社会で長年にわたって開発されてきたものである。</p>
<p><b>Option 4.5.2</b></p> <p>Traditional Knowledge means “information or individual or collective practices of an indigenous or local community associated with the genetic heritage having real or potential value”.</p>	<p><b>オプション 4.5.2</b></p> <p>伝統的知識とは、現実的なまたは潜在的な価値を持つ遺伝的遺産に関連する先住民や地域社会の、情報、または、個人あるいは集団的な習慣を意味する。</p>
<p><b>4.6 Prior Informed Consent (PIC)</b></p> <p>Prior Informed Consent means the unilateral declaration of the Provider that he/she has been informed about the planned research and that he/she is willing to provide the required access to the Genetic Resource.</p>	<p><b>4.6 事前の情報に基づく同意</b></p> <p>事前情報に基づく合意とは、提供者が計画された研究について情報を得ており、遺伝資源への必要なアクセスを提供する意思があることについて、提供者が一方的に宣言することを意味する。</p>
<p><b>4.7 Product</b></p> <p>Product means the result produced, obtained, extracted or derived from the Genetic Resource through research or research &amp; development (R&amp;D) activities, including data and information generated through analyses of the Genetic Resources.</p>	<p><b>4.7 製品</b></p> <p>製品とは、研究や開発活動を通じて、遺伝資源から生産された、取得された、抽出された、誘導された結果を意味する。製品には、遺伝資源の分析を通じて得られたデータや情報も含まれる。</p>
<p><b>4.8 Progeny</b></p>	<p><b>4.8 子孫</b></p>

Progeny means unmodified offspring from the Genetic Resource	子孫とは、遺伝資源から生じたのと同じ生物である。
<p><b>4.9 Third Party</b></p> <p>Third Party means any person or institution other than the Provider, the User and any collaborator under their control or supervision. A Third Party is not bound to the terms and conditions of this Agreement unless otherwise agreed with the User.</p>	<p><b>4.9 第三者機関</b></p> <p>第三者機関とは、提供者、利用者およびその管理や監督の下で行う共同研究者以外のいかなる研究者あるいは研究機関を意味する。利用者との合意がない限り、第三者機関は、本契約の用語と条件に拘束されない。</p>
<p><b>4.10 Unauthorized Person</b></p> <p>Unauthorized Person means any person that came into possession of the Genetic Resources without the authorization of the User.</p>	<p><b>4.10 許可されない者</b></p> <p>許可されない者とは、利用者の許可なく遺伝資源を保持する人物である。</p>
<p><b>5. Genetic Resources to be accessed</b></p> <p>The User shall have access to the following Genetic Resource(s): [Insert list of the Genetic Resources to be accessed].</p>	<p><b>5. アクセス可能な遺伝資源</b></p> <p>利用者は次の遺伝資源にアクセスする。（リストを挿入する）</p>
<p><b>Option 5.1</b></p> <p>Since the species/strains present at the collection site are not known to the User at the time of concluding this Agreement, a general account of species/strains most likely to be collected is given in Annex XX.</p>	<p><b>オプション 5.1</b></p> <p>本契約の締結時に、実際の採取地で存在する種/系統を利用者に知らされていないので、採取する可能性が最も高い種/系統の一般的な説明を別添 XX に示される。研究者のフィールドノートに基づく収集したサンプルのリスト</p>



<p>A list of the collected samples according to the researcher's field-notes is presented to the Provider within XX months after having gathered the samples.</p>	<p>は、サンプル収集後 XX ヶ月以内に提供者に示される。</p>
<p><b>Option 5.2</b></p> <p>If the collected samples cannot be identified in the list of collected samples within the above prescribed period, their identification has to be shared with the User as soon as it is available.</p>	<p><b>オプション 5.2</b></p> <p>上記規定期間内で、収集されたサンプルがリストの中で同定できない場合、それらの同定が可能になればすぐに、利用者と共有する必要がある。</p>
<p><b>6. Utilization</b></p> <p>The Material may be utilized for non-commercial purposes including for academic research and collections, and for training, teaching and education.</p> <p>The User must comply with the User's and Provider's national regulations and with relevant international law. The utilization of the Material or derived information for any type of Commercialization is prohibited.</p>	<p><b>6. 利用</b></p> <p>遺伝資源は、学術研究およびコレクション、トレーニング、指導、教育などを含む非営利目的のために利用される。利用者は利用者国及び提供者国の規制、および関連する国際法を遵守しなければならない。遺伝資源あるいは派生した情報を、いかなるタイプの商業化への利用は禁止されている。</p>
<p><b>Option 6.1</b></p> <p>The Genetic Material shall be used exclusively for the following purposes: [insert allowed activities and/or uses].</p>	<p><b>オプション 6.1</b></p> <p>遺伝素材は以下の目的にのみ独占的に利用されなければならない。（研究活動と利用について記載）</p>
<p><b>7. Change in Utilization from</b></p>	<p><b>7. 非商用から商用への利用変換</b></p>

<p><b>Non-commercial to Commercial</b></p> <p>The Commercialization of the Genetic Material and related information is prohibited. Any change in utilization from non-commercial to commercial shall require a new Prior Informed Consent in writing issued by the Provider. In this case, the terms of such Commercialization shall be subject to a separate agreement (MAT) between the involved parties.</p>	<p>遺伝資源と関連する情報の商用化は禁止されている。非商用から商用へのいかなる利用変換は、提供者によって発行された新たな PIC を必要とする。この場合、商用化の条件は、関連する組織の間での相互に合意する条件に基づく新たな契約の対象となる。</p>
<p><b>8. Transfer of Genetic Resources (and associated TK) to Third Parties</b></p> <p>Transfer of the Genetic Resources for the purposes of academic research and collections, and for training, teaching and education, or any other non-commercial activities is allowed under the condition that the User ensures that the subsequent person or institution (Third Party) is informed about the provisions under this Agreement and undertakes to pass on the Genetic Resources under the same obligations to any further recipient.</p>	<p><b>8. 第三者機関への遺伝資源とそれに付随する伝統的知識の移転</b></p> <p>学術研究とコレクション、トレーニング、教育と指導、またはその他の非商用活動を行うために、遺伝資源の移転は、本契約の利用者が保障する条件下で、許可される。その条件とは、以降の研究者または機関（第三者機関）が、本契約の規定を通知され、更なる移転者に渡す場合に、同様の義務の下で遺伝資源を移転することを約束する場合に限られる。</p>
<p><b>Option 8.1</b></p> <p>The User delivers to the Provider annually a list of the Third Parties to whom the Genetic Resource was transferred to.</p>	<p><b>オプション 8.1</b></p> <p>利用者は、遺伝資源を移転した第三者機関のリストを毎年提供者に提供する。</p>

<p><b>Option 8.2</b> The User shall maintain retrievable records of any transfer of the Genetic Resources to Third Parties under the conditions corresponding to this Agreement.</p>	<p><b>オプション 8.2</b> 利用者は、本契約の規定のもとで遺伝資源を移転した第三者機関の取り出し可能な記録を維持する。</p>
<p><b>Option 8.3</b> The User shall require the Third Party to sign an agreement containing identical obligations on Use and Transfer of the Genetic Resources (and associated TK) as set out in this Agreement.</p>	<p><b>オプション 8.3</b> 利用者は、第三者機関に対して、本契約で設定された遺伝資源（および関連する TK）の利用と移転に関する同一の義務を含む契約書に署名することを要求しなければならない。</p>
<p><b>Option 8.4</b> The Genetic Resources [and their associated TK] may be transferred to Third Parties only after having obtained the written consent of the Provider and in accordance with Mutually Agreed Terms between the Provider and the Third Party. Exempted is a temporary transfer of the Genetic Resource to taxonomic specialists for scientific identification.</p>	<p><b>オプション 8.4</b> 遺伝資源（とその関連する TK）は、提供者による書面による同意と、提供者と第三者機関の間の相互に合意した条件に従っての書面による同意を得たあとでのみ第三者機関に転送可能となる。科学的同定のために分類学的専門家への遺伝資源の一時的な移転は例外とされる。</p>
<p><b>Option 8.5</b> The User is entitled to deposit the Genetic Resources in collections that are accessible without restrictions for research purposes such as herbaria, museums and culture collections.</p>	<p><b>オプション 8.5</b> 利用者は、植物標本庫、博物館、カルチャーコレクションなどの研究目的のための制限なしにアクセス可能なコレクションに、遺伝資源を預ける権利がある。</p>
<p><b>Option 8.6</b> If the Genetic Resources are</p>	<p><b>オプション 8.6</b> 遺伝資源が、動物園や植物園などの教</p>

<p>transferred to an ex situ collection of living Genetic Resources for educational purposes (such as zoos, botanic gardens), this institution is – in addition to the obligations of this Agreement – obliged to take any appropriate precautions to prevent the Genetic Resource coming into the possession of any Unauthorized Person.</p>	<p>育目的のための生存遺伝資源域外コレクションに転送される場合、これらの施設は、本契約の義務に加えて、無許可者の所有にならないように遺伝資源を保護する適切な注意を行う義務を持つ。</p>
<p><b>Option 8.7</b> If the use or storage of the Genetic Resource is subject to special conditions or restrictions, such conditions/ restrictions have to be clearly indicated on the label or otherwise linked to the sample, when transferring the Genetic Resource to Third Parties, including the indication of where the information concerning the special conditions/restrictions can be found.</p>	<p><b>オプション 8.7</b> 遺伝資源の利用または保管が特別な条件や制限下にある場合、遺伝資源を第三者機関に移転するとき、その条件や制限はサンプルのラベルあるいはその他に明確に表示しなければならない。そうすれば、そのような条件や制限に関する情報をどこで見つけることができるか明らかになる。</p>
<p><b>9. Benefit Sharing</b> The benefits arising from the access and use of the Genetic Resources shall be shared fairly and equitably by the User, in accordance with the principles established in the CBD. Basic benefits to be shared include:</p>	<p><b>9. 利益配分</b> 遺伝資源のアクセスと利用から生じる利益は、生物多様性条約で確立された原則に基づいて、利用者によって公正かつ公平に配分しなければならない。基本的な配分利益は、</p>
<p>1. The offer to the Provider to include local researchers in the research activities, if such interest exists.</p>	<p>1. 関心がある場合、研究活動へ地域の研究者を参加させるよう提供者に申し出ること</p>

<p>2. In case of publications or oral presentation of the research results, full acknowledgement is to be given to the source of the Genetic Resource;</p>	<p>2. 研究結果の出版や口頭発表の場合、遺伝資源の源 (source) に対して最大限の謝辞を表明する。</p>
<p>3. If TK associated to the Genetic Resources is involved, the research results published or presented orally will include full acknowledgement of the source of the Genetic Resources and the TK, if so required by the providers.</p>	<p>3. 遺伝資源に付随する伝統的知識がある場合、研究結果の出版や口頭発表は、もし、提供者によって要求されたなら、遺伝資源と関連する伝統的知識のSourceに最大限の謝辞を含める。</p>
<p>4. The Provider will receive a copy of all publications;</p>	<p>4. 提供者はすべての出版のコピーを保有する。</p>
<p>5. Research results will be communicated to involved stakeholders (e.g. communities, indigenous people) in an adequate manner and according to reasonable requirements of the Provider;</p>	<p>5. 研究の結果は、適切な方法で、かつ提供者の合理的な要求に従って、地域社会や先住民などの利害関係者に伝達される。</p>
<p>6. If applicable, share duplicate specimens with the repository in the Provider country in accordance with good scientific practice. In addition, the User agrees to share the following benefits: [Choose from the list of benefits appended to this Agreement;</p>	<p>6. 必要に応じて、優れた科学的習慣に従って、提供国のリポジトリと標本を重複して保存する。 更に、利用者は次の利益を配分することに同意する。 [本契約に基づく利益のリストを挿入するか Annex にリストアップする]</p>

<p>insert a detailed lists of benefits here or in an annex]</p>	
<p><b>10. Rights and Obligations of the Provider</b></p> <p>The Provider defined in Article 1 is the responsible contact point for the User for the entire duration of the present Agreement.</p> <p>The Provider has the obligation to facilitate access to the Genetic Resources. This includes the facilitation of the acquisition of other permits required in accordance with the relevant national or regional regulations in the Provider country as well as export permits.</p>	<p><b>10. 提供者の権利と義務</b></p> <p>本契約のすべての期間にわたり、本契約第1条で同定された提供者は、利用者のコンタクトポイントとなる。</p> <p>提供者は、遺伝資源へのアクセスを促進する義務がある。これには、提供国の関連する国や地方の規制に従って要求されるその他の許可証や輸出許可証の円滑な取得が含まれる。</p>
<p><b>Option 10.1</b></p> <p>The Provider designates the following institution [insert the relevant institution] as the responsible contact point for the User for the entire duration of the present Agreement.</p> <p>Contact details of the technical contact point are provided in Annex [XX] to this Agreement.</p> <p>The Provider has the right to receive information on the state of the research from the User as agreed upon (see Article 12 on Reporting).</p>	<p><b>オプション 10.1</b></p> <p>提供者は、次の機関（名前を入れる）を、本契約の有効期間を通じて利用者のコンタクトポイントとして指名する。</p> <p>技術的なコンタクトポイントの詳細は、本契約書の Annex に示されている。</p> <p>第12条の報告に示されたように、提供者は合意に基づいて利用者から研究状況に関する情報を入手する権利を持つ。</p>
<p><b>Option 10.2</b></p> <p>The Provider requests that the</p>	<p><b>オプション 10.2</b></p> <p>提供者は、プロジェクトで決定された</p>

<p>following analytical parts as set out in the project are performed in the providing country: [insert a list of analyses to be performed in the Provider's country].</p> <p>The Provider confirms that all necessary conditions (equipment, staff and consumables) for conducting the analyses are available;</p> <p>The User confirms that he/she has the necessary resources (funding, time) for such an arrangement.</p>	<p>次の分析部分を提供国で実施することを要求する。（提供国で実施される分析のリスト）</p> <p>提供者は、分析を実施するのに必要なすべての条件（分析機器、技術者、消耗品）が利用可能であることを確認する。</p> <p>利用者は、実験を実施するのに必要な資源（資金、時間）を提供者が持っていることを確認する。</p>
<p><b>11. Rights and Obligations of the User</b></p> <p>The User is entitled to administrative support and guidance to facilitate the acquisition of the necessary permits required by the Providing country.</p> <p>The User shall not use the Genetic Resource nor derivatives generated in the research for any commercial purposes, nor shall the User commercialize any Product derived from the Genetic Resource, unless with the written consent of the Provider.</p> <p>The User is obliged to take all reasonable precautions to prevent the Genetic Resource coming into the possession of any Unauthorized Person.</p> <p>The User is obliged to inform the</p>	<p><b>11. 利用者の権利と義務</b></p> <p>利用者は、提供国で要求される許可証の取得を促進するための行政支援や案内に対する権利を持っている。</p> <p>利用者は、提供者の書面による同意なくして、遺伝資源や研究によって生じたその派生物を営利目的に利用してはならないし、遺伝資源から得られたあらゆる製品を商用化してはならない。</p> <p>利用者は、遺伝資源を無許可の者の所有物になることを防止するあらゆる合理的な注意を払う義務がある。</p> <p>利用者は、潜在的な商用化の可能性のある予期せぬ研究成果について、公開前に、提供者に通知する義務がある。</p>

<p>Provider about any unforeseen research results that are of potential commercial interest, prior to any disclosure of this information to the public.</p>	
<p><b>Option 11.1</b></p> <p>If the research implies TK associated to the Genetic Resource, the User is obliged to respect any relevant international law and the national and regional regulations in the Provider's country, and has to proceed according to the instructions of the Provider. In any case the User is obliged to respect the customary law of the holders of the TK and has to apply ethical standards.</p>	<p><b>オプション 11.1</b></p> <p>研究が、遺伝資源に関連した TK を含む場合は、利用者は、関連する国際法と提供国の国や地域の規制を尊重する義務がある。提供者の指示に従って行動する必要がある。いかなる場合においても、利用者は TK の所有者の習慣法を尊重する義務があり、倫理基準を適用する必要がある。</p>
<p><b>Option 11.2</b></p> <p>Corresponding to national law the User will conclude an ancillary contract with the holders of TK and/or the private land owners of the genetic resources.</p> <p>The ancillary contract forms an integral part of this Agreement.</p>	<p><b>オプション 11.2</b></p> <p>国内法に従えば、利用者は、TK の所有者、および/または、遺伝資源のある民間の土地所有者と補助的な契約が締結される。補助的な契約は、本契約の必須の部分形成する。</p>
<p><b>12. Data Sharing</b></p> <p>The User agrees that the Provider has the right to access the following data resulting from the research:</p> <p>The User shall facilitate access to the above defined data for the Provider.</p>	<p><b>11. データの共有</b></p> <p>提供者が研究の結果生ずる次のデータにアクセスする権利があることに合意する。</p> <p>[データタイプのリスト]</p> <p>利用者は、上記の定義済みのデータへ</p>



<p>The Provider agrees that for using the data in his own research, he needs the consent of the User.</p>	<p>の提供者のアクセスを容易にしなければならない。提供者は、そのデータを自身の研究に使用するために、利用者の同意を必要とすることに同意する。</p>
<p><b>Option 12.1</b></p> <p>Given the cooperative approach to the research, the Provider and the User agree in a separate agreement on the use of the data, annexed to this Agreement [Annex XX] and forming its integral part.</p>	<p><b>オプション 12.1</b></p> <p>研究に対する協調的なアプローチを想定すると、提供者と利用者は、本契約の附属書として、本契約に不可欠な一部を形成する個別契約書によって、データの使用に関して同意する。</p>
<p><b>13. Reporting</b></p> <p>The User will deliver a written report in accordance with the Provider's instructions as to its structure, information included, etc, upon his/her request.</p>	<p><b>13. 報告</b></p> <p>利用者は、提供者の要求がある場合、構造、情報などについて提供者の指示に従って書面にて提供する。</p>
<p><b>Option 13.1</b></p> <p>The User shall submit an annual written report on the research accomplished.</p>	<p><b>オプション 13.1</b></p> <p>利用者は、研究成果について年次報告書を提出しなければならない。</p>
<p><b>Option 13.2</b></p> <p>Upon request of the Provider, the User submits a written report on the research accomplished.</p>	<p><b>オプション 13.2</b></p> <p>提供者の要求に応じ、利用者は研究成果の報告書を提出しなければならない。</p>
<p><b>Option 13.3</b></p> <p>Upon request of the Provider, the</p>	<p><b>オプション 13.3</b></p> <p>提供者の要求に応じ、利用者は、研究</p>

<p>User submits an annual written report on the research accomplished. The report shall include a list of Third Persons to whom the Genetic Material has been transferred.</p>	<p>成果について年次報告書を提出しなければならない。報告書は、遺伝資源を移転した第三者機関のリストも含まなければならない。</p>
<p><b>Option 13.4</b></p> <p>Since the Provider is a private citizen, upon his/her request, the report is translated into the local language by the User and adapted to a non-scientific audience.</p>	<p><b>オプション 13.4</b></p> <p>提供者が私人である場合、その要求に応じて、レポートは、利用者によって現地語に翻訳され、一般人に理解できるような形にしなければならない。</p>
<p><b>14. Intellectual Property Rights</b></p> <p>The User shall not claim any intellectual property rights over the Genetic Resource in the form received.</p> <p>If the User wants to obtain intellectual property rights on research results such act shall be treated as change in utilization and thus shall be regulated under Article 7 of the present Agreement.</p> <p>If the Provider wishes to obtain IPR on research results, such act shall be treated as change in utilization and shall be regulated under Article 7 of the present Agreement. In particular the ownership of the IPR and the distribution of the value derived from the IPR are to be negotiated.</p>	<p><b>14. 知的財産権</b></p> <p>受け取った遺伝資源の現物に対して、利用者は知的財産権を主張してはならない。</p> <p>利用者が研究成果について知的財産権を取得したい場合、そのような行為は、利用の変更とみなされ、本契約第7条の下で規制しなければならない。</p> <p>利用者が研究成果について知的財産権を取得したいと希望する場合、そのような行為は、利用の変更とみなされ、本契約第7条の下で規制しなければならない。特に、知的財産の所有権と知的財産から派生する価値の分配は交渉事項となる。</p>

<p><b>15. Publications</b></p> <p>The User has the right to publish the results of the research related to the Genetic Resource according to Article 6 of the present Agreement, and according to good scientific practice. The origin of the Genetic Resource has to be acknowledged.</p>	<p><b>15. 出版</b></p> <p>利用者は、本契約第 6 条に従い、遺伝資源に関連する研究の結果を、善良な科学的習慣に従って出版する権利を有する。遺伝資源の出所は承認される必要がある。</p>
<p><b>Option 15.1</b></p> <p>The User has the right to publish the results of the research related to the Genetic Resource according to good scientific practice. The origin of the Genetic Resource has to be acknowledged, as well as the sources of TK associated with the Genetic Resource.</p>	<p><b>オプション 15.1</b></p> <p>利用者は、遺伝資源に関連する研究の結果を、善良な科学的習慣に従って出版する権利を有する。遺伝資源の出所は承認される必要がある。また、遺伝資源に付随する伝統的知識のソースについても承認される必要がある。</p>
<p><b>Option 15.2</b></p> <p>The holder of TK associated to the Genetic Material has the right to request confidentiality of specific information [describe the information subject to confidentiality] such as for spiritual reasons; to prevent the depletion of the genetic resources; and/or to prevent unsafe/hazardous applications of the TK in the health sector.</p>	<p><b>オプション 15.2</b></p> <p>遺伝物質に付随する伝統的知識の保持者は、精神的な理由、遺伝資源の枯渇を防止するため、および/または、伝統的知識の健康分野での安全でない/危険な応用を防ぐためなどに対して、特定情報（機密性対象情報のリスト化）の機密性を要求する権利がある。</p>
<p><b>Option 15.3</b></p>	<p><b>オプション 15.3</b></p>

<p>If the User, in the course of the research, discovers any unforeseen commercial potential of the Genetic Material, he/she is obliged to share such information with the Provider prior to any publication of such information.</p> <p>If the Provider intends to pursue a potential commercialization, this is subject to negotiations between the Provider and the User according to Article 7. The Provider agrees not to hold up the User's research work unless concerns are concrete and justified in terms of well-defined proprietary interest.</p>	<p>研究の過程で、利用者が遺伝資源から予期せぬ商業的潜在価値のある発見をした場合、研究者は、そのような情報の公開前に、提供者とそのような情報を共有する義務がある。提供者が商業的潜在価値を追求する意思がある場合、本契約第7条に従って、提供者と利用者間で交渉する事柄となる。懸案事項が、具体的かつ明確に定義された所有権という形で現実的に正当化されない限り、利用者の研究活動を妨げないことに同意する。</p>
<p><b>Option 15.4</b></p> <p>If the User is prevented from publishing the results of the research due to the Provider's wish to obtain a patent over the research results, the Provider shall file the patent application within [XX] months. After the agreed period, if the Provider has failed to file a patent application, the User has the right to proceed with the publication of the research.</p>	<p><b>オプション 15.4</b></p> <p>研究結果に対して特許を取得したいという提供者の意志のため、利用者が研究成果を公開するのを禁止された場合、提供者は[XX]ヶ月以内に特許出願を提出しなければならない。提供者が特許出願提出をしなかった場合、合意された期間の後、利用者は研究成果の公開を続ける権利がある。</p>
<p><b>16. Handling of the Genetic Material after Termination of the Agreement</b></p> <p>Upon completion of the project,</p>	<p><b>16. 契約の満了後の遺伝物質の取り扱い</b></p> <p>プロジェクトの完了に伴い、遺伝物質は本契約第6条で合意した利用に従</p>

<p>Genetic Material will be stored or disposed of according to the utilization agreed under Article 6.</p>	<p>い、保存されるか廃棄される。</p>
<p><b>Option 16.1</b></p> <p>If the Genetic Material has been placed in storage, or in public collections, upon expiration of the Agreement or its termination, the Genetic Material may be available for use only under the same conditions as contained in this Agreement.</p>	<p><b>オプション 16.1</b></p> <p>遺伝物質が保存されているかあるいは公共保存場所にある場合、本契約の終了あるいは満了時に、遺伝物質は、本契約に含まれていると同じ条件下でのみ利用できる可能性がある。</p>
<p><b>17. Duration and Termination of the Agreement</b></p> <p>The present Agreement shall end on [insert the date] and may be renewed upon the mutual agreement of the Parties.</p>	<p><b>17. 契約の満了期間</b></p> <p>本契約は（期間挿入）により終了するか、双方の合意により更新される。</p>
<p><b>Option 17.1</b></p> <p>The present Agreement shall be deemed to be in force until the Genetic Material is returned to the satisfaction of the Provider upon completion of the Project. Regarding the Genetic Material related information, the present Agreement shall be subject to any associated rights, such as copyright or trade secrets.</p>	<p><b>オプション 17.1</b></p> <p>プロジェクトの完了に伴い、遺伝物質が提供者の satisfaction に変換されるまで、本契約は有効とみなされるべきである。遺伝物質に関連する情報に関しては、著作権、企業秘密などの関連する権利の対象にしなければならない。</p>
<p><b>Option 17.2</b></p>	<p><b>オプション 17.2</b></p>

<p>When a Party to the present Agreement wants to terminate the Agreement prior to the completion of the Project, the Party shall give written notice [XX] months in advance. The present Agreement may be terminated at any time by mutual agreement of the Parties. The present Agreement may be terminated immediately, in case of its breach.</p>	<p>プロジェクトの完了の前に、本契約の片方の当事者が、本契約を終了したいと希望する時、その当事者は、[XX] 箇月前に書面による通知をしなければならない。本契約は、当該当事者の合意によって、いつでも終了可能である。本契約に違反がある場合、本契約は直ちに終了される可能性がある。</p>
<p><b>18. Settlement of Disputes</b></p> <p>The Parties agree to make attempts in good faith to negotiate the resolution of any disputes that may arise under this Agreement. If the Parties are not able to resolve a dispute within a period of [XX] months, such dispute shall be finally settled by an arbiter to be mutually agreed between the Parties.</p>	<p><b>18. 紛争解決</b></p> <p>当該当事者は、本契約下で生じるすべての紛争の解決に誠意をもって交渉しようとすることに合意する。当該当事者が、[XX] ヶ月の期間内に紛争を解決できない場合は、当事者間で合意する調停者によって最終解決されるものとする。</p>
<p><b>Option 18.1</b></p> <p>If the Parties are not able to resolve any dispute within a period of [XX] months, such dispute shall be resolved before the [XXXX] Court law as the only competent body for resolving disputes arising under this Agreement and in accordance with [XXX]. [Insert applicable Law; Jurisdiction]</p>	<p><b>オプション 18.1</b></p> <p>当該当事者が、[XX] ヶ月の期間内にすべての紛争を解決できない場合、そのような紛争は、本契約と[XXX]に従って、発生した紛争を解決する唯一の審査権を有する機関として [XXXX] 裁判所法のもとで解決されなければならない。 [適用される関連法、裁判権]</p>
<p><b>19. Other Provisions</b></p>	<p><b>19. その他の条項</b></p>



英国王立植物園Kew標準共同研究覚書

<p><b>Memorandum of Collaboration between The Board of Trustees of the Royal Botanic Gardens, Kew and [Insert name of counterparty]</b></p>	<p>キュー王立植物園理事会と、〈カウンターパートの名称〉との間の、共同研究の覚書</p>
<p>A MEMORANDUM OF COLLABORATION (“MoC”) made on this the [insert date] day of [insert month] 200[ ] between the Board of Trustees of the Royal Botanic Gardens, Kew (“<b>RBG Kew</b>”), whose principal place of business is at Kew, Richmond, Surrey TW9 3AB and [insert name of counterparty] (“[insert brief name of counterparty]”), whose principal place of business is at [insert place of business].</p>	<p>20__年__月__日、主たる事業所が Kew, Richmond, Surrey TW9 3AB にあるキュー王立植物園理事会（以下、「<b>RBG Kew</b>」とする）と、主たる事業所が〈住所を記入〉にある〈カウンターパートの名称〉〈カウンターパートの略称〉との間での、共同研究の覚書（以下、「<b>MoC</b>」とする）を締結する。</p>
<p><b>BACKGROUND</b></p> <p>A. RBG Kew is a botanical garden incorporated in the United Kingdom by the National Heritage Act 1983 and an exempt charity whose mission is to inspire and deliver science-based plant conservation worldwide, enhancing the quality of life. Kew is supported by the United Kingdom Department for Environment, Food and Rural Affairs (“<b>Defra</b>”), which is ultimately responsible to Parliament for Kew’s key aims and activities.</p>	<p><b>背景</b></p> <p>A. <b>RBG Kew</b>は、英国において国家遺産法1983にもとづき法人化された植物園であり、価額に基づいて世界中の植物の保全を促した提供し、生活の質を向上させることをミッションとした、イングランド及びウェールズ慈善事業委員会への登録及び管理を免除された慈善団体（=exempt charity）である。<b>Kew</b>は環境食糧省（以下、「<b>Defra</b>」とする）の支援を受けており、最終的には<b>Defra</b>は<b>Kew</b>の主目的や活動について、議院に対し責任を負っている。</p>
<p>B. In pursuit of its not-for-profit mission, Kew works together with international partners to:</p>	<p>B. 非営利目的のミッションを追求すべく、<b>Kew</b>は海外のパートナーと以下のような活動を行っている：</p>



<ul style="list-style-type: none"> <li>· Collect and curate plant material, including seeds, herbarium specimens and tissue samples for DNA extracts;</li> <li>· Carry out scientific research projects to better evaluate and conserve plant biodiversity, for example, taxonomic verification of herbarium plant material and seed studies to determine the viability of seeds and to enable their long-term conservation;</li> <li>· Exchange plant material with other research institutes for further scientific study world-wide; and</li> <li>· Establish a leading worldwide seed conservation network, capable of safeguarding targeted wild plant species and contributing to global conservation targets.</li> </ul>	<ul style="list-style-type: none"> <li>□ 種子、ハーバリウムの標本、DNA抽出のための組織サンプルを含む植物資料を集め監督する</li> <li>□ 例えばハーバリウムの標本の分類学的な検証や、種子の生存能力を決定し、長期的な保存を可能にするための、種子についての研究など植物の生物多様性をよりよく評価し保存するための科学研究プロジェクトを遂行する</li> <li>□ 世界規模でさらなる科学研究を進めるために、他の研究機関と植物資料を交換する</li> <li>□ 世界規模での種子保存ネットワークを設立し、標的となる野生植物種の保護や、世界中の保護の対象への貢献を可能にする。</li> </ul>
<p>C. [Insert description and mission of counterparty].</p>	<p>C. 〈カウンターパートについての記述及びミッションを記載〉</p>
<p><b>D. <i>Either:</i></b>  RBG Kew and [insert name of counterparty] have worked together over [many/some] years on mutually beneficial projects [focused on the collection, study and conservation of the flora of [insert country of counterparty]] and wish formally to recognise this [long-standing] relationship, and to promote its continuance for many years into the future.</p> <p><b><i>Or:</i></b>  RBG Kew and [insert name of counterparty] wish to work together on mutually beneficial projects focused on the collection, study and conservation of</p>	<p><b>D.</b>  RBG Kew及び〈カウンターパート〉は、〈カウンターパートのある国〉の植物相のコレクション、研究、保存に関する互恵的なプロジェクトにおいて、[長年/数年]の間協力してきており、この[長期的な]関係を公式に認め、将来的な継続を促進することを望んでいる。</p> <p><b>あるいは</b>  RBG Kew及び〈カウンターパート〉は、〈カウンターパートのある国〉の植物相のコレクション、研究、保存に関する互恵的なプロジェクトにおいて、協力することを望んでいる。</p>

the flora of [insert country of counterparty].	
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<p>E. The parties to this MoC are committed to implementing the letter and the spirit of the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (“<b>CITES</b>”), the 1992 Convention on Biological Diversity (“<b>CBD</b>”) and relevant national and regional laws and regulations concerning biodiversity including laws relating to access to plant genetic resources, associated benefit sharing and traditional knowledge.</p>	<p>E. 本MoCの当事者は、絶滅のおそれのある野生動植物の種の国際取引に関する条約（以下、「<b>CITES</b>」とする）及び生物多様性条約（以下、「<b>CBD</b>」とする）、そして植物遺伝資源へのアクセス及び利益配分や伝統的知識に関する法を含む、生物多様性についての国及び地域の関連法規の精神と条文を執行するよう尽力する。</p>
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<p>[F The parties recognise the potential benefits of co-operation with other organisations dedicated to the understanding, conservation and sustainable use of wild plant diversity and hereby express their interest in assisting with development of an international seed conservation network, through which technology can be transferred and standards enhanced.]</p> <p>[<i>Note: Article F should be reviewed for appropriateness</i>]</p>	<p>[F. 当事者らは、野生植物の多様性への理解、及びその保全と持続的利用に専念する他の組織との連携の潜在的利益を認識し、これによって、技術の移転及び水準の向上をもたらす国際的な種子保存ネットワークの開発支援への関心を表明する。]</p> <p>[注： Fは、妥当性を検討する必要あり]</p>
<p><b>ARTICLE 1</b> <b>Institutional Co-ordinators</b></p> <p>1.1 For RBG Kew: [insert name of lead scientist on partnership].</p> <p>1.2 For [insert counterparty name]: [insert name of lead scientist on partnership].</p> <p>1.3 The Institutional Co-ordinators shall be responsible for overseeing and progressing the activities of their respective institutions pursuant to this MoC.</p>	<p><b>第1条</b> <b>機関のコーディネーター</b></p> <p>1.1 RBG Kew：〈当該共同研究における主任科学者の氏名を記載〉</p> <p>1.2 〈カウンターパート〉：〈当該共同研究における主任科学者の氏名を記載〉</p> <p>1.3 機関のコーディネーターは、本MoCに準じて、各機関の監督及び活動の進行について責任を負う。</p>
<p><b>ARTICLE 2</b> <b>Areas of Co-operation</b></p> <p>2.1 RBG Kew and [insert name of counterparty] wish to work together to collect, study and conserve plant material such as seeds, herbarium specimens [and tissue samples] for science and to create and exchange associated data and images. All co-operation will be implemented in</p>	<p><b>第2条</b> <b>協力の範囲</b></p> <p>2.1 RBG Kew及び〈カウンターパート〉は、種子、ハーバリウムの標本[及び組織サンプル]などの植物資料を科学のために採取、研究、保存し、またデータ及び画像を作成、交換するために、共同で取り組むことを望む。共同の活動はすべて、CITES、CBD、そして植物遺伝資源へのアク</p>

<p>accordance with CITES, the CBD and relevant national and regional laws and regulations concerning biodiversity including laws relating to access to plant genetic resources, associated benefit sharing and traditional knowledge.</p>	<p>セス及び利益配分や伝統的知識に関する法を含む、生物多様性についての国及び地域の関連法規に従う。</p>
<p>2.2 Areas of co-operation may include, but will not be limited to:</p> <p>(a) [Continued collaboration and support in specific joint projects already underway, such as [insert names of any such projects];]</p> <p>(b) The conducting of joint fieldwork expeditions, to be carried out in accordance with all applicable access laws and regulations and in accordance with all applicable permits, prior informed consents and/or licences and in an ecologically sustainable manner;</p> <p>(c) The transfer of duplicate plant material (the “<b>Material</b>”) and associated data and images (respectively, the “<b>Transferred Data</b>” and the “<b>Transferred Images</b>”) by [insert name of counterparty] to RBG Kew for accession into the collections at RBG Kew to be used as set out in Article 3 below;</p> <p>(d) Capacity-building in the areas of [insert relevant areas eg seed-bank design] to ensure greater long-term conservation of plant genetic resources in [insert name of counterparty country];</p> <p>(e) Attendance by appropriate staff</p>	<p>2.2 協力の範囲は以下を含むが、これらに限定されない：</p> <p>(a) [〈プロジェクト名を記載〉など、既に進行中の特定の共同プロジェクトにおける、協力及び支援の継続]</p> <p>(b) 適用可能な許可、事前を取得する合意（PIC）及び／あるいはライセンスに従い、生態学的に持続可能な方法で、適用されるすべてのアクセス法規を遵守した共同での実地調査の実行</p> <p>(c) 〈カウンターパート〉からRBG Kewに対し、複製された植物資料（以下、「資料」とする）及び関連するデータや画像（以下、それぞれ「移転データ」及び「移転画像」とする）を、下記第3条に定める利用のために移転し、RBG Kewのコレクションに登録。</p> <p>(d) 〈カウンターパートのある国〉における、植物遺伝資源のより良い長期的な保全を確実にするための、〈関連地域名を記載。例えばシードバンクの設計〉地域における能力構築（キャパシティ・ビルディング）。</p> <p>(e) RBG Kewの運営する関連する研修コースへの、〈カウンターパート〉の適切なスタッフによる出席</p> <p>(f) 〈カウンターパート〉での研修取</p>

<p>members of [insert name of counterparty] at relevant training courses run by RBG Kew;</p> <p>(f) Support by RBG Kew to training initiatives at [insert name of counterparty];</p> <p>(g) Collaboration on <i>ex situ</i> and <i>in situ</i> conservation in [insert name of counterparty country], including species and habitat conservation assessments;</p> <p>(h) The exchange of relevant institutional literature, such as the Kew Bulletin and [insert name of any counterparty literature];</p> <p>(i) The generation and dissemination of appropriate scientific information to encourage and facilitate conservation by, for instance, joint publications in peer-reviewed journals; and</p> <p>(j) The preparation and submission of applications to national and/or international bodies for funding to enable further collaboration between RBG Kew and [insert counterparty name].</p> <p>[Note: Articles for Millennium Seed Bank partnerships:]</p> <p>[j] The sharing of selected data relating to seed collections held for long term conservation by RBG Kew and [insert counterparty name]. Such data will be accessible through an appropriate online data portal managed by RBG Kew.</p> <p>(k) Periodic joint assessment of the</p>	<p>り組みに際しての、RBG Kewによる支援</p> <p>(g) 種及び生息地保全の評価を含む、〈カウンターパートのある国〉における生息域外及び生息域内での保全についての共同研究</p> <p>(h) Kew Bulletinや、〈カウンターパートの所持する文献名を記載〉など、機関の関連文献の交換</p> <p>(i) 保全を奨励し促進するための、例えば査読付き専門誌への共同出版などによる、適切な科学的情報を生成及び普及</p> <p>(j) RBG Kewと〈カウンターパート〉とのさらなる共同研究を可能にするための、国内及び／あるいは国際資金提供団体への申請の準備</p> <p>[注： ミレニアム・シード・バンク・パートナーシップ (MSBP) の記事]</p> <p>[j] 種子のコレクションに関連する選択データの共有は、RBG Kew及び〈カウンターパート〉が長期の保存のために適用される。これらのデータは、RBG Kewの管理する適切なポータルサイトから、オンラインでアクセス可能となる。</p> <p>(k) 代表的な標本及び関連するハーバリウムの資料について、その保存、同定、生存能力、発芽の状態を定期的に共同で行う評価は、〈カウンターパート〉での長期の保存のために適用される。]</p> <p>[注： ミレニアム・シード・バンク・パートナーシップの記事]</p>
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<p>storage, identification, viability and germination status of a representative sample of seed collections and associated herbarium material held for long term conservation by [insert counterparty name].]</p> <p><i>[Note: Articles for Millennium Seed Bank partnerships:]</i></p>	
<p>2.3 Seed collections resulting from the above areas of cooperation will be acknowledged by RBG Kew and [insert counterparty name] as MSB Partnership collections subject to meeting the following criteria:</p> <p>(a) to have been collected in accordance with accepted international standards including adherence to MSBP protocols on identification, sampling, handling and data collection and</p> <p>(b) to be stored and monitored to international standards in a minimum of two recognised seedbanks and</p> <p>(c) to be available for research, education and conservation purposes, subject to quantity and quality criteria, and subject to national and international laws and regulations.</p>	<p>2.3 上記の地域の協力によって得られた種子コレクションは、以下の基準に従い、MSBパートナーシップのコレクションとして、RBG Kew及び〈カウンターパートによって〉認識される</p> <p>(a) 同定、抽出、取扱い、データ収集に関してMSBPの手続きを遵守していることを含め、国際的に認められた基準に従って採取されている</p> <p>(b) 国際的基準によって、最低2つの広く認められた種子バンクで保管及び監視されている</p> <p>(c) 研究、教育、保存目的での入手が可能で、量及び質の基準に合致し、国内外の法や規則に従っている</p>
<p>2.4 The technical detail of the above-mentioned areas of co-operation will be developed and reviewed on a regular basis by RBG Kew and [insert counterparty name] in accordance with available funds.</p>	<p>2.4 上述の地域での協力における技術的な詳細は、入手可能な資金に応じて、RBG Kew及び〈カウンターパート〉により定期的に発展及び検証させるものとする。</p>
<p><b>ARTICLE 3</b>  <b>Use of the Material by RBG Kew</b>  3.1 The Material [and the Transferred</p>	<p><b>第3条</b>  <b>RBG Kewによる、資料の利用</b>  3.1 資料[及び移転データ、移転画</p>

<p>Data and the Transferred Images] shall be accessioned into the Kew collections at Wakehurst Place, Ardingly, West Sussex, or at Kew, Richmond Surrey, as appropriate.</p>	<p>像]は、必要に応じて、Wakehurst Place, Ardingly, West Sussex, or at Kew, Richmond SurreyにあるKewのコレクションに登録される。</p>
<p>3.2 [Insert name of counterparty] confirms that RBG Kew shall be permitted to use the Material and the Transferred Data and the Transferred Images for scientific research by RBG Kew staff and by authorised visitors to Kew, and for the purposes of education and long-term conservation. The Material and the Transferred Data may be digitally imaged and, together with the Transferred Images, may be published in freely available botanical databases available on the internet and/or used by RBG Kew for publicity and fundraising purposes. Seed may be grown and the resulting plants used for the purposes of public display and education or scientific research at RBG Kew.</p>	<p>3.2 〈カウンターパート〉は、RBG Kewが、資料、移転データ及び移転画像を、科学研究目的で、また教育や長期の保全目的でRBG Kewの職員及び許可されたKewの訪問者が、利用することを認めることを確認する。資料及び移転データはデジタル画像処理され、移転画像とともに、インターネットでアクセス可能な無料の植物データベース内で公表することができ、また／あるいはRBG Kewにより、広報及び資金集め目的で利用することができる。種子は育成することができ、その結果生じた植物は、RBG Kewにおいて、公開や教育、あるいは科学研究目的で利用することができる。</p>



<p>3.3 Scientific research carried out on the Material may include, but will not be limited to:</p> <p>(a) Seed studies, such as tests required to better understand seed storage requirements including post harvest seed handling, germination tests and dormancy studies, moisture relation tests, seed morphology studies and diagnostic characterisation;</p> <p>(b) Herbarium studies, such as the comparative observation, characterisation, analysis, databasing and imaging of the herbarium specimens to better understand their identification and classification, including the carrying out of sampling for pollen, DNA and anatomical preparations;</p> <p>(c) Horticultural studies, such as cultivation of plant material to better understand how to grow and reproduce the plant, including the use of micropropagation techniques where required;</p> <p>(d) Genetic studies, such as DNA extraction and banking, PCR amplification, DNA sequencing and fingerprinting and DNA barcoding from tissue samples, for use to infer phylogenetic relationships or to study and help conserve the diversity of genes and genomes at the population level.</p>	<p>3.3 資料について行われる科学研究は以下を含むが、これらに限定されない：</p> <p>(a) 収穫後の種子の取扱いを含め、種子の保存に必要なことについてより理解するために必要な実験、発芽試験、休眠についての研究、湿度関連試験、種子の形態学、診断特性といった、種子についての研究</p> <p>(b) 花粉やDNA、解剖標本のサンプリングも含め、ハーバリウム標本の特定と分類をより理解するための比較観察、特性分析、データベース化、画像化などといった、ハーバリウムについての研究</p> <p>(c) 必要に応じて微細繁殖技術を用いることも含め、どのように植物を育成し繁殖させるかをより理解するための植物資料の栽培といった、園芸についての研究</p> <p>(d) DNAの抽出やDNAバンクの作成、PCR増殖、DNAの配列決定やフィンガープリンティング、組織標本からのDNAバーコーディングなど、系統発生上の関係を推測するため、あるいは集団レベルでの遺伝子及びゲノム多様性の保全を助けるため、遺伝子についての研究</p>
<p>3.4 RBG Kew shall not, without the prior written consent of [insert counterparty name], sell, distribute,</p>	<p>3.4 RBG Kewは、〈カウンターパート〉の書面による同意なくして、資料及び／あるいは移転データと移転</p>

<p>transfer or use the Material and/or the Transferred Data and the Transferred Images for profit or for any other commercial application.</p>	<p>画像を、営利目的その他商用のために移転あるいは利用してはならない。</p>
<p>3.5 RBG Kew may loan or supply the Material or any derivatives from the Material and the Transferred Data and the Transferred Images to other institutions for the purposes of scientific research or education, provided that such loan or supply is on terms which prohibit commercialisation. {NB: in the case of MSB agreements consider whether herbarium voucher specimens need to be dealt with separately with less restrictive loaning conditions etc}</p>	<p>3.5 RBG Kewは、資料そのもの、あるいは資料、移転データ及び移転画像から生じた派生物を、他の機関に対して、商用化しないという条件のもとであれば、科学研究あるいは教育目的で、貸し出しあるいは提供することができる。 [注： MSBの契約で、ハーバリウムの証拠標本がより制限的でない貸し出し条件等で別に取り扱うべきか考慮する事例]</p>
<p><b>ARTICLE 4</b> <b>Permissions to collect, transfer, study and conserve the Material; Notification of Transfer</b> 4.1 [Insert name of counterparty] shall work with the appropriate [insert name of counterparty country] authorities [and relevant stakeholders], and RBG Kew shall work with the appropriate British authorities, to facilitate the acquisition of the necessary authorisation(s) to enable the lawful collection and transfer of the Material to RBG Kew. [Note: this article must always be reviewed for appropriateness.]</p>	<p><b>第4条</b> 資料の採取、移転、研究および保存についての許可； 移転通知書 4.1 必要な承認の獲得を促進し、資料の合法的なコレクション及びRBG Kewへの移転を可能にするため、〈カウンターパート〉は、適切な〈カウンターパートのある国〉の権力者[及び関連する以外関係者]と協力し、またRBG Kewは適切な英国の権力者と協力する。[注： 本条は、常に妥当性を検討しなければならない]</p>
<p>4.2 Each party shall, on request, provide the other with reasonable</p>	<p>4.2 各当事者は、依頼に応じて、もう一方当事者に対し、〈カウンター</p>

<p>assistance in obtaining the necessary authorisation(s) to enable the lawful attendance of appropriate staff personnel at relevant courses, workshops and research projects in [insert counterparty country] and in the United Kingdom.</p>	<p>パートのある国) 及び英国での関連するコースやワークショップ、研究プロジェクトへ、適切な人員が合法的に参加できるよう、必要な承認を得るための合理的な援助を行うものとする。</p>
<p>4.3 All plant material transferred by [insert name of counterparty] to RBG Kew shall be listed in a Notification of Transfer, a proforma copy of which is attached at Annex 1. All plant material transferred by [insert name of counterparty] to RBG Kew which is listed in a Notification of Transfer shall be transferred pursuant to the terms of this MoC.</p>	<p>4.3 〈カウンターパート〉からRBG Kewへ移転された植物資料は、別添1にその形式のコピーが添付されている「移転通知書」に掲載される。〈カウンターパートのある国〉からRBG Kewへ移転され、「移転通知書」に掲載された植物資料はすべて、本MoCの条項に従って移転されなければならない。</p>
<p>4.4 The signature of the authorised representative of [insert name of counterparty] on a Notification of Transfer shall confirm that the plant material has been collected and is being transferred into the collections at RBG Kew in accordance with all applicable laws and regulations, permits, consents and/or licences.</p>	<p>4.4 〈カウンターパート〉の権威ある代表者による移転通知書への署名は、当該植物資料があらゆる適用法、規則、許可、同意、及び/あるいはライセンスに従って収集され、RBG Kewのコレクションに移転したことを確認する。</p>
<p><b>ARTICLE 5</b> <b>Benefit Sharing</b> 5.1 RBG Kew and [insert name of counterparty] shall work together to share fairly and equitably the benefits that may arise from the collection, study and conservation of the Material and the Transferred Data and the Transferred Images.</p>	<p><b>第5条</b> <b>利益配分</b> 5.1 RBG Kew及び〈カウンターパート〉は、資料や移転データ、移転画像のコレクション、研究、及び保全から生じた利益を公正で衡平に配分するために協力する。  [互いに共有されるべき利益とは、例えば以下を含む:]</p>

<p>[Benefits to be so mutually shared may include, for instance:</p> <ul style="list-style-type: none"> <li>· Informing one another of the results of relevant scientific studies;</li> <li>· Sharing specimen data and images, where appropriate;</li> <li>· Providing one another with copies of relevant subsequent publications;</li> <li>· Informing one another of relevant opportunities for formal or informal training and/or study by appropriate staff personnel at [insert name of counterparty] or at RBG Kew; and</li> <li>· Acknowledging [insert name of counterparty] and the origin of the Material in publications arising out of this collaboration.]</li> </ul>	<ul style="list-style-type: none"> <li>□関連する科学研究の結果について、互いに情報提供する、</li> <li>□必要に応じて、標本のデータや画像を共有する、</li> <li>□関連する後続の出版物のコピーを互いに提供する、</li> <li>□〈カウンターパート〉あるいはRBG Kewにおける、適切な人員による公式・非公式の研修及び／あるいは研究の機会について、互いに情報提供する、</li> <li>□共同研究にもとづく出版物において、〈カウンターパート〉及び資料の起源について謝辞を述べる。]</li> </ul>
<p>5.2 The parties also agree to consider whether it is appropriate to effect the sharing of any benefits arising from the collection, study and conservation of the Material and the Transferred Data and the Transferred Images with other relevant stakeholders.</p> <p><i>[Note: Articles for Millennium Seed Bank partnerships:]</i></p>	<p>5.2 当事者らは、資料、移転データ、及び移転画像のコレクションや研究、保全から生じた利益を、関連する他の利害関係者にも配分することが適切か否か、検討することについて合意する。</p> <p><i>[注: ミレニアム・シード・バンク・パートナーシップについての記事]</i></p>
<p><b>ARTICLE 6</b></p> <p><b>Repatriation of seed samples</b></p> <p>6.1 Subject to retaining sufficient seed stock at RBG Kew for conservation, in the event of the loss or destruction of the seed collections stored at [insert counterparty name] or the extinction of a species in [insert counterparty country], upon request by [insert counterparty name], RBG Kew will</p>	<p><b>第6条</b></p> <p><b>種子サンプルの本国送還</b></p> <p>6.1 RBG Kewにおいて、保存のために十分な種子の在庫を保持する条件で、〈カウンターパート〉で保管された種子コレクションの逸失や破壊があったとき、あるいは〈カウンターパートのある国〉で種が絶滅したときには、RBG Kewは〈カウンターパート〉の依頼に応じて、〈カウ</p>

supply [insert counterparty name] with samples from seed transferred by [insert counterparty name] to RBG Kew under this MoC.	ターパート) に対し、〈カウンターパート) から移転された種子標本を、本MoCに基づき提供する。
6.2 [Insert counterparty name] shall use its best efforts to return to RBG Kew within a reasonable time the proportion of the seed made available by RBG Kew under Article 6.1 above.]	6.2 〈カウンターパート) は、上記6.1に基づきRBG Kewから入手した種子と同比率の物を、RBG Kewに対して合理的な期間内に返還できるよう最善を尽くす。
<b>ARTICLE 7</b> <b>Duration, Renewal and Amendment</b> 7.1 This MoC will come into force on the date of the final signature. It will be valid for [insert number of years in text and number] years from that date.	<b>第7条</b> <b>期間、更新、及び修正</b> 7.1 本MoCは、最終的な署名がなされた日に発効する。また、当該期日から、〔数字とフリガナを記入〕年間有効とする。
7.2 This MoC can be renewed for further periods of [insert number of years in text and number] years through mutual agreement expressed in writing.	7.2 本MoCは、書面によるお互いの合意によって、〔数字とフリガナを記入〕年間の更新が可能である。
7.3 This MoC can be amended at any time through mutual agreement expressed in writing. Such amendments, once approved by the parties, will become part of this MoC.	7.3 本MoCは、書面によるお互いの合意によって、いつでも修正できる。このような修正は、両当事者に承認されると、MoCの一部となる。
<b>ARTICLE 8</b> <b>Termination</b> 8.1 Either party may terminate this MoC by giving the other party [insert number] months' notice in writing.	<b>第8条</b> <b>終了</b> 8.1 どちらの当事者も、相手方に〔数字を記入〕ヶ月前に書面で通知することで、本MoCを終了させることができる。
8.2 A party (the " <b>Non-defaulting Party</b> ") may by notice to the other party (the " <b>Defaulting Party</b> ") terminate this MoC with immediate	8.2 本MoCの条項について修復不可能な重大な違反があった場合、あるいは修復可能であるが、違反のない当事者が、違反をした当事者に対し

<p>effect if the Defaulting Party is in material breach of any provision of this MoC which is not remediable or, if remediable, is not remedied with a period of thirty (30) days after the Non-Defaulting Party has given notice to the Defaulting Party requiring such breach to be remedied.</p>	<p>て当該違反を修復するよう通知した後、30日以内に修復が行われない場合、違反のない当事者は、違反をした当事者への通知により、本MoCを即座に終了することができる。</p>
<p>8.3 Articles 3, 5 and 6 shall survive termination or expiry of this MoC unless mutually agreed to the contrary, such mutual agreement being expressed in writing.</p>	<p>8.3 第3、5、6条は本MoC終了後も有効に存続する。あるいは、反対の内容で書面により明示的に合意した場合は、MoCの終了と共に失効する。</p>
<p><b>ARTICLE 9</b> <b>Dispute Resolution, Jurisdiction and Choice of Law</b> 9.1 In the event of any dispute between the parties arising in connection with this MoC, the Director of RBG Kew and [insert name of senior official at counterparty] will communicate using their best efforts to resolve the dispute or disagreement.</p>	<p><b>第9条</b> <b>紛争解決、裁判管轄、法律の選択</b> 9.1 両当事者間で本MoCに関する紛争が生じた場合、RBG Kewの所長及び〈カウンターパートの幹部の氏名を記入〉は、当該紛争や論争を解決すべく、最善を尽くして意思の疎通を図る。</p>
<p>9.2 If the dispute cannot be so resolved, the parties will refer it to an independent mutually agreed expert or, in the absence of any agreement between the parties, [insert name of an appropriate figure], and ask that expert to recommend a resolution of the dispute.</p>	<p>9.2 それでも紛争が解決されないときには、両当事者は、当該紛争に関し、お互いに合意した専門家、あるいは合意が得られないときには〈適切な人物名を記入〉に依頼し、紛争解決についての勧告を求めることができる。</p>
<p>9.3 Neither party may commence any proceedings in any court of law in relation to any dispute arising in connection with this MoC until it has attempted to settle the dispute by use of</p>	<p>9.3 本条（第9条）に定める手段によって紛争を解決しようと試み、両当事者に満足の行く結果を生み出せなかった時まで、いずれの当事者も本MoCに関して生じた紛争について、</p>

<p>the procedure set out in this Article 9 and that procedure has failed to produce an outcome satisfactory to both parties, provided that nothing in this clause shall prevent either party seeking a preliminary injunction or other judicial relief at any time if in its judgment such action is necessary to prevent irreparable damage.</p>	<p>いかなる訴訟法に基づく手続きも開始してはならない。ただし、回復困難な損害を避けるために必要であれば、本条は、いずれの当事者がいつでも暫定的な差止命令あるいは他の裁判上の救済を求めることは妨げない。</p>
<p>9.4 This MoC shall be governed by English law and subject to the exclusive jurisdiction of the English courts.</p>	<p>9.4 本MoCは英国法に準拠し、英国の裁判所が専属管轄を有する。</p>
<p><b>ARTICLE 10</b> <b>General</b> 10.1 This MoC in no way restricts either party from any involvement in similar activities with other public and private organisations and individuals.</p>	<p><b>第10条</b> <b>総則</b> 10.1 本MoCは、当事者らが他の公共・民間や個人と共に類似の活動に関与することを制限するものではない。</p>
<p>10.2 [Nothing in this MoC shall be construed as placing a financial commitment upon either party.]</p>	<p>10.2 [本MoCの内容はいずれも、当事者らに金銭的な貢献を求めるとは解されない。]</p>
<p>10.3 Neither party may use any brand name, logo, trade mark or other similar mark of the other party without the prior written consent of that other party.</p>	<p>10.3 いずれも当事者も、相手方との事前の書面の合意なしに、相手方のブランド名、ロゴ、登録商標あるいは他の商標を用いてはならない。</p>
<p>10.4 Subject to Article 10.5 and save that RBG Kew shall have the right to acknowledge [insert name of counterparty] and the origin of the Material in publications arising out of this collaboration in accordance with Article 5.1, neither party may make any press release or other public statement relating to this MoC or the relationship</p>	<p>10.4 RBG Kewが5.1に基づいて、本共同研究から生じた出版物において、〈カウンターパート〉及び資料の起源について謝辞を述べる権利を有することと、10.5に基づく場合とを除き、相手方との事前の書面の合意なしに、本MoCあるいはMoCに基づいて築かれた関係について、プレスリリースや公式声明を発表しては</p>

<p>established under this MoC without the prior written consent of the other party.</p>	<p>ならない。</p>
<p>10.5 [Insert counterparty name] acknowledges that RBG Kew may be subject to obligations relating to freedom of information, for example, under the Freedom of Information Act 2000. RBG Kew will make reasonable efforts to inform [insert counterparty name] of any proposed disclosure under freedom of information obligations in relation to this MoC or the relationship established under this MoC but shall not be bound to obtain the prior consent of [insert counterparty name] to any such disclosure.</p>	<p>10.5 〈カウンターパート〉は、RBG Kewが、例えば情報公開法2000などにより、情報の自由に関する義務に従わねばならない可能性について認識する。RBG Kewは、情報の自由に関する義務の下で提示された、本MoCあるいはMoCに基づいて築かれた関係についての情報公開に関し、〈カウンターパート〉に通知するよう合理的な努力を行うが、このような情報公開について、〈カウンターパート〉の事前の同意を得る必要はない。</p>
<p>10.6 [Insert counterparty name] agrees to keep confidential, and use only for the purposes of carrying out its obligations under this MoC, any documents, information or other data relating to the business or affairs of RBG Kew.</p>	<p>10.6 〈カウンターパート〉は、RBG Kewの業務に関するあらゆる文書、情報、その他のデータについて守秘義務を負い、それらを本MoCに基づく義務を履行する目的においてのみ利用することに合意する。</p>
<p>10.7 Each party acknowledges that the other party may be prevented, either temporarily or permanently, from carrying out projects under this MoC by reason of force majeure.</p>	<p>10.7 各当事者は、相手方が、本MoCに基づくプロジェクトの遂行を、不可抗力によって一時的あるいは恒久的に阻害されうることを認識する。</p>
<p>10.8 Any notice or other document to be served under this MoC must be delivered by hand or sent by registered mail or international courier service to the address below or to such other address as has been notified to the sending party. For RBG Kew: Head of Legal and</p>	<p>10.8 本MoCに基づいて送達される通知あるいは他の文書はすべて、手渡し、書留郵便、国際宅配便によって、以下の住所か、あるいは送付者に知らされていた住所宛に送らなければならない。 RBG Kew宛 : Head of Legal and Governance, the Royal Botanic</p>



<p>Governance, the Royal Botanic Gardens, Kew, Richmond, Surrey TW9 3AB, United Kingdom. For [insert counterparty name]: [Insert post and address].</p>	<p>Gardens, Kew, Richmond, Surrey TW9 3AB, United Kingdom. 〈カウンターパート〉宛： [住所を記入]</p>
<p>10.9 All notices or documents shall be deemed to have been served at the date and time of delivery of the said notices or documents to the recipient party.</p>	<p>10.9 すべての通知あるいは文書は、当該通知あるいは文書が受領者に届いた日時に送達されたものとみなす。</p>
<p>10.10 Nothing in this MoC is intended to, or shall be deemed to, constitute a partnership or joint venture of any kind between the parties, nor constitute either party the agent of the other for any purpose. Neither party shall have authority to act as agent for, or to bind, the other party in any way.</p>	<p>10.10 本MoCの内容はいずれも、両当事者間でパートナーシップあるいはあらゆる類の合弁事業を形成したり、一方が何らかの目的で他方の代理人となると見なしたり意図したりするものではない。いずれの当事者も、もう一方の代理人としてふるまったり、何らかの義務を負わせたりする権限はない。</p>
<p>10.11 This MoC is personal to the parties and neither party may assign or charge any of its rights under or the benefit of all or part of this MoC or transfer, delegate or sub-contract any of its duties or obligations under this MoC.</p>	<p>10.11 本MoCは各当事者にとって私的なものであり、いずれの当事者も、MoCの一部又は全部の利益や権利を譲渡あるいは課金したり、本MoCに基づく責任や義務を移転、委任、下請けさせたりしてはならない。</p>
<p>10.12 Each party shall execute such deeds or documents or do such acts or things as may be necessary to give full effect to the provisions of this MoC.</p>	<p>10.12 各当事者は、本MoCの条項を実効させるのに必要な証書の作成や文書の処理、その他の行為を行うものとする。</p>
<p><b>THE PARTIES TO THIS MEMORANDUM OF COLLABORATION SHOW THEIR AGREEMENT TO ITS TERMS BY SIGNING BELOW.</b> Signed: For and on behalf of RBG Kew For and</p>	<p>本共同研究覚書の当事者は、以下に署名することをもって、契約条項に合意したものとする。 RBG Kewを代表して署名： 職責： 日付：</p>

on Name: Position: Date:  Signed: behalf of [insert party name] Name: Position: Date:	〈カウンターパート〉を代表して署名： 職責： 日付：
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**Annex 1****PRO FORMA****NOTIFICATION OF TRANSFER**

The following plant material is transferred to the Board of Trustees of the Royal Botanic Gardens, Kew, United Kingdom (“RBG Kew”) in accordance with the terms and conditions of the Memorandum of Collaboration between [insert name of counterparty] and RBG Kew, dated [insert date].

By signing this Notification of Transfer, [insert name of counterparty] hereby confirms that the plant material and associated data has been collected and is being transferred into the collections at RBG Kew in accordance with all applicable laws and regulations, permits, consents and/or licences.

<b>D</b>	<b>CO</b>	<b>CO</b>	<b>FA</b>	<b>GE</b>	<b>SPE</b>
<b>A</b>	<b>LL</b>	<b>LL</b>	<b>MI</b>	<b>NU</b>	<b>CIM</b>
<b>T</b>	<b>EC</b>	<b>EC</b>	<b>LY</b>	<b>S</b>	<b>EN</b>
<b>E</b>	<b>TO</b>	<b>TI</b>	<b>(I</b>	<b>OR</b>	<b>TYP</b>
<b>C</b>	<b>R</b>	<b>ON</b>	<b>F</b>	<b>SP</b>	<b>E(S)</b>
<b>O</b>	<b>NA</b>	<b>NO</b>	<b>K</b>	<b>ECI</b>	<b>(E.G</b>
<b>L</b>	<b>ME</b>	<b>.</b>	<b>N</b>	<b>ES</b>	<b>HER</b>
<b>L</b>			<b>O</b>	<b>(IF</b>	<b>BAR</b>
<b>E</b>			<b>W</b>	<b>KN</b>	<b>IUM</b>
<b>C</b>			<b>N)</b>	<b>OW</b>	<b>SPE</b>
<b>T</b>				<b>N)</b>	<b>CIM</b>
<b>E</b>					<b>ENS</b>
<b>D</b>					<b>/</b>
					<b>SEE</b>
					<b>DS/</b>

**別添1****定型****移転通知書**

下記の植物資料は、[日時]に、英国のKew王立植物園理事会（以下、「RBG Kew」とする）に対し、〈カウンターパート〉とRBG Kewの間の共同研究覚書に基づいて移転される。

本移転通知書への署名により、〈カウンターパート〉は、植物資料と関連データがあらゆる適用法、規則、許可、同意、及び／あるいはライセンスに従って収集され、RBG Kewのコレクションに移転したことを確認したものとする。

採 取 日 時	採 取 者 氏 名	コ レ ク シ ヨ ン 番 号	科 （ わ か れ ば）	種 ま た は 属 （ わ か れ ば）	標 本 タ イ プ （ 例 ： ハ ー バ リ ウ ム 標 本 ／ 種 子 ／
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					MAT ERI AL FOR DNA STU DIE S/ LIVI NG PLA NT MAT ERI AL)						DN A研 究 用 資 料 / 生 体 植 物)

SIGNED: DATE:  
**For and on behalf of [insert name of counterparty]**  
 Name:  
 Position:

署名 :  
 日付 :  
 〈カウンターパート〉を代表して、  
 氏名 :  
 職責 :

SIGNED: DATE:  
**For and on behalf of the Board of Trustees of the Royal Botanic Gardens, Kew**  
 Name:  
 Position:

署名 :  
 日付 :  
 キュー王立植物園理事会を代表して、  
 氏名 :  
 職責 :

**A copy of this document signed by [insert name of counterparty] will be forwarded to RBG Kew with each consignment of plant material. RBG Kew will**

〈カウンターパート〉の署名入り文書のコピーは、植物資料の委託ごとに、RBG Kewに送られる。RBG Kewは、共同研究覚書に基づき、RGB Kewによる受領の承

<b>countersign this copy and return it to [insert name of counterparty] as acknowledgement of receipt by RBG Kew under the terms of the Memorandum of Collaboration</b>	認としてそのコピーに署名をして、〈カウンターパート〉へ返送する。
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英国王立植物園 Kew とオーストラリア北部準州アクセス利益配分契約

ACCESS AND BENEFIT-SHARING AGREEMENT

BETWEEN

THE NORTHERN TERRITORY OF AUSTRALIA

REPRESENTED BY

THE DEPARTMENT OF INFRASTRUCTURE, PLANNING AND  
ENVIRONMENT

AND

THE BOARD OF TRUSTEES OF THE  
ROYAL BOTANIC GARDENS, KEW, UNITED KINGDOM

[http://www.kew.org/science/directory/projects/annex/MSBP\\_Aus\\_NT\\_Final\\_AB.doc](http://www.kew.org/science/directory/projects/annex/MSBP_Aus_NT_Final_AB.doc)

An AGREEMENT made on this the                      day of  
2004 between The Northern Territory of Australia represented by the  
Department of Infrastructure, Planning and Environment (hereinafter  
referred to as the “NT Government”); and The Board of Trustees of the Royal  
Botanic Gardens, Kew, Richmond, Surrey, TW9 3AE, United Kingdom  
(hereinafter referred to as “RBG Kew”).

P R E A M B L E

WHEREAS:

The Parties to this Agreement recognise the sovereign rights of States over their own biological resources and are committed to implementing the letter and the spirit of the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the 1992 Convention on Biological Diversity (CBD), the 2002 Global Strategy for Plant Conservation, and national laws and regulations concerning biodiversity, including access to and the transfer of plant genetic resources;

The Department for Infrastructure, Planning and Environment (“DIPE”) is responsible, *inter alia*, for the conservation and protection of flora and fauna in the Northern Territory, Australia. DIPE reports to two Ministers: the Minister for Parks and Wildlife and the Minister for Environment and Heritage. The Minister for Parks and Wildlife is responsible for authorising, licensing and permitting the taking of protected flora and flora seed from the wild, including seed collection for research and conservation purposes. The Minister for Parks and Wildlife, acting through his or her delegate or authorised representative, is the appropriate government authority to grant RBG Kew access to seed and associated herbarium specimens collected on land controlled by the Northern Territory;

RBG Kew is a botanical garden incorporated in the United Kingdom by the *National Heritage Act 1983* and an exempt charity whose mission is to ensure better management of the Earth's environment by increasing knowledge and understanding of the plant and fungal kingdoms - the basis of life on earth. RBG Kew is supported by the United Kingdom Department of Environment, Food, and Rural Affairs (“DEFRA”), which is ultimately responsible to Parliament for RBG Kew’s key aims and activities;

In pursuit of its not-for-profit mission, RBG Kew works together with international partners to:

Collect and curate plant material, including seeds and herbarium specimens;

Carry out scientific research projects to better evaluate and conserve plant biodiversity: for example taxonomic verification of herbarium plant material and seed studies to determine the viability of seeds and to enable their long-term conservation; and

Exchange plant material with other research institutes for further scientific study world-wide;

AND WHEREAS the NT Government, through DIPE, and RBG Kew have jointly developed a long-term collaborative project with the purpose of working with local counterparts such as the Charles Darwin University (“CDU”) to complement *in situ* plant conservation activities in the Northern Territory by enhancing *ex situ* conservation of plant biodiversity indigenous to the Northern Territory;

NOW THEREFORE THE NT GOVERNMENT AND RBG KEW HAVE AGREED AS FOLLOWS:

DEFINITIONS

1. In this Agreement the expressions set out below shall mean as follows:
  - 1.1 “Agreement” shall mean and include this Access and Benefit-Sharing Agreement together with Annex 1 and Annex 2;
  - 1.2 “ASDP Seed Bank” shall mean the Seed Bank maintained by the Botany Unit of the Alice Springs Desert Park, Larapinta Drive, Alice Springs, 0870 Northern Territory;
  - 1.3 "Commercialise" and "Commercialisation" shall mean filing a patent application, obtaining, or transferring intellectual property rights or other tangible or intangible rights by sale or licence or in any other manner; commencement of product development; conducting market research; seeking pre-market approval; and/or the sale of any resulting product;
  - 1.4 “Genetic Resources” shall mean any biological



material of plant, animal, microbial, fungal or other origin of actual or potential value containing functional units of heredity transferred to RBG Kew under this agreement and its progeny and derivatives, including extracts and compounds obtained from genetic resources and analogues of those compounds;

1.5 “Herbarium Studies” shall mean the comparative observation, characterisation and analysis of plant material to better understand its identification and classification;

1.6 “Intellectual property” shall mean all inventions, innovations, improvements, patents, patent applications, trade marks (whether registered or not), trade secrets, know-how (whether patentable or not), plant breeders’ rights and copyright in any drawings, plans, specifications and any other literary or artistic work, which have been created or acquired or which are in the process of being created or acquired in relation to the project;

1.7 “Kew Herbarium” shall mean the Herbarium maintained by RBG Kew at Richmond, Surrey, TW9 3AE, United Kingdom where the duplicate herbarium specimens shall be accessioned for scientific research, education and/or long-term conservation. For the avoidance of doubt, on accession, ownership of and title to the duplicate herbarium specimens shall be transferred to RBG Kew;

- 1.8 “Kew Seed Bank” shall mean the Seed Bank maintained by RBG Kew at Wakehurst Place, Ardingly, West Sussex, United Kingdom where the duplicate seeds shall be accessioned for scientific research, education and/or long-term conservation. For the avoidance of doubt, on accession, ownership of and title to the duplicate seeds shall be transferred to RBG Kew;
- 1.9 “Material” shall mean the duplicate seeds and herbarium material transferred to RBG Kew under this agreement including the genetic resources contained therein and any other genetic resources inadvertently transferred to RBG Kew under this agreement;
- 1.1 “Material Supply Agreement” shall mean the standard RBG Kew document setting out the terms under which RBG Kew may supply plant or fungal material to a third party for non-commercial uses such as scientific research, education, long-term conservation and/or the development of botanic gardens;
- 1.1 “Notification of transfer” shall mean the documentation recording the material transferred to RBG Kew under this agreement, a *pro forma* copy of which is attached to the agreement at Annex 2;
- 1.1 “Partners” shall mean DIPE and RBG Kew;
- 1.1 “Project” shall mean the long-term

3 collaboration between DIPE and RBG Kew as described at Annex 1 to this Agreement;

1.1 "Seed Studies" shall mean tests required to  
4 better understand seed storage requirements including post harvest seed handling, germination tests, moisture relation tests, seed dormancy tests and diagnostic characterisation;

1.1 "State Herbarium" shall mean the herbaria  
5 maintained by the NT Government at the Alice Springs Desert Park in Alice Springs ("NT") and in the Gaymark Building, Darwin ("DNA");

1.1 "Third Party" shall mean any person or  
6 institute other than the NT Government and RBG Kew.

OBJECTIVE OF THIS AGREEMENT

2. The objective of this Agreement is the transfer by the NT Government to RBG Kew of Material collected in collaboration with DIPE for scientific research, education and long-term conservation.

CONSENT

3. In consideration of the undertakings given by RBG Kew in this Agreement as set out in Clauses 7, 8 and 9, 10 and 11 the NT Government hereby gives its prior informed consent to the Project as described in Annex 1 to the Agreement.

ACTIVITIES

4.1 Subject to the terms and conditions set out in

this Agreement, the Partners will work together with agreed local counterparts, such as CDU, to collect, study and conserve the flora of the Northern Territory as is more fully set out in the Project synopsis at Annex 1 to the Agreement. Project activities will include, but will not be limited to:

- a. The conducting of joint plant collecting expeditions in the Northern Territory in accordance with all applicable access laws and regulations, permits, prior informed consents and/or licenses and in an ecologically sustainable manner;
- b. The storage of collected plant material at the ASDP Seed Bank and at the State Herbarium with duplicate Material transferred to the United Kingdom for accession into the collections at the Kew Herbarium and the Kew Seed Bank;
- c. The conducting of Seed Studies and Herbarium Studies upon the Material to determine its viability and to enable long-term conservation of the material;
- d. The generation and mutual sharing of information arising from the Project, including the exchange of research reports from the above-mentioned Seed and Herbarium Studies and the acknowledgement by each party of the other party in all publications and reports arising from the Project; and
- e. The dissemination of appropriate information to aid the conservation of the biological diversity of the Northern Territory, by written

and/or electronic media.

- 4.2 The technical detail of the Project activities, including the identification of priority species, will be developed by the Partners on an annual basis and in accordance with available funds.
- 4.3 The Partners will write formal annual reports to report against these agreed Project activities. At the end of years three and six, an evaluation of the Project shall be carried out by a mutually agreed independent consultant.

#### ACCESS

5. The NT Government, through DIPE, shall use reasonable endeavours to secure the prior informed consents, permissions and/or licences from any relevant State and/or Commonwealth Government authorities and other Australian stakeholder(s), such as local or indigenous communities, to enable the Partners to:
  - a. Enter the land where the Material is located;
  - b. Access the Material and, where relevant and appropriate, any associated traditional knowledge;
  - c. Obtain an export authorisation for scientific collections to enable the duplicate Material to be exported to the United Kingdom; and
  - d. Conduct the aforesaid Project activities in the Northern Territory and in the United Kingdom.

#### NOTIFICATION OF TRANSFER

- 6.1 All Material collected by or sent to RBG Kew will be listed in a Notification of Transfer, a *pro*

*forma* copy of which is at Annex 2. All material listed in a Notification of Transfer will be transferred pursuant to the terms of this Agreement.

6.2 The signature of the Minister for Parks and Wildlife or of his or her delegate or authorised representative on a Notification of Transfer will confirm that, to the best of his or her knowledge, the Material has been collected and is being transferred into the collections at RBG Kew in accordance with all applicable laws and regulations, permits, prior informed consents and/or licenses.

BENEFIT-SHARING

7.1 The Partners agree to share fairly and equitably the benefits that arise from the collection, study and conservation of the Genetic Resources.

7.2 Furthermore, the Partners agree to work together to support and strengthen institutional development through the provision of technical and academic training, as is more fully detailed in Annex 1.

INTELLECTUAL PROPERTY

8.1 NT Government and RBG Kew recognize, and will respect, any pre-existing intellectual property rights in any software, data, images, analysis, techniques, opinion, review, or other contributing effort in any form, including without limitation electronic or hardcopy, that is contributed to the Project by the other party. The contributing party will grant a

non-exclusive, royalty free license to the other party for use by it of such pre-existing intellectual property rights in the Project, subject to acknowledgment.

8.2 Apart from copyright in any thesis produced by a student, Intellectual Property shall be owned by the NT Government and RBG Kew in equal proportions as tenants in common. Accordingly, each party shall bear equally any expenses (such as copyright or patent registration fees) incurred in connection with protecting such Intellectual Property.

8.3 Such Intellectual Property may not be commercially exploited by a party without the prior written consent of the other party, such consent not to be unreasonably withheld.

8.4 Save as aforesaid, NT Government and Kew hereby grant each other a perpetual, non-exclusive, royalty free, world-wide license to use any Intellectual Property arising out of the Project for non-commercial research, education and/or conservation-related purposes.

NON  
COMMERCIALIS  
ATION

9.1 RBG Kew shall not Commercialise any Genetic Resources transferred under this Agreement.

9.2 Without prejudice to the above, any Commercialisation to which the NT Government and RBG Kew may agree will be subject to a separate written agreement and

will be:

- a. In accordance with all applicable Northern Territory laws and regulations;
  - b. Respect the need to acquire new authorisations, permits, prior informed consents and licences to reflect the proposed change of use of the Genetic Resources; and will be
- 9.3 In accordance with Clauses 7 and 8 above; namely, unless otherwise agreed, all Intellectual Property will be owned by the NT Government and RBG Kew in equal proportions as tenants in common, and benefits from the Commercialisation will be shared fairly and equitably.

TRANSFER TO  
THIRD PARTIES

- 10.1 Subject to Clause 10.2, RBG Kew may supply the seed to a Third Party provided the Third Party signs a Material Supply Agreement with RBG Kew, prohibiting, *inter alia*, any Commercialisation of the seed by that Third Party.
- 10.2 Seed that is listed as threatened by either the Government of Australia or by the Northern Territory Government may only be supplied by RBG Kew to a Third Party with the prior written consent of the NT Government, such consent is not to be unreasonably withheld.
- 10.3 As part of the annual reporting process referred to in clause 4.3 above, RBG Kew will provide the NT Government with a list of all Third Parties to whom RBG Kew has supplied seed



material in any one year.

10. RBG Kew may loan or supply samples from the  
4 duplicate herbarium specimens to a Third  
Party provided that the Third Party signs a  
Material Supply Agreement with RBG Kew,  
prohibiting, *inter alia*, any Commercialisation  
of the material supplied to that Third Party.

#### REPATRIATION

11. In the event of a total loss of the ASDP Seed  
1 Bank's seed collection, or the extinction of a  
species within the Northern Territory, RBG  
Kew shall make available to the NT  
Government from the Material at the Kew Seed  
Bank up to 50% of any taxon destroyed or  
extinct.

11. The NT Government shall use its best efforts to  
2 return to RBG Kew, within a reasonable time,  
the proportion of the species so made available  
by RBG Kew.

11. Subject to Clause 11.1 above and  
3 notwithstanding the expiration or termination  
of this Agreement, RBG Kew shall continue to  
store the Material in accordance with standard  
seed banking and herbarium regulations and  
practice.

#### DURATION

12. This Agreement shall come into effect on the  
1 date of the last signature. It shall be valid for  
a term of 6 (six) years after such date.

12. It can be renewed and extended for further  
2 fixed periods thereafter through mutual  
agreement expressed in writing signed on  
behalf of the NT Government and RBG Kew.

12. It can be amended through mutual agreement  
3 expressed in writing signed on behalf of the NT  
Government and RBG Kew.

#### TERMINATION

13. Notwithstanding Clause 12.1 above, either  
1 party to this Agreement may give six (6)  
months written notice to the other party to  
terminate this Agreement.

13. The obligations and rights contained in Clauses  
2 4.1b, 4.1c, 4.1d, 7.1, 8, 9, 10, 11, 14, 16, 18 and  
19 inclusive shall survive the expiration or  
other termination of this Agreement unless  
mutually agreed to the contrary.

#### FORCE MAJEURE

14. Neither party shall be liable to the other party  
1 for any delay or non-performance of its  
obligations under this Agreement arising from  
any cause beyond its reasonable control,  
including, but not limited to, any of the  
following: Act of God, governmental act, war,  
fire, flood, explosion, civil commotion or  
industrial dispute.

14. The affected party must promptly notify the  
2 other party in writing of the cause and the  
likely duration of the cause. Such notice having  
been given, the performance of the affected  
party's obligations, to the extent affected by the

cause, shall be suspended during the period the cause persists.

14. Without prejudice to the above, the affected party must take all reasonable measures to minimise the impact of any force majeure on the performance of its obligations under the Agreement and to ensure, as soon as possible, the resumption of normal performance of the obligations affected by the force majeure.

DISPUTE  
RESOLUTION

15. Any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination (a "Dispute"), shall, to the extent possible, be resolved by good faith negotiation. For the purposes of this clause, "good faith" means in accordance with standards of honesty, sincerity or lawfulness of purpose and applies to both the substance of and the machinery of any such negotiations.

15. At any time within the period of three (3) months referred to in clause 14.1 above, the parties may agree that the dispute be referred to mediation.

15. *If the parties agree that the dispute be referred to mediation, then the parties may by agreement between them appoint from the panel of mediators kept by "Lawyers Engaged in Alternative Dispute Resolution" ("LEADR"), National Dispute Centre, Level 4, 233 Macquarie Street, Sydney, NSW, 2000,*

*AUSTRALIA, a mediator to mediate the dispute. The language to be used in the mediation shall be English. The mediation shall take place at a venue to be agreed by the parties within fourteen (14) days after agreeing to mediate or failing agreement in Sydney, New South Wales.*

15. If the dispute is not resolved by a date which is  
4 the later of the end of three (3) months from the date when the dispute is first notified in writing by either party to the other party, or three (3) months from the date of appointment of the mediator under clause 15.3, then the Dispute shall be referred to and finally settled by an arbitrator appointed in accordance with, and subject to, the Institute of Arbitrators Australia Rules for the Conduct of Commercial Arbitrations.

15. Such arbitration shall be conducted by a single  
5 arbitrator agreed by the parties or failing agreement appointed by the President of the Northern Territories Law Society. Any arbitrator so appointed shall not be the same person as any mediator appointed under clause 15.3.

NOTICE

16. Any notice or other document to be served  
1 under this Agreement must be delivered by hand or sent by registered mail or by international courier service to be served at the address below.

The NT Government:

The Minister for Parks and Wildlife, P O Box  
3146, Parliament House, Darwin NT 0801

RBG Kew:

Head of Corporate Services, Royal Botanic  
Gardens, Kew, Richmond, Surrey TW9 3AB,  
UNITED KINGDOM

16. All notices or documents shall be deemed to  
2 have been served at the date and time of  
delivery of the said notices or documents to the  
recipient party.
- ENTIRE AGREEMENT 17 The provisions of this Agreement together with  
Annexes 1 and 2 constitute the entire  
Agreement between the parties relating to the  
subject matter and the parties do not make any  
representations or warranties except those  
contained in this Agreement and Annexes 1  
and 2 inclusive.
- NO ASSIGNMENT 18 This Agreement is specific to the parties and  
none of the rights or the obligations under this  
Agreement may be assigned or transferred  
without the prior written consent of the other  
party.
- NO PARTNERSHIP  
IN LAW 19 Nothing contained in this Agreement shall  
constitute a partnership in law between the NT  
Government and RBG Kew or constitute either  
of them the agent of the other.

NON-EXCLUSIVI 20 This Agreement in no way restricts the  
TY Partners from involvement in similar Project  
activities with other public and/or private  
organisations and/or individuals.

AS WITNESSED IN TWO IDENTICAL COPIES IN THE ENGLISH  
LANGUAGE, ALL COPIES BEING EQUALLY AUTHENTIC, BY THE  
DULY AUTHORISED REPRESENTATIVES OF THE PARTIES HERETO

SIGNED:

SIGNED:

For and on behalf of the  
Northern Territory Government,  
Australia

For and on behalf of the Board of  
Trustees of the Royal Botanic  
Gardens, Kew, United Kingdom

Prof. Sir Peter Crane

Director, RBG Kew

Chris Burns

Minister for Parks and Wildlife Date:

Date:



カナダ農業食品省植物生殖質ライセンス契約

カナダ農業食品省植物生殖体ライセンス契約

**Germplasm License Agreement for "Line Ten" between Her Majesty the Queen in Right of Canada (Licensor) and Company Canada Inc. (Licensee)**

背景

**Subject matter** Plant Genetic Resources; the high oil line of Brassica napus known as "Line Ten".

**Summary of use(s)** Line Ten is going to be used as a parent in a Company breeding program to develop new hybrid lines, and new open pollinated lines, which may become varieties sold to farmers. No other permitted use or applications. The Company is a grain company in Canada; its actual identity is confidential.

**Purpose or background** The objective of the license is to provide the Company with a parent for their breeding program which will create better quality, higher yielding varieties for sale to producers.

**Contact details** Carl Lynn, Commercialization Officer, Agriculture and Agri-Food Canada, Research Branch, 107 Science Place, Saskatoon, Saskatchewan, S7N 0X2, Canada.

E-mail: lynnc@agr.gc.ca

Telephone: (306) 956-7656; Fax: (306) 956-2867

カナダ農業食品省植物生殖質ライセンス契約本文  
For Line Ten

**With Company Canada Inc.**

**BETWEEN:**

**HER MAJESTY THE QUEEN IN RIGHT OF CANADA  
(Licensor)**



**AND:**  
Company Canada Inc.  
(Licensee)

**GERMPLASM LICENSE AGREEMENT**

**LINE Ten**

**BETWEEN: HER MAJESTY THE QUEEN IN RIGHT OF CANADA**  
as represented by the Minister of Agriculture and Agri-Food  
("CANADA")

**AND: COMPANY CANADA INC.,** carrying on business under the  
name of "Seed Company", of Unit 3 - 75 Scurvy Road, Grainfield,  
Manitoba,  
(hereafter known as the **LICENSEE**),

**INTRODUCTION**

A. WHEREAS the Agriculture and Agri-Food Canada Research Centre,  
Saskatoon, Saskatchewan, has developed the high oil line of Brassica napus  
known as Ten hereafter known as "Line Ten";

B. Line Ten has been tested in Canada and other countries;

C. CANADA licenses Line Ten and grants the right to license the VARIETY  
to canola industry clients for the benefit of the canola industry in western  
Canada and for the creation of value for the LICENSEE;

D. Breeder seed is available to the Licensee;

E. CANADA wishes to have Line Ten used in a breeding program by the  
LICENSEE and the resultant Variety(s) propagated and marketed as a  
commercial Variety in the LICENSED TERRITORY; and

F. CANADA has a mandate to assist canola industry representatives  
improve the varieties of canola available to producers and consumers of  
canola.

NOW THEREFORE in consideration of the premises, the terms and conditions hereinafter contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by each party, the parties hereto covenant and agree as follows:

## 1. DEFINITIONS

"LICENSE AGREEMENT" means this agreement which includes attached appendices and refers to the whole of this agreement, not to any particular section or portion thereof.

"LICENSED TERRITORY" means the World.

"PBR" means Plant Breeders' Rights.

"PBRO" means the Plant Breeders' Rights Office in Canada or the equivalent in other countries within the LICENSED TERRITORY.

1.5 "VARIETY" means Line Ten, a line developed by AAFC' s Saskatoon Research Centre, as identified in Appendix "A", which when combined in a Licensee breeding program produces a germplasm product which may be grown, produced, developed, marketed, retailed, sold, as a result of the breeding program and which then becomes commonly known as a " VARIETY" .

1.6 "BREEDER SEED and CERTIFIED SEED" have the meaning prescribed in the regulations and procedures for the production of Pedigree Seed Crop, Circular No. 6-94 of the Canadian Seed Growers' Association (CSGA). Grade standards for all classes shall be as defined under Schedule A of Regulations made pursuant to the Seeds Act. The purity of BREEDER SEED will be at least equivalent to Foundation No. 1 Seed.

1.7 "SOLD or SALE" means the commercial or retail sales of VARIETY to customers, without discount, rebate or incentive.

1.8 "Party" means either CANADA or LICENSEE, "Parties" means both.

1.9 "Line Ten" means the AAFC wholly owned line of B. napus germplasm licensed to the LICENSEE for use in the breeding program of the LICENSEE in order to create a VARIETY or VARIETIES. (Described in Appendix A, attached)

## **2. GRANT OF BASIC LICENCE**

Grant

2.1 Subject to the provision of this LICENSE AGREEMENT, CANADA hereby grants to the LICENSEE a non-exclusive royalty-bearing, fixed term licence to use Line Ten in a LICENSEE breeding program and to produce, market, sell the resulting VARIETY in the LICENSED TERRITORY.

Sublicensing

2.2

2.2.1 Line Ten

The LICENSEE shall not have the right to grant written royalty-bearing sub-licenses within the LICENSED TERRITORY for the use or purposes of Line Ten. If the LICENSEE wishes to sub-license, the LICENSEE must consult with CANADA and obtain the right to grant a sub-license according to terms agreed to both Parties.

2.2.2 VARIETY

The LICENSEE will be granted the right to sub-license the VARIETY which is a product of this License. The LICENSEE shall pass on all obligations of this License to the sub-licensee, especially the requirement of royalties paid for Line Ten inclusion in any VARIETY sold by the sub-licensee.

## **3. TERM OF THE LICENSE AGREEMENT**

The LICENSE AGREEMENT shall remain in force for ten (10) years from the date of signing of the LICENSE AGREEMENT, unless terminated pursuant to the provisions of paragraph 16 (Termination). At any time prior to the expiration of this period, CANADA may, with the concurrence of the

LICENSEE, and as long as the LICENSEE is not in breach of this LICENSE AGREEMENT, extend this period for one or more successive five (5) year terms.

#### **4. OWNERSHIP**

4.1 The LICENSEE agrees that Line Ten, its creation, discovery, development and every matter relating thereto, forming part thereof and arising therefrom are vested in and are the sole property of CANADA.

4.2 Ownership and all rights to, related to, connected with or arising out of the foregoing, including but without limiting the generality of the foregoing, patent rights and copyright in and the right to produce and publish or cause to be produced and published all information material and documents, and the right pursuant to the Plant Breeders' Right Act to issue a license, are vested in and are the sole property of CANADA.

4.3 It is agreed that CANADA is the sole owner of Line Ten and has the right pursuant to the Plant Breeders' Right Act to issue a license. The LICENSEE shall have no rights in and to the foregoing except as may be expressly granted hereunder and the LICENSEE shall not apply for any patent or other right and shall not divulge or disclose, without the prior written consent of CANADA, any information, material or documents concerning same or make available in any way or use Line Ten except as expressly provided in this LICENCE AGREEMENT, mainly to use the Line Ten in a breeding program of the LICENSEE to produce a VARIETY OR VARIETIES for the use of the LICENSEE.

#### **5. RELEASE OF MATERIAL**

The Minister agrees for the term of this LICENSE AGREEMENT to maintain a supply of Breeder seed of Line Ten and further agrees to provide the LICENSEE, from time to time, with new Breeder seed of Line Ten for a fee established by the Seed Multiplication Unit of Agriculture and Agri-Food Canada, Indian Head, Saskatchewan.

#### **6. LINE Ten**

6.1 CANADA makes no warranties expressed or implied on merchantability or fitness for any or a particular purpose for Line Ten provided to the LICENSEE pursuant to this agreement.

6.2 The LICENSEE agrees that CANADA makes all best efforts to identify the significant characteristics of the Line Ten and that CANADA makes no representation that all the characteristics, including those relating to disease, both favourable and unfavourable have been identified. The LICENSEE agrees to accept CANADA'S best efforts to identify the characteristics of the Line Ten covered by this LICENSE AGREEMENT. With respect to the Line Ten, the LICENSEE shall not hold CANADA liable for any claims resulting from the action or negligence of the LICENSEE.

## **7. PROTECTION**

CANADA has PBR on the Line Ten. The LICENSEE agrees to the terms and conditions of PBR and agrees to abide and assist CANADA for the purposes of Article 16, Infringement.

## **8. FEES AND ROYALTIES**

In consideration of the rights granted hereunder,

### **PBR Registration**

8.1 The LICENSEE shall pay all costs of securing PBR for any VARIETY resulting from the use of Line Ten.

### **PBR Fees**

8.2 The LICENSEE shall pay PBR application costs and the maintenance fees that may come due.

### **VARIETY Registration Fees**

8.3 The LICENSEE shall pay for VARIETY registration costs and the maintenance fees that may come due during the term of this LICENSE AGREEMENT.

#### 8.4 Royalty Rate

The LICENSEE shall pay to CANADA a royalty of 3.5 cents per pound of certified seed resulting from the use of the Line Ten in the LICENSEE breeding program, sold by the LICENSEE for domestic sales and sold for export sales . The royalty shall be paid by the LICENSEE to CANADA by August 1 of each calendar year.

#### Mode of Payment to Canada

8.5 Royalties collected by the LICENSEE shall be paid to CANADA not later than August 1<sup>st</sup> of each calendar year with respect to sales effected up to April 30<sup>th</sup> of the current year.

8.6 Cheques for the payment of royalties shall be in Canadian funds and made payable to the "Receiver General for Canada". They shall be sent to:

Financial Clerk,  
Agriculture and Agri-Food Canada  
Research Centre  
107 Science Place  
Saskatoon, Saskatchewan  
S7N 0X2

8.7 Each cheque shall be accompanied by a statement bearing the Financial Coding of this LICENSE AGREEMENT and the VARIETY name/identification, and showing the period covered, the total sales, the royalty applicable and the total royalty paid.

#### Payments to CANADA after Termination

8.8 The LICENSEE shall pay to CANADA any royalties, annual royalties due and payable pursuant hereto beyond the termination of the LICENSE AGREEMENT in accordance with paragraph 17 (Termination).

### **9. REPORTS**

9.1 The LICENSEE shall on or before the 30th day of July of each calendar year during the term hereof and any renewal, submit to CANADA written

reports as to the LICENSEE's activities with respect to the VARIETY during the preceding twelve months. Such reports shall contain:

9.1.1 a description of the steps taken by the LICENSEE to develop and market the VARIETY;

9.1.2 a description of the marketing conditions for the VARIETY;

9.1.3 an audited statement including the tonnage of the VARIETY sold by the LICENSEE, and amount of royalties payable;

9.1.4 an audited statement including the names and addresses of all sub-licenses to whom the VARIETY has been sub-LICENSED, a full account of all revenues generated by such sub-licenses, including the number of tonnes of VARIETY sold, and a calculation of the amount due to CANADA for the royalties stipulated herein; and

9.1.5 a remittance to CANADA payable to the Receiver General for CANADA of the amount of royalties so payable, such remittance to be clearly labelled with Canada's financial code .

## **10. RECORDS AND AUDIT**

### **Access to Outside Records**

10.1 The LICENSEE specifically authorizes Canadian Seed Growers Association (CSGA) or designate by CANADA to provide to CANADA any information it may have with respect to the production and sale of seed of the VARIETY by the LICENSEE.

### **Audit**

10.2 The LICENSEE agrees, at the request of Canada, to permit an independent public accountant retained by CANADA to inspect all the aforementioned records in order to ascertain the accuracy of such royalties and reports. The auditing and verification provisions herein shall extend for 10 years following the expiry or earlier termination of this LICENSE AGREEMENT. In the event of any discrepancy uncovered by the audit in

excess of 5% of the amount payable, the LICENSEE shall pay forthwith to CANADA both the cost of the audit as well as the discrepancy in funds. (Assuming the Licensee statement of payable is lower than what the audit shows is payable.) If the audit shows CANADA received more than is payable, CANADA shall forthwith pay the LICENSEE the amount due.

## **11. MEMBER INFORMATION**

The parties agree that any document having information with respect to:

11.1 trade secrets of the LICENSEE;

11.2 financial, commercial, scientific or technical information that is confidential information supplied to CANADA by the LICENSEE and is treated consistently in a confidential manner by the LICENSEE;

11.3 information the disclosure of which could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, the LICENSEE;

11.4 information the disclosure of which could reasonably be expected to interfere with contractual or other negotiations of the LICENSEE;

will be treated as third party information as per Section 20 of the *Access to Information Act*. Any request for information will be subject to a notice to the LICENSEE as per Section 27 of the *Access to Information Act*.

## **12. WARRANTY**

The LICENSEE

12.1 It is a fundamental condition of this agreement that the LICENSEE hereby expressly warrants and guarantees that it has the necessary knowledge, ability, facilities and resources to perform all of the obligations and undertakings to which it has agreed pursuant to this agreement.

Canada



12.2 CANADA makes no warranties, express or implied, of the merchantability, patentability, or fitness for a particular purpose of the Line Ten or its use for any purpose.

### **13. PRODUCT LIABILITY**

#### Release Waiver

13.1 The LICENSEE releases CANADA and waives any cause of action the LICENSEE might have against CANADA, her employees, agents, servants, and officers arising from the production, marketing, sale and use of the Line Ten or the resulting product, the VARIETY by the LICENSEE or any third party.

#### Indemnity

13.2 Notwithstanding any other provision in the LICENSE AGREEMENT the LICENSEE shall indemnify and save harmless CANADA, her employees, agents, servants and officers from and against all demands, losses, damages (including economic loss) costs (including solicitor/own client costs) actions, suits or other proceedings, all in any manner, based upon, arising out of, related to or occasioned by or attributable to the production, marketing, sale and use of the Line Ten or the VARIETY by any party.

### **14. COMMERCIAL GENERAL LIABILITY INSURANCE**

14.1 The LICENSEE shall ensure that a minimum, it maintains in force, throughout the duration of the licence, commercial general liability insurance for a limit of liability not less than \$1,000,000 per accident, loss or occurrence.

### **15. INDEMNIFICATION**

15.1 The LICENSEE shall indemnify and save harmless CANADA, its employees and agents from and against all claims, demands, losses, damages, costs (including solicitor and clients costs), actions, suits or other proceedings, all in any manner based upon, arising out of, related to, occasioned by or attributable to, any acts or conduct of the LICENSEE, its employees or agents, (whether by reason of negligence or otherwise) in the performance by the LICENSEE of the provisions of the LICENSE AGREEMENT or any

activity undertaken or purported to be undertaken under the authority or pursuant to the terms of the LICENSE AGREEMENT. The LICENSEE shall not be liable for the negligence of CANADA, its employees or agents.

## **16. INFRINGEMENT**

16.1 Subject to paragraph 15 (Indemnification) in the event of any threatened or actual suit against the LICENSEE in consequences of the exercise of the right and license granted herein, the LICENSEE shall promptly inform CANADA and the PARTIES will jointly decide on the steps to be taken in the circumstances.

16.2 It is understood and agreed that, with regard to the threatened litigation or litigation arising from the license granted herein, or infringement of the LICENSED rights by others, the PARTIES will at all times consult each other and give to one another free of charge information or advice that may be helpful for such purpose. However, neither PARTY shall bind or commit the other PARTY to any course of action that involves liability for legal costs, expenses or damages. Nonetheless, should the PARTIES fail to agree, within a reasonable time, as to any course of action jointly to be taken, either PARTY shall be at liberty to take or defend any proceedings alone at its own expense and shall be entitled to retain anything awarded to it by a court in excess of royalties owing to CANADA.

## **17. TERMINATION**

By CANADA for Cause

17.1 The LICENSE AGREEMENT, at the option of CANADA, may be terminated forthwith by CANADA without compensation to the LICENSEE if:

17.1.1 The LICENSEE fails to provide their best efforts to commercialize the VARIETY;

17.1.2 The LICENSEE fails to make any payment provided for herein and does not make such payment within sixty (60) days;

17.1.3 The LICENSEE commits or permits a breach of any of the other terms and conditions herein contained and does not remedy such breach within ninety (90) days after being required in writing to do so by Canada;

17.1.4 The LICENSEE becomes bankrupt or insolvent, or has a receiving order made against it or has a receiver appointed to continue its operations, or passes a resolution for winding up, or takes the benefit of any statute for the time being in force relating to bankrupt or insolvent debtors of the orderly payment of debts; or

17.1.5 The LICENSEE assigns this agreement without the prior written consent of Canada, contrary to the provisions of paragraph 21.2 (Assignment).

#### Procedure

17.2 Early termination shall be effected by a notice that shall, as of the date stated therein, but subject to paragraph 17.3 (LICENSEE Duties on Termination) terminate the licence herein granted, together with all rights of the LICENSEE hereunder, without prejudice to the right of CANADA to sue for and recover any royalties or other sums due CANADA and without prejudice to the remedy of either PARTY in respect of any previous breach of the LICENSE AGREEMENT.

#### LICENSEE Duties on Termination

17.3 Upon termination or expiration of the LICENSE AGREEMENT, the LICENSEE shall, at its own cost;

17.3.1 Deliver a detailed statement to CANADA of the inventory of the LICENSED PRODUCT then existing but not sold by the LICENSEE as of the date of expiration or termination;

17.3.2 Provide CANADA or a designate of CANADA the right of first refusal to purchase from the LICENSEE any remaining seed stocks at fair market value; and

17.3.3 Pursuant to section 17.3.2, and subsequent to any exercise or waiving of this right, the LICENSEE shall dispose of any remaining pedigreed seed stocks as prescribed by Canada.

#### Surviving Obligations

17.4 The LICENSEE's obligations under paragraphs 8.8 (Payment to CANADA after Termination), 13.1 and 13.2 (Product Liability), 15 (Indemnification), and 17 (Termination) shall survive early termination or expiration of the AGREEMENT.

### **18. ARBITRATION**

#### Arbitration

18.1 Any dispute or difference between the parties hereto arising under this LICENSE AGREEMENT which involves only a question of fact may be referred to an arbitration tribunal for an award and determination by written submission signed by either CANADA or the LICENSEE.

18.2 The parties hereto agree that the award and determination of the arbitration tribunal shall be final and binding on both parties hereto.

18.3 The arbitration tribunal shall be governed by the Commercial Arbitration Code referred to in the *Commercial Arbitration Act*, R.S.C. 1985, c. C-34.6.

#### Arbitration Tribunal

18.4 The arbitration tribunal shall consist of three (3) arbitrators, one (1) appointed by each of the parties hereto and the third appointed by the first two (2) arbitrators.

18.5 The arbitration tribunal shall decide the dispute or difference in accordance with the laws in force in the Province of Saskatchewan. The arbitration tribunal shall be authorized to decide *ex aequo et bono* or as *amiable compositeur*.

#### Proceedings

18.6 The proceedings shall take place in the Province of Saskatchewan, unless the parties hereto agree otherwise.

18.7 The language to be used in the proceedings is English, unless the parties hereto agree otherwise.

18.8 All written communication shall be delivered to the parties hereto in the manner provided for in Section 22.5.

#### Obligations During Arbitration

18.9 During the progress of arbitration, the parties hereto shall continue to perform their obligations under the LICENSE AGREEMENT.

### **19. OTHER LEGAL REQUIREMENTS**

The LICENSEE shall obtain any other authorizations or permits which may be required in order for the LICENSEE to legally carry out all of its activities under this LICENSE AGREEMENT. Failure to do so shall be deemed a material breach of this license.

### **20. INTENT AND INTERPRETATION**

#### Entire AGREEMENT

20.1 The LICENSE AGREEMENT constitutes the entire agreement between the PARTIES. The LICENSE AGREEMENT sets forth all representations forming part of or in any way affecting or relating to the LICENSE AGREEMENT. The PARTIES acknowledge that there are no representations either oral or written, between the LICENSEE and CANADA other than those expressly set out in the LICENSE AGREEMENT.

20.2 The LICENSE AGREEMENT supersedes and revokes all negotiations, arrangements, letters of intent, offers, proposals, brochures, representations and information conveyed, whether oral or in writing, between the PARTIES hereto or their respective representatives or any other person purporting to represent the LICENSEE or Canada. The PARTIES agree that:

20.2.1 none has been induced to enter into the LICENSE AGREEMENT by any representations not set forth in the LICENSE AGREEMENT;

20.2.2 none has relied on any such representations;

20.2.3 no such representations shall be used in the interpretation or construction of the LICENSE AGREEMENT;

20.3.4 no claims for any damages arising as a result of, or from, any such representations shall accrue to or be pursued by the PARTIES and no PARTY shall have any liability for any such claims; and

20.4.5 the LICENSEE has conducted its own due diligence examination and has satisfied itself of the full and plain disclosure of all the material facts.

#### Independent Legal Advice

20.3 It is acknowledged by the PARTIES that each has had legal advice to the full extent deemed necessary by each PARTY. Furthermore the PARTIES acknowledge that neither acted under any duress in negotiating, drafting and executing the LICENSE AGREEMENT.

#### No Adverse Presumption in Case of Ambiguity

20.4 There shall be no presumption that any ambiguity in the LICENSE AGREEMENT be resolved in favour of either of the PARTIES. For greater certainty, the *contra proferentum* rule shall not be applied in any interpretation of the LICENSE AGREEMENT.

#### Severability

20.5 If any part of the LICENSE AGREEMENT is declared or held invalid for any reason, the invalidity of that part will not affect the validity of the remainder which will continue in full force and effect and be construed as if the LICENSE AGREEMENT had been executed without the invalid portion. The intention of the PARTIES is that the LICENSE AGREEMENT would have been executed without reference to any portion which may, for any reason, be declared or held invalid.

## Plurality and Gender

20.6 The LICENSE AGREEMENT will be for the benefit of and be binding upon the heirs, executors, administrators, successors, permitted assigns of the LICENSEE and other legal representatives, as the case may be, of each of the PARTIES. Every reference in the LICENSE AGREEMENT to any PARTY includes the heirs, executors, administrators, successors, permitted assigns and other legal representatives of the PARTY.

20.7 Reference to a PARTY will be read as if all required changes in the singular and plural and all grammatical changes rendered necessary by gender had been made.

## Not a Joint Venture

20.8 The PARTIES expressly disclaim any intention to create a partnership, joint venture or joint enterprise.

20.9 The PARTIES acknowledge and agreed that:

20.9.1 nothing contained in the LICENSE AGREEMENT nor any acts of any PARTY shall constitute or be deemed to constitute the PARTIES as partners, joint venturers or principal and agent in any way or for any purpose;

20.9.2 no PARTY has the authority to act for or to assume any obligation or responsibility on behalf of any other PARTY; and

20.9.3 the relationship between the PARTIES is that of licensor and licensee.

## Minister Not Fettered

20.10 Nothing in the LICENSE AGREEMENT shall derogate or otherwise fetter the ability of CANADA to regulate, administer, manage or otherwise deal with agriculture and all attendant matters thereto.

## Federal Legislation

20.11 The reference in the LICENSE AGREEMENT to any Federal act or regulation includes any subsequent amendment, revision, substitution, consolidation to that act or regulation, notwithstanding that such amendment, revision or substitution occurred after the execution of the LICENSE AGREEMENT or may have a retroactive effect.

#### Right to Legislate

20.12 Nothing in the LICENSE AGREEMENT shall prohibit, restrict or affect the right or power of the Parliament of Canada to enact any laws whatsoever with respect to any area of law for which the Parliament of Canada has legislative jurisdiction, even if the enactment of any such law affects the LICENSE AGREEMENT, its interpretation or the rights of either PARTY.

#### No Implied Obligations

20.13 No implied terms or obligations of any kind by or on behalf of either of the PARTIES shall arise from anything in the LICENSE AGREEMENT. The express covenants and agreements herein contained and made by the PARTIES are the only covenants and agreements upon which any rights against either of the PARTIES may be founded.

#### Access to Information

20.14 Notwithstanding any provision to the contrary in the LICENSE AGREEMENT, the LICENSEE acknowledges that CANADA is subject to the *Access to Information Act*, R.S.C. 1985, c.A-1, and related acts and may be required to release, in whole or in part, the LICENSE AGREEMENT and any other information or documents in Canada's possession or control relating to the LICENSE AGREEMENT and the PARTIES.

#### Governing Law

20.15 The LICENSE AGREEMENT shall be governed firstly by applicable Federal laws, and secondly by the laws of the Province of Saskatchewan.

#### Contract Always Speaks



20.16 Where a matter or thing is expressed in the present tense, it shall be applied to the circumstances as they arise, so that effect may be given to the LICENSE AGREEMENT according to its true spirit, intent and meaning.

## Headings

20.17

20.17.1 All headings in the LICENSE AGREEMENT have been inserted as a matter of convenience and for reference only and in no way define, limit, enlarge, modify the scope or meaning of the LICENSE AGREEMENT or any of its provisions.

20.17.2 Any reference in the LICENSE AGREEMENT to an Article, paragraph, subparagraph will mean an Article, paragraph or subparagraph of the LICENSE AGREEMENT unless otherwise expressly provided.

## Appendices

20.18 The document attached hereto as Appendix "A" forms an integral part of this LICENSE AGREEMENT as fully as if it were set forth herein *in extenso*, and consists of:

Appendix "A" - Description of the VARIETY

## **21. LEGAL RIGHTS**

### Amendments

21.1 No modification, or waiver of any provision of the LICENSE AGREEMENT will be inferred from anything done or omitted by either of the PARTIES except by an express amendment in writing duly executed by the PARTIES.

### Assignment

21.2 The LICENSEE will not assign the whole or any part of the LICENSE AGREEMENT without the prior written consent of CANADA, which consent will not be unreasonably withheld.

21.2.1 It will not be unreasonable for CANADA to refuse to consent to any assignment, if it is foreseeable that the assignment might negatively affect CANADA in any way or derogate from the commercialization of the VARIETY.

21.2.2 Consent to any assignment will not be construed as consent to any other assignment.

21.2.3 Failure of the LICENSEE to obtain the prior written consent of CANADA to any assignment shall be deemed to be a breach of the LICENSE AGREEMENT.

#### No Third Party Rights

21.3 Nothing expressed or implied in the LICENSE AGREEMENT is intended to or shall be construed to confer on or give to any person, other than the PARTIES and their respective successors and permitted assigns, any rights or remedies under or by reason of the LICENSE AGREEMENT.

#### Waiver

21.4 No condoning, excusing or overlooking by either of the PARTIES of any default by the other PARTY at any time or times in performing or observing any of the PARTIES respective covenants will operate as a waiver of or otherwise affect the rights of the PARTIES in respect of any continuing or subsequent default. No waiver of these rights will be inferred from anything done or omitted by the PARTIES except by an express waiver in writing.

21.5 For greater clarity, the failure by either of the PARTIES or their authorized representatives, as the case may be, to require the fulfilment of these obligations, or to exercise any rights herein contained shall not constitute a waiver, a renunciation or a surrender of those obligations or rights.

#### Remedies Cumulative

21.6 All rights and remedies of the PARTIES are cumulative and are in addition to and do not exclude any other right or remedy provided in the LICENSE AGREEMENT or otherwise allowed by law.

#### Mutual Assistance

21.7 The PARTIES will at all times hereafter upon every reasonable request of the other make, do and execute or cause to be procured, made, done and executed, all such further acts, deeds and assurances for the carrying out of the terms, covenants and agreements of the LICENSE AGREEMENT according to the true intent and meaning of the LICENSE AGREEMENT.

## **22. GENERAL**

#### Time is of the Essence

22.1 Time shall be of the essence in this LICENSE AGREEMENT.

#### No Bribes

22.2 The LICENSEE warrants that no bribe, gift, or other inducement has been paid, given, promised or offered to any Government official or employee for the obtaining of this LICENSE AGREEMENT.

#### No Share to Members of Parliament

22.3 Pursuant to the *Parliament of Canada Act*, R.S.C. 1985, c.P-1, no member of the House of Commons or Senate will be admitted to any share or part of the LICENSE AGREEMENT or to any benefit to arise from the LICENSE AGREEMENT.

#### Public Office Holders

22.4 It is a term of this LICENSE AGREEMENT that no former public office holder who is not in compliance with the post employment provisions of the *Conflict of Interest and Post-Employment Code for Public Office Holders* shall derive a direct benefit from this LICENSE AGREEMENT.

#### Notice

22.5 Wherever in this LICENSE AGREEMENT, it is required or permitted that notice or demand be given or served by either PARTY to or on the other PARTY, such notice or demand will be in writing and will be validly given or sufficiently communicated if forwarded by certified mail, priority post mail, telegram, telex or facsimile as follows:

The addresses for delivery are:

To the LICENSEE:

Howard Grain, General Manager  
Company Canada Inc.  
Unit 3 - 75 Scurvy Road  
Grainfield, Manitoba  
Telephone: (204) 489-4069  
Facsimile: (204) 489-4769  
Cellular: (204) 779-2990

To CANADA:

Dr. P. A. O'Sullivan, Director  
Agriculture and Agri-Food Canada  
Saskatoon Research Centre  
107 Science Place  
Saskatoon Saskatchewan S7N 0X2  
Telephone: (306) 956-7211  
Facsimile: (306) 956-7248

22.6 Notice will be deemed to have been delivered:

22.6.1 if delivered by hand, upon receipt;

22.6.2 if sent by electronic transmission, 48 hours after the time of transmission, excluding from the calculation weekends and public holidays;

22.6.3 if sent by certified mail, four (4) days after the mailing thereof, provided that if there is a postal strike or other disruption such notice will be delivered by hand or electronic transmission.

22.7 The PARTIES may change their respective addresses for delivery by delivering notice of change as provided in this paragraph.

**IN WITNESS WHEREOF** this LICENSE AGREEMENT has been executed by duly authorized representatives of the parties.

Done in duplicate and effective this \_\_\_\_\_ day of \_\_\_\_\_, 2000.

**- For CANADA:**

\_\_\_\_\_  
(Witness) (Signature)  
P. A. O' Sullivan, Director  
Saskatoon Research Centre

**- For the LICENSEE:**

\_\_\_\_\_  
(Witness) (Signature)  
Howard Grain, General Manager  
Company Canada Inc.

FINANCIAL CODE:

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## APPENDIX "A"

*(to the License Agreement)*

Description of Line Ten

欧州 MicroB3 プロジェクト海洋微生物標準アクセスと利益配分契約

欧州 MicroB3 プロジェクト海洋微生物標準アクセスと利益配分契約  
 Agreement on Access to Marine Microorganisms and Benefit-Sharing

<p>THIS AGREEMENT is made  <b>BETWEEN:</b></p> <hr/> <p>[Insert the name of the Provider State institution<sup>1</sup> and its representative and the full contact details] (“the Provider”)</p> <p>AND:</p> <hr/> <p>[Insert the name of the Recipient institution<sup>2</sup> and its representative and the full contact details] (“the Recipient”) hereinafter referred to as “the Parties”.</p>	<p>本契約は、</p> <hr/> <p>-          [提供国の施設名とその代表者及び連絡先を記載する]          (以下、「提供者」とする)          と、</p> <hr/> <p>-          [受領国の施設名とその代表者及び連絡先を記載する]          (以下、「提供者」とする)          の間で締結され、両者を以下「当事者」とする。</p>
<p><b>PREAMBLE</b></p> <p>Considering that the European Union funded research project Micro B3 (hereinafter the “Micro B3 Project”) is a scientific research program with the following objectives:</p> <ul style="list-style-type: none"> <li>- to cooperatively sample marine microbial biodiversity at various sites, including through global coordinated actions called “Ocean Sampling Days”</li> <li>- to generate large-scale knowledge on marine microbial genomes in an environmental context and on actual or potential biotechnological applications</li> <li>- to develop innovative bioinformatics approaches for the large scale integration of genomic data of marine</li> </ul>	<p>序文：</p> <p>欧州連合の資金提供による Micro B3 研究プロジェクト (以下、「Micro B3 プロジェクト」とする) が、以下を目的とした科学研究プログラムであることを考慮すると、</p> <ul style="list-style-type: none"> <li>- 「Ocean Sampling Days (海洋標本採取日)」と呼ばれる、世界的に協同で行われる試料採取 (サンプリング) も含め、海洋のさまざまな場所における微生物の生物多様性を協同でサンプリングすること</li> <li>- 環境という文脈で、また実際の、あるいは潜在的な生物工学的応用の観点から、海洋微生物のゲノムに関する大規模な知識を生み</li> </ul>

<p>microbes with environmental and ecosystems data</p> <p>- to make the resulting knowledge accessible for the research and development community for policy makers and the public at large,</p>	<p>出すこと</p> <ul style="list-style-type: none"> <li>- 環境や生体系のデータ、及び海洋微生物のゲノムデータの大規模な統合のための、革新的な生物情報学的アプローチを開発すること</li> <li>- 結果として得られた知識を、政策担当者や一般の人々のための研究開発コミュニティに対してアクセス可能にすること</li> </ul>
<p>Recalling that access to and utilization of genetic resources taken from the marine internal waters, territorial sea, exclusive economic zone or continental shelf of coastal states should be consistent with the provisions of the Convention on Biological Diversity (CBD) taking into account their specifications by the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization, and, where appropriate, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization (NP, not yet in force), as well as with the United Nations Convention on the Law of the Sea (UNCLOS) and the customary law expressed by UNCLOS,</p> <p>Recalling that according to these provisions access to and utilization of genetic resources taken from the above described maritime zones is subject to prior informed consent of the coastal state and mutually agreed terms if the</p>	<p>また、海の内水、領海、排他的経済水域</p> <p>沿岸諸国の大陸棚から採取される遺伝資源へのアクセスと利用は、生物多様性条約の規定に従わねばならず、遺伝資源へのアクセスとその利用から生じる利益の公正・衡平な配分に関するボン・ガイドラインや生物の多様性に関する条約の遺伝資源の取得の機会及びその利用から生ずる利益の公正かつ衡平な配分に関する名古屋議定書（NP、未発効）、国連海洋条約及び国連海洋法条約で明文化されている慣習法などの詳細についても考慮しなければならないことを想起すると、</p> <p>また、これらの規定によると、上記の海域から採取される遺伝資源へのアクセスと利用は、沿岸国による事前の情報にもとづく合意（PIC）、及び沿岸国の要求があれば相互に合意する条件（MAT）を前提としていることを想起すると、</p>

coastal state so requires,	
<p>Recalling that according to these provisions coastal states have the right to regulate, authorize and conduct marine scientific research in their marine internal waters, territorial sea, exclusive economic zone and on their continental shelf; and that in the case of research undertaken by other states or international organizations the coastal state has the right, if it so desires and if practicable, to participate or be represented in the marine scientific research project and to access data and samples and receive preliminary reports, and final results,</p> <p>Recalling that according to these provisions non-monetary and/or monetary benefits from the utilization of the genetic resources shall be shared with the Provider State if the same so requires and as it is set out in mutually agreed terms,</p> <p>Recalling that according to these provisions the transfer of genetic resources to third parties shall be set out in a material transfer agreement,</p> <p>Recalling that according to these provisions measures on access for non-commercial research purposes shall be simplified with a view to contribute to the conservation and sustainable use of biodiversity, and</p> <p>Acknowledging that research and development on genetic resources can be for the public domain or for</p>	<p>また、これらの規定によると、沿岸諸国は海の内水、領海、排他的経済水域及び大陸棚での海洋科学研究を認可、遂行する権利を有しており、他の国や国際組織によって研究が行われる場合に、もしそのように希望しかつ実行可能であれば、沿岸国は海洋科学研究プロジェクトに参加あるいは代表し、データや試料にアクセスして、予備調査報告や最終結果を受け取る権利を有することを想起すると、</p> <p>また、これらの規定によれば、遺伝資源の利用による非金銭的及び／あるいは金銭的利益は、そのように要求があり、また互に合意する条件（MAT）において提示された場合、提供国と共有されるべきであることを想起すると、</p> <p>また、これらの規定によれば、遺伝資源の第三者への移転は、素材移転契約（MTA）において提示されるべきであることを想起すると、</p> <p>また、これらの規定によれば、非商業目的の研究のためのアクセスについての法令は、生物多様性の保護や持続的な利用への貢献という観点から簡略化されるべきであることを想起すると、</p> <p>また、遺伝資源についての研究開発は公有または専有目的がありうることを認識すると、</p>



<p>proprietary purposes,</p> <p>The Parties to this agreement hereby agree as follows:</p> <p><b>Article 1 AGREEMENT</b></p> <p>1.1 The agreement sets out the terms for the access to genetic resources found in/on the Provider State’s marine internal waters, territorial sea, exclusive economic zone or continental shelf, for the utilization and transfer to third parties of the accessed genetic resources, for the management and transfer to third parties of associated knowledge and for the sharing of benefits drawn from the same</p> <p>1.2 The agreement is part of the Micro B3 Consortium Agreement<sup>3</sup>. Its rights and obligations extend to all Micro B3 partners.</p> <p>1.3 The Parties agree to release a copy of the agreement to the registered users of the web portal built by the Micro B3 project.</p>	<p>両当事者は本契約において、以下について合意したものとする</p> <p><b>第 1 条 契約</b></p> <p>1.1 本契約は、提供国の海の内水や領海、排他的経済水域または大陸棚で発見された遺伝資源へのアクセス、アクセスされた遺伝資源の利用及び第三者への移転、関連知識の管理及び第三者への移転、同じものから引き出される利益の共有について、条件を提示したものである。</p> <p>1.2 本契約は、Micro B3 コンソーシアム契約の一部である。ここでの権利義務は、すべての Micro B3 パートナーに及ぶものとする。</p> <p>1.3 当事者らは、Micro B3 プロジェクトが作成したポータルサイトの登録ユーザーに対し、本契約のコピーを公開することに同意するものとする。</p>
<p><b>Article 2 DEFINITIONS OF TERMS</b></p> <p>As used in this agreement, the following terms shall have the meaning provided below:</p> <p>a) <b>Access</b> means collecting genetic resources from the location where they are found.</p> <p>b) <b>Accessed genetic resources</b> means the genetic resources collected</p>	<p><b>第 2 条 用語の定義</b></p> <p>本契約で用いられる以下の用語は、次のような意味を有する：</p> <p>a) アクセス (Access) とは、遺伝資源をそれらが発見された場所から採取することである。</p> <p>b) アクセスされた遺伝資源 (Accessed genetic resources) とは、本契約にもとづいて採取された遺伝資源のことである。</p>

<p>on the basis of this agreement.</p> <p>c) <b>Associated genetic knowledge</b> means any experimental or observational data, information and other findings on the composition, life conditions and functions of the accessed genetic resources.</p> <p>d) <b>Derivative</b> means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.</p> <p>e) <b>Genetic resources</b> means any material of plant, animal, microbial or other origin containing functional units of heredity which is of actual or potential value.</p> <p>f) <b>Micro B3 partner</b> means an institution that is a Party to the Micro B3 Consortium Agreement.</p> <p>g) <b>Ocean Sampling Days</b> are simultaneous sampling campaigns in the world's oceans, as part of the Micro B3 project, aiming at providing insights about the microbial diversity and the identification of novel ocean-derived biotechnologies.</p> <p>h) <b>Provider State</b> means the coastal state from whose marine internal waters, territorial sea, exclusive</p>	<p>c) 関連遺伝的知識 (Associated genetic knowledge) とは、アクセスされた遺伝資源の機能や生育条件、組成物に関するあらゆる実験・観察データや情報、その他の知見のことである。</p> <p>d) 派生物 (Derivative) とは、生物・遺伝資源の遺伝子発現あるいは代謝の結果、自然に生じた生化学化合物のことで、遺伝の機能単位を有しないものも含む。</p> <p>e) 遺伝資源 (Genetic Resources) とは、植物、動物、微生物、あるいは他の起源のあらゆる物質で、実測値あるいは潜在値で、遺伝の機能単位を有するもののことである。</p> <p>f) Micro B3 パートナー (Micro B3 partner) とは、Micro B3 コンソーシアム契約の当事者のことである。</p> <p>g) 海洋標本採取日 (Ocean Sampling Days) とは、Micro B3 プロジェクトの一環として、微生物の多様性についての見識の提供や、海洋由来の新たなバイオテクノロジーの確認を目的に、世界中の海で同時に試料採取を行うキャンペーンのことである。</p> <p>h) 提供国 (Provider State) とは、海の内水や領海、排他的経済水域や大陸棚において、その位置で遺伝資</p>
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<p>economic zone or continental shelf genetic resources are collected <i>in situ</i>.</p> <p>i) <b>Third party</b> means any institution other than Micro B3 partners.</p> <p>j) <b>Utilization for proprietary purposes</b> means research and development that aims at protecting the associated knowledge, including products and processes developed, by patent rights, keeping the associated knowledge secret, making the associated knowledge accessible at more than incremental costs for dissemination and/or bringing the products and processes developed from the accessed genetic resources on the market.</p> <p>k) <b>Utilization for the public domain</b> means research and development that aims at making the associated knowledge, including products and processes developed, publicly available at no more than incremental costs for dissemination, and without being protected by patent rights or further restricted by other intellectual property rights.</p> <p>l) <b>Utilization of genetic resources</b> means research and development on the genetic and/or biochemical composition of the accessed genetic resources, including through the</p>	<p>源が採取できる沿岸国のことである。</p> <p>i) 第三者 (Third party) とは、Micro B3 パートナー以外のあらゆる機関のことである。</p> <p>j) 専有目的での利用 (Utilization for proprietary purposes) とは、特許権や関連知識の秘匿、普及のためにかかった費用以上での知識の入手、及び／あるいは市場におけるアクセスされた遺伝資源による製品やプロセスの開発によって、関連する知識 (開発された製品やプロセスも含む) を保護する目的で行われた研究開発のことである。</p> <p>k) 公有のための利用 (Utilization for the public domain) とは、関連する知識 (開発された製品やプロセスも含む) が普及のためにかかった費用を越えることなく公的に入手可能であり、特許による保護あるいは他の知的財産権によって使用制限がされないことを目的とした研究開発のことである。</p> <p>l) 遺伝資源の利用 (Utilization of genetic resources) とは、アクセスされた遺伝資源の、遺伝的及び／あるいは生化学的組成における研究開発。生物システムや生体、その派生物を用いたあらゆる技術により、製品やプロセスを特定の用途のために作り出す又は改変するよう</p>
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<p>application of biotechnology which is any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.</p>	<p>な、バイオテクノロジーを応用した結果のものも含む。</p>
<p><b>Article 3 ACCESS TO GENETIC RESOURCES</b></p> <p>3.1 The Recipient shall be entitled to collect samples as follows:</p> <p>a) Kinds of samples<sup>4</sup>, including the kind of genetic resources<sup>5</sup>, if known:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>b) Number and quantity of samples:</p> <p>_____</p> <p>_____</p> <p>c) Geographical location of collection<sup>6</sup>:</p> <p>_____</p> <p>_____</p> <p>d) Time period for collection:</p> <p>_____</p> <p>_____</p> <p>3.2 The Recipient shall within ... [time period to be specified by the Parties] after collection of the samples notify to the Provider the kinds of genetic resources the Recipient intends to utilize. The Provider may, within ... weeks [to be specified], raise objections in which case the Parties will seek agreement on the kinds of genetic resources allowed to be utilized. (This clause is to be crossed out if not</p>	<p><b>第 3 条 遺伝資源へのアクセス</b></p> <p>3.1 &lt;受領者&gt;は、以下の試料を収集する権利を有する：</p> <p>a) 資料の種類、わかれば遺伝資源の種類も含む</p> <p>_____</p> <p>b) 試料の数及び量</p> <p>_____</p> <p>c) コレクションの地理的位置</p> <p>_____</p> <p>d) 収集の時期</p> <p>_____</p> <p>3.2&lt;受領者&gt;は、試料の採取後、[当事者の明記した期間]以内に、&lt;受領者&gt;が利用しようとする遺伝資源の種類について、&lt;提供者&gt;に知らせるものとする。利用を許可する遺伝資源の種類について当事者が合意を求める必要があるときは、&lt;受領者&gt;は、...週間[明記予定]以内に、異議を述べることができる。</p> <p>(本条は、該当しない場合は削除する)</p> <p>3.3 &lt;受領者&gt;は、アクセスした遺伝資源を自らの施設、または本契約</p>

<p>applicable)7</p> <p>3.3 The Recipient shall be entitled to move the accessed genetic resources to its premises and, subject to Article 1.2 of this agreement, to the premises of other Micro B3 partners, as well as to an institution or individual which is contractually bound with the Recipient to provide specified assistance concerning the utilization of the accessed genetic resources 8</p> <p>3.4 The Recipient shall deliver a portion of the accessed genetic resources to the Provider or an institution designated by the same:</p> <p>The samples shall be delivered in the following form:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>(This clause or part of it is to be crossed out if not applicable)</p> <p>3.5 The Recipient shall bear all the costs incurred in accessing and delivering the genetic resources.</p>	<p>1.2にしたがって他の B3 パートナーの施設に、またはアクセスされた遺伝資源の使用に関して特定の援助を与える者として、契約により&lt;受領者&gt;に拘束された機関または個人に対して、移動させる権利を有する。</p> <p>3.4 &lt;受領者&gt;はアクセスされた遺伝資源の一部を&lt;提供者&gt;または同者に指定された機関に対して給付するものとする：</p> <p>試料は、以下の形で給付されるものとする：</p> <p>_____</p> <p>_____</p> <p>(本条またはその一部は、該当しなければ削除する)</p> <p>3.5 &lt;受領者&gt;は、遺伝資源へのアクセス及び給付に際して発生したすべての費用を負担するものとする。</p>
<p><b>Article 4 UTILIZATION OF THE GENETIC RESOURCES</b></p> <p>4.1. The Recipient shall be entitled to the utilization of the accessed genetic resources.</p> <p>Specifications, if deemed necessary:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p><b>第 4 章 遺伝資源の利用</b></p> <p>4.1 &lt;受領者&gt;は、アクセスされた遺伝資源を利用する権利を有する。</p> <p>必要であれば、詳細：</p> <p>_____</p> <p>_____</p> <p>4.2 アクセスされた遺伝資源の利用は、公有目的のためとする。</p> <p>必要であれば、詳細：</p> <p>_____</p> <p>_____</p>

<p>4.2 The utilization of the accessed genetic resources shall be for the public domain.</p> <p>Specifications, if deemed necessary:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p>(本条は、該当しない場合は削除する)</p> <p>4.3 &lt;受領者&gt;は アクセスされた遺伝資源の一部/全部 (どちらかを削除してください) について、専有目的で利用する権利を有する。 必要であれば、詳細：</p> <p>_____</p>
<p>(This clause is to be crossed out if not applicable)</p> <p>4.3 The Recipient shall be entitled to utilize part/all (please cross out) of the accessed genetic resources for proprietary purposes:</p> <p>Specifications, if deemed necessary:</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p>(本条は、該当しない場合は削除する)</p> <p>4.4 &lt;受領者&gt;が、本契約の締結後に、アクセスされた遺伝資源及び/あるいは関連遺伝知識を専有目的で利用しようとする場合、&lt;受領者&gt;は、&lt;提供者&gt;の承諾を求めなければならない。 承諾方法について、必要であれば、詳細：</p> <p>_____</p>
<p>(This clause is to be crossed out if not applicable)</p> <p>4.4 Should the Recipient, after the conclusion of this agreement, intend to utilize the accessed genetic resources and/or use the associated genetic knowledge for proprietary purposes the Recipient shall seek the consent of the Provider.</p> <p>Specifications of the consent procedure, if deemed necessary:</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p>4.5 &lt;受領者&gt;が、本契約の締結後に、アクセスされた遺伝資源及び/あるいは関連遺伝知識を専有目的で利用しようとする場合、 &lt;提供者&gt;は、契約の修正や終了について、&lt;受領者&gt;との友好的な交渉に着手するものとする。 (本条は、該当しない場合は削除する)</p>

<hr/> <hr/> <hr/> <p>4.5 Should the Provider, after the conclusion of this agreement, intend to utilize the accessed genetic resources and/or use the associated genetic knowledge for proprietary purposes the Provider shall enter into amicable negotiations with the Recipient on the modification or termination of this agreement. (This clause is to be crossed out if not applicable)</p>	
<p><b>Article 5 TRANSFER OF GENETIC RESOURCES TO THIRD PARTIES</b></p> <p>5.1 The Recipient may transfer to a third party the accessed genetic resources, or parts of them, provided that the third party agrees with the Recipient, to apply to the transferred genetic resources Articles 4 to 16 of this agreement.</p> <p>5.2 If the Recipient intends to transfer to a third party the associated genetic knowledge which is not yet submitted to the public domain according to Article 6, the third party shall agree with the Recipient, to apply to the transferred knowledge Articles 4 to 16 of this agreement.</p> <p>5.3 In case of transfer to a third party, the Recipient needs the prior informed consent of the Provider, under one of the following modalities:9</p>	<p><b>第 5 章 遺伝資源の第三者への移転</b></p> <p>5.1 第三者が、移転された遺伝資源について、本契約の第 4 条から第 16 条までを適用することに合意した場合には、＜受領者＞は、アクセスされた遺伝資源、あるいはその一部を第三者に移転することができる</p> <p>5.2 ＜受領者＞が、第 6 条の定めるパブリックドメインにまだ提出されていない関連遺伝知識を第三者に移転しようとするときは、第三者は、＜受領者＞が移転された知識を本契約の第 4 条から第 16 条までを適用することに合意するものとする。</p> <p>5.3 第三者への移転の際には、＜受領者＞は、以下のいずれかの手順で、＜提供者＞の事前の情報に基づく同意（PIC）を得る必要がある。</p> <ul style="list-style-type: none"> <li>- ＜提供者＞あるいは同者に指定された機関により、移転契約のコピーとともに送られてきた通知は、事前</li> </ul>

<p>- a notification of the transfer to the Provider or an institution designated by the same, along with the sending of a copy of the transfer agreement, will be considered as proof of prior informed consent. The institution shall be the following [if applicable]:</p> <hr/> <hr/> <hr/> <p>- other [specification of the modality]:</p> <hr/> <hr/> <hr/> <p>[This clause is to be crossed out upon agreement that the consent is not required]</p>	<p>の情報に基づく同意（PIC）の証拠とみなされる。機関とは、以下を示す（該当するものがあれば）：</p> <hr/> <hr/> <p>- その他（手順についての詳細）：</p> <hr/> <hr/> <p>（同意が不要との合意があれば、本条は削除する）</p>
<p><b>Article 6 DISSEMINATION OF KNOWLEDGE</b></p> <p>6.1 The Recipient shall make the associated genetic knowledge publicly available at no more than incremental costs of dissemination. The dissemination can be through online media, print media or delivery upon request. The recommended forums for online dissemination are the Micro B3 Information System (<a href="http://www.microb3.eu">www.microb3.eu</a>) and existing data bases and information networks such as the Global Biodiversity Information Facility (GBIF), SeaDataNet, Pangaea and the International Nucleotide Sequence Database Collaboration (INSDC).</p> <p>6.2 Such knowledge shall be made</p>	<p><b>第 6 条 知識の普及</b></p> <p>6.1 &lt;受領者&gt;は、関連遺伝知識を、普及のためにかかった費用を越えることなく公的に入手できるようにしなければならない。普及手段はオンライン媒体、印刷媒体、あるいはその他要望に応じたものとする。オンラインでの普及について望ましいフォーラムは、Micro B3 情報システム (<a href="http://www.microb3.eu">www.microb3.eu</a>)、及び Global Biodiversity Information Facility (GBIF) や SeaDataNet、Pangaea、International Nucleotide Sequence Database Collaboration (INSDC) など、既存のデータベースや情報ネットワークである。</p> <p>6.2 こうした知識は、特別の定めがない限り生み出されたらなるべく速やかに入手可能にしなければならない</p>



<p>available as soon as possible after its generation unless otherwise specified. No embargo period is allowed for the raw sequence data and the oceanographic data associated to the samples collected upon the Ocean Sample Days.</p> <p>Specifications if deemed necessary: _____          _____          _____          _____</p> <p>6.3 The Recipient shall make reasonable efforts to ensure that the release of associated genetic knowledge through online media, print media or delivery upon request will be organized such that users are bound not to use the associated genetic knowledge taken from the portals for proprietary purposes unless they have obtained prior informed consent of the Provider.</p> <p>6.4 Paragraphs 1-3 of this Article do not apply to associated genetic knowledge used for proprietary purposes specified under Articles 4.3 and 4.4.</p> <p>6.5 The Recipient shall make reasonable efforts to ensure that the users of knowledge accessed from the Micro B3 Information System provide to the System the knowledge from their own research in such form and format as the System will reasonably require in order to promote the objectives of the utilization for the public domain.</p>	<p>い。Ocean Sample Day に採取された試料に関連する生の配列データや海洋学データには、輸出入禁止期間を設けてはならない。</p> <p>必要であれば、詳細：</p> <hr/> <p>6.3 &lt;受領者&gt;は、&lt;提供者&gt;から事前の情報に基づく同意（PIC）を得ていない場合には、ユーザーらが「タルから得られた関連遺伝知識を専有目的で利用できない拘束を受けるよう、オンライン媒体や紙媒体、その他要望に応じた手段での配信による関連遺伝知識の公開の組織化を保証すべく、相応の努力を払わなければならない。</p> <p>6.4 4.3 及び 4.4 に明記された専有目的で関連遺伝知識が利用される場合には、本条の 1～3 パラグラフは適当されない。</p> <p>6.5 Micro B3 情報システムの情報にアクセスしたユーザーらが、彼ら自身の研究から得られた知識を、公有利用の目的を促進するために、システムが合理的に要求する形態及び体裁で提供することを保証すべく、&lt;受領者&gt;は相応の努力を払わなければならない</p>
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<p><b>Article 7 ACKNOWLEDGING THE CONTRIBUTION OF THE PROVIDER STATE</b></p> <p>7.1 When making associated genetic knowledge publicly available under Article 6 the Recipient shall indicate the country of origin of the utilized genetic resource.</p> <p>7.2 When making associated genetic knowledge publicly available under Article 6 the Recipient shall acknowledge the role of scientists from the Provider State, and, where any work, significant advice or recommendations have been provided by such scientists, their (co-)authorship.</p>	<p><b>第 7 条 提供国の貢献を認識</b></p> <p>7.1 第 6 条にもとづいて関連遺伝知識を公的に入手可能にする際には、        &lt;受領者&gt;は利用した遺伝資源の原産国を明示しなければならない。</p> <p>7.2 第 6 条にもとづいて関連遺伝知識を公的に入手可能にする際には、        &lt;受領者&gt;は、提供国の科学者の役割、及びあらゆる業績において、そうした科学者や彼らの（共）著作物から提供された重要な助言や提言について謝辞を述べなければならない。</p>
<p><b>Article 8 RECORDING AND REPORTING</b></p> <p>8.1 The Recipient shall maintain records concerning the storage and transfer of the accessed genetic resources and allow access to such records to the Provider or the authority designated by the same.</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____ (insert name and address of authority if applicable)</p> <p>8.2 The Recipient shall report in writing to the Provider or the authority designated by the same every _____ [insert duration] months, beginning _____ and ending _____, providing details of the</p>	<p><b>第 8 条 記録及び報告</b></p> <p>8.1 &lt;受領者&gt;は、アクセスされた遺伝資源の保管及び移転についての記録を整備し、&lt;提供者&gt;あるいは同者に指定された機関がこれらの記録にアクセスするのを許可しなければならない。</p> <p>_____</p> <p>(該当するものがあれば、機関の名称と住所を記載する)</p> <p>8.2 &lt;受領者&gt;は        &lt;提供者&gt;あるいは同者に指定された機関に対し、_____から開始して_____までの間、__ヶ月（期間を挿入）ごとに、利用の進捗状況の詳細について、報告書を執筆しなければならない。</p> <p>_____</p> <p>_____</p>

<p>progress of utilization.</p> <p>_____ _____ _____</p> <p>__(insert name and address of authority if applicable)</p> <p>8.3 With relation to associated genetic knowledge used for proprietary purposes specified under Articles 4.3 and 4.4, the Recipient shall, when reporting according to paragraph 2 of this Article, also report on any steps taken towards obtaining or implementing intellectual property protection and the selling of products or processes based on this knowledge</p> <p>10</p>	<p>(該当するものがあれば、機関の名称と住所を記載する)</p> <p>8.3 4.3 及び 4.4 に定める専有目的で利用された関連遺伝知識に関して、&lt;受領者&gt;は、本条第 2 パラグラフにもとづいて報告する際、知的財産保護の獲得あるいは実施、及び知識にもとづく商品やプロセスの販売のために講じたあらゆる対策について、報告しなければならない。</p>
<p><b>Article 9 SHARING OF KNOWLEDGE</b></p> <p>9.1 The Recipient shall provide the Provider, or the authority designated by the same, with the associated genetic knowledge and provide assistance in their assessment or interpretation as reasonably requested.</p> <p>_____ _____ _____</p> <p>__(insert name and address of authority if applicable)</p> <p>9.2 Such knowledge shall, at the latest, be provided once it has been made publicly available.</p> <p>Specifications if deemed</p>	<p><b>第 9 条 知識の共有</b></p> <p>9.1 &lt;受領者&gt;は、&lt;提供者&gt;あるいは同者に指定された機関に対して、関連遺伝知識を提供し、合理的な要求に応じて、彼らの評価や解釈について支援を行うものとする。</p> <p>_____ _____</p> <p>(該当するものがあれば、機関の名称と住所を記載する)</p> <p>9.2 こうした知識は、遅くともそれが公に入手可能になった時点で提供されるべきである。</p> <p>必要と思われる明細事項：</p> <p>_____ _____</p> <p>9.3 本条第1段落に定める義務は、4.3及び4.4で定める専有目的利用の</p>

<p>necessary11: _____  _____  _____  _____</p> <p>9.3 The obligation under paragraph 1 of this Article extends to associated genetic knowledge used for proprietary purposes specified under Articles 4.3 and 4.4. When using the knowledge the Provider shall not prejudice any use for proprietary purposes by the Recipient.  12  Specifications, if deemed necessary:  _____  _____  _____  _____</p> <p>(This clause is to be crossed out if not applicable)</p> <p>9.4 The Recipient shall furnish the Provider or the authority designated by the same with _____ (insert number) copies of any publication based on the utilization of the accessed genetic resources.  _____  _____  _____</p> <p>(insert name and address of authority if applicable) .</p>	<p>関連する遺伝知識についても適用される。知識を利用する際には、＜提供者＞は  ＜受領者＞の専有目的でのいかなる利用をも概してはならない、  必要と思われる明細事項：  _____</p> <p>(本条は、該当しない場合は削除する)</p> <p>9.4 ＜受領者＞は、＜提供者＞、あるいは同者に指定された機関に対して、アクセスされた遺伝資源の利用にもとづくあらゆる出版物のコピーを、__（数値を挿入）部、供給するものとする。  _____</p> <p>(該当するものがあれば、機関の名称と住所を記載する)</p>
<p><b>Article 10 SCIENTIFIC COLLABORATION WITH THE PROVIDER STATE AND</b></p>	<p><b>第 10 条 提供国との科学的共同研究及びキャパシティビルディング</b></p>



<p>associated knowledge for proprietary purposes according to Articles 4.3 and 4.4, it must fairly and equitably share with the Provider any monetary benefit obtained.</p> <p>11.3 The share shall be determined by further negotiations between the Parties to this agreement.</p> <p>11.4. (Alternatively to 11.3) The share shall be _____percent of the revenue from sales of the product or process based on the accessed genetic resources. It shall be paid on the basis of a financial report to be sent to the Provider or an authority designated by the same at the end of any year of any revenue generation to the account designated by the same.</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>(Insert authority and account details if applicable)</p> <p>11.5 If the Recipient utilizes the accessed genetic resources or utilizes the associated genetic knowledge for proprietary purposes without being entitled according to Articles 4.3 or 4.4, and therefore in breach of the conditions of this agreement, it must share with the Provider any monetary benefit obtained from such utilization or use. The share shall be _____</p>	<p>者たちのさらなる交渉によって決定されるものとする。</p> <p>11.4 (11.3 の代わりとして) 取り分は、アクセスされた遺伝資源にもとづく製品またはプロセスの売り上げ収入のうち、__パーセントとする。支払いは、&lt;提供者&gt;あるいは同者に指定された機関に毎年送られる財務報告書にもとづき、利益の発生したすべての年の末に、同者に指定された口座に送金されるものとする。</p> <p>_____</p> <p>(該当する場合は機関や口座の詳細を記載する)</p> <p>11.5 &lt;受領者&gt;が、4.3あるいは4.4にもとづかない方法で、アクセスされた遺伝資源や関連知識を利用専有目的で利用し、したがって本契約の違反があった場合、それらの利用に際して生じたあらゆる金銭的利益が共有されなければならない。取り分は、アクセスされた遺伝資源にもとづく製品またはプロセスの売り上げ収入のうち、__パーセントとする。支払いは、&lt;提供者&gt;あるいは同者に指定された機関に毎年送られる財務報告書にもとづき、同者からの要求によって適切な時期に行われるものとする。</p> <p>_____</p> <p>(該当する場合は機関や口座の詳細を記載する)</p> <p>(本条、あるいは各パラグラフは、該当しない場合は削除する)</p>
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<p>percent of the revenue from sales of the product or process based on the accessed genetic resources. It shall be paid on the basis of a financial report to be sent to the Provider or an authority designated by the same in due time upon request by the same.</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>(Insert authority and account details if applicable)</p> <p>(This Article or single paragraphs of it are to be crossed out if not applicable)</p>	
<p><b>Article 12 OTHER LAWS TO BE RESPECTED</b></p> <p>The Recipient shall ensure that the collection, storage, transfer, utilization and exportation of the genetic resources complies with all applicable laws of the Provider State on the protection of human health and the environment, on taxes, on customs and any other concern.</p>	<p><b>第 12 条 留意すべき他の法</b></p> <p>&lt;受領者&gt;は、遺伝資源の収集、保管、移転、利用、輸出に際して、ヒトの健康や環境、租税、税関その他あらゆる事項について、提供国のすべての関連法規に準拠していることを保証しなければならない</p>
<p><b>Article 13 DURATION OF THE AGREEMENT</b></p> <p>The agreement is of unlimited duration, except for the obligations under Articles 8.2 and 10 which shall end on [date to be inserted; e.g. 2 years after the termination of the Micro B3 project]: _____</p> <p>_____</p>	<p><b>第 13 条 本契約の期間</b></p> <p>本契約は、8.2 条及び 10 条に定める義務が[日時を挿入； 例-Micro B3 プロジェクト終了の 2 年後] _____に終了しない限り、期限なく継続するものとする。</p>

<p><b>Article 14 APPLICABLE LAW</b></p> <p>14.1 The applicable law on any matters relating to the interpretation and the application of the present agreement shall be:</p> <hr/> <hr/> <hr/> <p>14.2 The competent court for dispute settlement shall be:</p> <hr/> <hr/> <hr/>	<p><b>第 14 条 適用法</b></p> <p>14.1 現在の契約の適用や解釈についてのあらゆる問題において、適用される方は、</p> <hr/> <p>であるとする。</p> <p>14.2 紛争解決のための管轄裁判所は、</p> <p>competent court</p> <hr/> <p>であるとする。</p>
<p><b>Article 15 DISPUTE SETTLEMENT</b></p> <p>15.1 No Party shall, in the event of a dispute arising from this agreement, commence court proceedings (except proceedings for urgent interlocutory relief) before searching for an amicable solution according to paragraphs 2 and 3 of this Article.</p> <p>15.2 A Party to this agreement claiming that a dispute has arisen under or in relation to this agreement must serve the other Party with a written notice specifying the nature of the dispute on receipt of which the dispute resolution shall forthwith begin.</p> <p>15.3 Any dispute arising from this agreement shall be resolved expeditiously foremost by negotiation in good faith failure to which the Parties shall engage informal dispute resolution techniques, such as</p>	<p><b>第 15 条 紛争解決</b></p> <p>15.1 いずれの当事者も、本条の第 2 および第 3 段落に従った友好的な解決策を模索する前に、訴訟手続きを開始してはならない（ただし、緊急の中間判決を求める訴訟をのぞく）</p> <p>15.2 本契約下で、あるいは契約に関連して紛争が生じたと主張する当事者は、相手方に対し、紛争の本質を明らかにした書面を提出しなければならず、それを受け取り次第、紛争解決をただちに開始するものとする。</p> <p>15.3 本契約にもとづいて生じたいかなる紛争も誠意ある交渉をもって最大限迅速に行い、失敗したときは、両当事者は仲裁や調停など、あるいは合意の上でそれらと似た手法を用いて、非公式の紛争解決を行うものとする。</p>



<p>mediation and arbitration or similar techniques agreed to by them.</p>	
<p><b>Article 16 TERMINATION OF THE AGREEMENT</b></p> <p>16.1 The agreement may be terminated at any time by mutual agreement in writing.</p> <p>16.2 The agreement may be terminated by default if the Recipient fails to satisfy any of the following obligations under this agreement: Articles 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 6.1, 6.3, 7, 8, 9.1 and 9.3, 11.2 and 11.5.</p> <p>16.3 In the case of default the Provider may immediately terminate this agreement by giving written notice to the Recipient of the termination, provided that:</p> <p>a) the Provider has given prior notice to the Recipient of the alleged default; and</p> <p>b) the Recipient fails to respond to the Provider within the period specified by the notice (being not less than 20 business days and not more than 60 business days) to rectify or explain to the satisfaction of the Provider the reasons for the default.</p> <p>16.4 If this agreement is terminated under paragraph 2 of this Article the Recipient will not thereafter utilize or transfer the accessed genetic resources or use or transfer associated genetic knowledge; and it will transfer back to the Provider or destroy, at the Provider's discretion, all genetic resources or associated genetic</p>	<p><b>第 16 条 契約の終了</b></p> <p>16.1 本契約は、書面上で相互に合意したときはいつでも終了できる。</p> <p>16.2 本契約は、＜受領者＞が、本契約の以下のいずれかの義務を果たさない場合には、放棄により（？）終了することができる：4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 6.1, 6.3, 7, 8, 9.1, 9.3, 11.2, 11.5</p> <p>16.3 放棄の際には、＜提供者＞は＜受領者＞に対し、以下の条件のもと、書面による通知で本契約をすみやかに終了することができる：</p> <p>a) ＜提供者＞が、＜受領者＞に対し、いわゆる放棄について事前通知している；かつ、</p> <p>b) ＜提供者＞が事前通知において指定した期日（20 日以上 60 日以下）の間に＜提供者＞を納得させる放棄の理由を説明するための返答を行わない</p> <p>16.4 本契約が本条 2 段落（16.2？）の事情もの下で終了する場合、＜受領者＞はそれ以降アクセスした遺伝素材を利用及び移転したり、関連遺伝知識を利用あるいは移転したりできず、すべての遺伝譲歩または関連遺伝知識を＜提供者＞に返却するか、＜提供者＞の裁量のもとで破壊する。本条に定める操作については、契約終了後も有効とする。</p>

knowledge. The operation of this clause survives the termination of this agreement.	
(Location, Date) (Provider) (Recipient)	(場所、日時) <提供者> <受領者>

米国機関のアクセスと利益配分契約案

米国 NIH の標準秘密保持契約

米国 NIH の標準秘密保持契約

<p><b>CONFIDENTIAL DISCLOSURE AGREEMENT</b></p>	<p>秘密保持契約</p>
<p>This Agreement is made by and between the Public Health Service ("PHS"), through the Office of Technology Transfer at the National Institutes of Health, which is located at 6011 Executive Blvd., Suite 325, Rockville, MD 20852, and the company indicated below (hereinafter "Company").</p>	<p>この契約書は、米国国立衛生研究所の技術移転室の管理を通じて米国保健衛生省と下記記載企業の間で結ばれるものである。</p>
<p>In consideration of receiving for review from PHS a copy of the Patent Application(s) and Claims bearing the serial number(s) and title(s) indicated below (hereinafter "Application(s)"), Company agrees as follows:</p>	<p>米国保健衛生省の審査のために、出願番号と名前を記載した特許出願書類と特許請求項のコピーを受け取ることを想定して、企業は次の事項に同意する。</p>
<p>1. Company agrees not to disclose any portion of the Application(s) to any third party without prior written permission from PHS, shall use reasonable care to maintain the confidentiality of the Application(s) with at least the same degree of care as is exercised in respect of Company's own proprietary information, and shall disclose the Application(s) only to those of Company's employees who have a need to review the Application(s) for the</p>	<p>第1条 米国保健衛生省の書面による事前の許可なしに、第6項の書類のどの部分であっても、いかなる第三者に開示してはならない。企業自身の秘密保持方法と同様のレベルで当該書類の秘密保持を合理的に行わなければならない。下記第4条項で特定した目的のために、当該書類の審査を行う必要のある当該企業の従業員のみが開示することができる。</p>

<p>purposes specified in paragraph 4 below.</p>	
<p>2. The following information categories are excluded from the confidentiality obligation of Paragraph 1:</p> <p>a. Information that was known to Company about the Application(s) prior to their disclosure under this Agreement;</p> <p>b. Information about the Application(s) that is or becomes generally available to the public through no fault of Company;</p> <p>c. Information about the Application(s) that is subsequently made available to Company from any third party that is not under a confidentiality obligation to PHS.</p>	<p>第2条</p> <p>a. 本契約に基づく情報開示の以前に当該書類について当該企業が知っていた情報</p> <p>b. 当該企業の過失なしで公共に一般に利用可能であるかそのようになる当該書類に関する情報</p> <p>c. 米国保健衛生省の秘密保持義務のない第三者から当該企業に利用可能になりうる当該書類に関する情報</p>
<p>3. This Agreement does not grant any license rights under the Application(s).</p>	<p>第3条</p> <p>本契約は当該書類の基にあるいかなる特許権を付与するものではない。</p>
<p>4. Company represents that the purpose of requesting the Application(s) is only to assess interest in obtaining a license under the Application(s). Company further represents that its request for the Application(s) is not to form the basis for filing a patent application or instituting any other proceeding in any patent office or court. Company agrees not to use, copy, or disseminate the Application(s) or the information contained in the Application(s) except for the purposes, and under the specific</p>	<p>第4条</p> <p>当該企業は、当該書類の基でライセンスを得るという希望を評価するためにのみ当該書類を請求しているという目的を実行しなければならない。更に、当該企業は、当該書類の請求は特許出願するための基礎としないこと、あるいは特許審査機関や裁判所のあらゆる審査過程に用いるための基礎としないことを実行しなければならない。本契約書に記載されているように、特殊な条件下で、目的以外に当該書類やそ</p>

<p>circumstances, stated in this Agreement.</p>	<p>れに含まれる情報内容を使用したり、コピーしたり、広めたりしないことに合意する。</p>
<p>5. Company's obligations under this Agreement shall remain in effect for five (5) years from the date specified below. Upon termination or expiration of this Agreement, Company shall promptly return the Application(s) to PHS, or shall verify in writing to PHS that the Application(s) has been destroyed, with no copies retained.</p>	<p>第5条 本契約の基での当該企業の義務は、下記で特定した日付から5年間有効である。本契約の終了あるいは満了に伴い、当該企業は当該書類を米国保健衛生省に直ちに交換しなければならない。あるいは、当該書類を破壊し、コピーも廃棄していることを米国保健衛生省に文章で確認しなければならない。</p>
<p>Application(s): XXXX</p>	<p>当該書類の特定</p>
<p>UNDERSTOOD AND ACCEPTED BY COMPANY: COMPANY: _____ _____ _____ _____ _____ _____  By _____ _____ Authorized Signature  _____ _____</p>	<p>当該企業による同意と容認</p>

<p>Name</p> <p>_____</p> <p>_____</p> <p>Title</p> <p>_____</p> <p>_____</p> <p>Date</p>	
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NIH Office of Technology Transfer

CONFIDENTIAL DISCLOSURE AGREEMENT

940329 (updated 6-2010) -

米国国立衛生研究所癌研究所治療開発プログラムと提供国機関の覚書

米国国立衛生研究所癌研究所治療開発プログラムと提供国機関の覚書 (MOU)

<p>MEMORANDUM OF UNDERSTANDING BETWEEN SOURCE COUNTRY ORGANIZATION (SCO) AND THE DEVELOPMENTAL THERAPEUTICS PROGRAM DIVISION OF CANCER TREATMENT AND DIAGNOSIS NATIONAL CANCER INSTITUTE</p>	<p>提供国機関 (SCO) と NCI の治療開発プログラム (DTP) がん治療と診断部門 (DCTD) の間の覚書</p>
<p>The Developmental Therapeutics Program (DTP), Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI) is currently screening synthetic compounds and natural product materials derived from plants, marine macro-organisms and micro-organisms as potential sources of novel anticancer drugs. The DTP is the drug discovery program of the NCI which is an Institute of the National Institutes of Health (NIH), an arm of the Department of Health and Human Services (DHHS) of the United States Government. While investigating the potential of natural products in drug discovery and development, NCI wishes to promote the conservation and sustainable</p>	<p>DTP、DCTD、国立ガン研究所(NCI) は、現在、新規な制ガン剤の可能な起源として、植物、海洋のマクロ生物、および微生物から得られた自然生成物と合成品をスクリーニングしています。 DTP は、国立衛生研究所 (NIH)(合衆国政府の保健・福祉省 (DHHS)の下部機関)の内部一研究機関である NCI に属する創薬プログラムです。 創薬と開発で天然産物の可能性を探索している間、NCI は、生物学的多様性の保全と持続可能な利用を促進することを願っている。提供国の境界の中で集められた生物から発達した医薬品の商業化の場合、提供国組織と住民を補償する必要性がと認めます。</p>

<p>utility of biological diversity, and recognizes the need to compensate source country organizations and peoples in the event of commercialization of a drug developed from an organism collected within their countries' borders.</p>	
<p>DTP/NCI has an interest in investigating plants, terrestrial and marine micro-organisms and marine macro-organisms from [Source Country] and wishes to collaborate with the [Source Country Organization, SCO] in this investigation. DTP/NCI will make sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to [SCO] in [Source Country, SC] (as the agent appointed by the [Source Country] Government), subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. [SCO], in turn, desires to collaborate closely with the DTP/NCI in pursuit of the investigation of [Source Country]'s plants, terrestrial and marine micro-organisms and marine macro-organisms and selected synthetic compounds subject to the following conditions and stipulations of this Memorandum of Understanding (MOU). [SCO] will</p>	<p>DTP/NCI は、提供国の植物、陸上あるいは海洋の微生物やマクロ生物を調査するのに関心を持っている。そして、この調査で提供国と協力して作業する願望がある。DTP/NCI は、どのような特許で保護される技術に関連している知的財産の保護のための互いに許容できる保証の支給を条件として、提供国の SCO (提供国政府の任命した機関) で関連する、知識、専門的技術、および技術を移すための誠実な努力を行います。SCO は、本覚書 (MOU) の約款を条件として、提供国の植物、陸上および海洋のマクロ生物または微生物、選択された合成品の収集と処理において、密接に DTP/NCI と協力する願望を持っている。SCO は、適切に、陸上植物、海洋のマクロ生物または微生物を収集し、処理する。SCO は、収集の実施にあたって提供国のアクセス政策や事前同意要件を守るのに唯一責任があることを理解されている。NCI はそのような政策の SCO によるどんな違反に対する責任も全く担いません。</p>



<p>perform the collection and processing of terrestrial plants, marine macro-organisms or micro-organisms as appropriate. It is understood that the [SCO] will be solely responsible for abiding by all source country's access policies and requirements for prior informed consent in the performance of collections. The NCI bears no responsibility for any contravention of such policies by the [SCO].</p>	
<p>1) On the basis of in-house screening results in its anticancer screens, [SCO] may select both synthetic compounds and extracts of plants, marine macro-organisms and micro-organisms (subject to previously determined limits as to numbers per year) for anticancer testing at DTP/NCI. If suitable in-house screens are not available at [SCO], a list of available materials may be sent to DTP/NCI.</p>	<p>1) 制癌活性スクリーンの in-house 選別結果に基づいて、合成化合物と植物の抽出、海洋生物および微生物(1年あたりの数に関する以前の決定した限界を条件とした)の両方を、SCOはDTP/NCIでの制癌性のテストのために選択するかもしれません。適切な in-house スクリーンが SCO で利用可能でないなら、利用可能な材料のリストを DTP/NCI に送るかもしれません。</p>
<p>2) Prior to submission of the materials, [SCO] will send a data sheet, to be held in confidence by DTP/NCI, on each material so that DTP/NCI may check its databases for records of prior submission to DTP/NCI.</p>	<p>2) 材料の送付の前に、DTP/NCIの信頼のために、SCOが各材料に関するデータシートを送るので、DTP/NCIは、DTP/NCIへの以前の送付に関する記録のデータベースをチェックすることができる。</p>
<p>3) For pure compounds, the data</p>	<p>3) 純粋な化合物については、データ</p>

<p>sheet(s) will give pertinent available data as to chemical constitution, structure, available biological data including in-house screening results, solubility, toxicity and any precautions which need to be followed in handling, storage and shipping.</p> <p>For crude extracts, data will be provided as to the source organism taxonomy, location and date of collection, any hazards associated with the organism, available biological data and any known medicinal uses of the organism/extracts.</p>	<p>シートは化学組成、構造式に加え、in-house の選別結果、溶解度、毒性などの利用可能な生物学的データ、および取り扱い、保存、および出荷が必要があるどんな注意も含む適切で有効データを示す。</p> <p>生エキスについては、もとの生物の分類、収集場所、および収集の日付に関してデータを提供するでしょう。更に、生物に関連した有害物、生物あるいは抽出物の利用可能な生物学的データおよび既知の医学的用途に関するデータも提供される。</p>
<p>4) DTP will inform [SCO] which of the materials are new to the program, and such materials will be shipped to DTP for screening. DTP will provide a record of the accession number for the materials. Quantities of materials required for initial testing are 5 mg for pure compounds and 10 mg for crude extracts.</p>	<p>4) DTP は、材料のどれがプログラムにとって新しいかを SCO に知らせる。そして、スクリーニングのためにその材料を DTP に出荷される。DTP は材料の受入番号記録を提供する。最初のテストに必要な材料の量は、純粋な化合物の場合 5mg、生エキスの場合 10mg である。</p>
<p>5) a) Data provided by [SCO] will be considered as confidential information of [SCO], if so labeled, and will be held confidentially by DTP/NCI, unless the data are otherwise available from public sources. No confidential information</p>	<p>5) SCO によって提供されたデータは、そのようにラベルされると SCO の秘密情報であるとみなされる。さらに、公共のソースからデータを得ることができないなら、DTP/NCI によって秘密に保持される。SCO の非秘密情報は、全くそのすべてが、米国の</p>

<p>of [SCO] will be kept in files open to the public either by DTP/NCI, testing laboratories, or data processing facilities, all of which are U.S. government contractors. Only those employees directly engaged in the operation of DTP/NCI will have access to the files of information regarding the source and nature of confidential materials, unless the release of data about the materials is required under law or by court order. In the event of expiration of this agreement, the confidentiality of data provided by the [SCO] will be maintained.</p>	<p>政府委託機関である DTP/NCI、試験研究室、またはデータ処理施設によって公共に公開されたファイルとされる。材料に関するデータのリリースが法か裁判所命令によって要求されない限り、DTP/NCI の操作に直接従事している従業員だけが、機密資料ソースや性質に関する情報のファイルにアクセスする。この契約書が期限切れになったとしても、SCO によって供給されたデータの秘密性は保たれる。</p>
<p>b) All test results will be provided to [SCO] as soon as they are available, but not later than 270 days (nine months) from the date of receipt of the sample. If available, <i>in vitro</i> test results will be delivered within 90 days from receipt of the sample. [SCO] will be informed in writing of any delays beyond this period (270 days) together with an explanation of the reason(s) for delay.</p>	<p>b) 全てのテスト結果は得られ次第 270 日（9 か月）以内に SCO に供給される。可能ならば、<i>in vitro</i> のテスト結果はサンプルを入手してから 90 日以内に供給される。もし、270 日以上に遅れる場合はその理由説明と共に書類にて送られる。</p>
<p>c) Unless the release of test results is required under law or by court order, the parties will keep the test results and subsequently-developed data confidential until published in accordance with Article 15 or until corresponding patent applications</p>	<p>c) 試験結果の報告が法あるいは裁判所命令によって要求されない限り、当事者は、テスト結果とその後開発されたデータの機密性を、15 条に従った出版または第 9 に従った特許出願が提出されるまで、保持す</p>

<p>are filed in accordance with Article 9.</p>	<p>る。</p>
<p>6) Any extracts exhibiting significant activity will be further studied by bioassay-guided fractionation in order to isolate the pure compound(s) responsible for the observed activity. Such fractionation will be carried out in [SCO] laboratories. If [SCO] has no available bioassay, DTP/NCI may assist [SCO] to establish the necessary bioassay systems subject to the availability of the necessary resources. Alternatively, or in addition, suitably qualified designated [SCO] scientists may be sent to DTP/NCI for the isolation studies subject to the terms stated below in Article 7. In addition, DTP/NCI may assist the [SCO], thereby assisting the [Source Country], to develop the capacity to undertake drug discovery and development, including capabilities for the screening and isolation of active compounds from terrestrial and marine organisms.</p>	<p>6) 顕著な活性を示すどんな抽出物も、観察された活動の原因となる純粋な化合物を単利するためにバイオアッセイとリンクした分別法によってさらに研究される。そのような分別法は SCO の実験室で行われる。もし、SCO に利用可能なバイオアッセイがない場合、DTP/NCI は、必要な資源の有用性を条件として、SCO が必要なバイオアッセイ系を確立するのを補助します。あるいは、またはそれに追加して、適切に選ばれた SCO の研究者が、第 7 条に述べられた条件のもと、単離研究のために DTP/NCI に送られることができる。さらに、DTP/NCI は SCO を援助し、創薬と開発を実施する能力を開発するために提供国を援助します。それには、陸上あるいは海洋生物から活性のある化合物のスクリーニングと単離のための能力を含んでいる。</p>
<p>7) Subject to the provision that suitable laboratory space and other necessary resources are available, DTP/NCI agrees to consider inviting senior technician(s) and/or scientist(s) designated by [SCO] to work in the laboratories of DTP/NCI</p>	<p>7) 適当な実験室スペース他の必要なリソースは利用可能であることを条件として、DTP/NCI は、DTP/NCI の実験室、または、両者が合意するなら、この MOU のもとで更に進んだ研究を行うのに必要な技術を持つ実験室で、働くために SCO によって任命された</p>

<p>or, if the parties agree, in laboratories using technology which would be useful in furthering work under this MOU. The duration of such visits would not exceed one year except by prior agreement between [SCO] and DTP/NCI. The designated visiting scientist(s) will be subject to provisions usually governing Guest Researchers at NIH. Cost-sharing and other conditions of visits will be negotiated in good faith prior to the arrival of the visiting scientist(s).</p>	<p>経験豊富な技術者、そして/または、科学者を招待することに同意する。SCO と DTP/NCI の間にあらかじめ決めがない場合を除き、滞在時間は1年間を越えない。指定された訪問科学者は、NIH ではゲスト研究者を取り扱うのと同じ条件で取り扱う。訪問研究の費用の共同負担とその他の条件は、訪問科学者の到着前に誠実に交渉される。</p>
<p>8) In the event that an agent isolated and purified from materials provided by [SCO], and/or a synthetic compound provided by [SCO] meets the criteria established by the Drug Development Group (DDG) of NCI's DCTD (DTP's parent organization), which would include, but not be limited to, <i>in vivo</i> activity in rodent models, further development of the agent may be undertaken by DTP/NCI in agreement with the [SCO]. Further development of the specific agent may include but not be limited to analog development through medicinal and/or combinatorial chemistry, formulation, pharmacology and/or toxicology studies. Once an active agent is approved by DTP/NCI for preclinical development (<i>i.e.</i>, has passed the</p>	<p>8) SCO によって供給された材料から分離精製された化合物、そして/または、SCO によって提供された合成化合物が、NCI の DCTD(DTP の母体)の Drug Development Group(DDG)によって確立された評価基、例えば準齧歯動物モデルでの <i>in vivo</i> 活性やそれ以外の活性も含むが、SCO と合意の上、化合物の更なる開発は DTP/NCI によって行われるだろう。特別の化合物の更なる開発とは、メディシナルケミストリーとコンビナトリアルケミストリーによる類縁体の開発、剤型設計、薬理的あるいは毒性学的研究を含んでいる。活性のある化合物を前臨床開発へ前進させることを DTP/NCI によって承認されると、DTP/NCI は SCO の科学者とその活性のある化合物に開発を共同で行う。</p>

<p>DDG at Stage IIA), DTP/NCI may collaborate with [SCO] scientists in the development of the specific agent.</p>	
<p>9) Both [SCO] and DTP/NCI recognize that inventorship will be determined under patent law. DTP/NCI/NIH and [SCO] will, as appropriate, jointly seek patent protection on all inventions developed jointly under this MOU by DTP/NCI and [SCO] employees, and will seek appropriate protection abroad, including in [Source Country], if appropriate. Application for patent protection on inventions made by [SCO] employees alone will be the responsibility of [SCO]. Application for patent protection on inventions made by DTP/NCI employees alone will be the responsibility of DTP/NCI.</p> <p>With respect only to those compounds that have been determined to possess such significant anti-cancer potential as to be scheduled for clinical trials by DCTD, the U.S. Government shall have a royalty-free, irrevocable, nonexclusive license to manufacture and/or use by or for the U.S. Government the invention(s) claimed in any patents that [SCO] may have or may obtain on such compounds or on a process for use of such</p>	<p>SCO と DTP/NCI とともに、発明者適格を特許法の下で決定すると認める。DTP/NCI/NIH と SCO は、この MOU の下で、DTP/NCI と SCO の研究者の協力により開発された発明に、特許保護を共に求めます。更に提供国を含む海外での適切な特許保護を求めます。SCO の研究者が単独行った発明の特許保護出願は、SCO の責任になる。DTP/NCI の研究者だけで行った発明の特許保護出願は DTP/NCI の責任になる。</p> <p>DCTD によって臨床試験が想定できる程度まで重要な抗癌の可能性を持つと決定された化合物だけに関して、米国政府は、そのような化合物やその使用方法について、SCO が持つ特許に請求された発明に対して、米国政府自身が製造したり、あるいは/または、使用したりする、ロイヤリティーフリーで、最終的な通常実施権を持つ。しかしながら、このライセンスは、DTP/NCI やそのテスト研究室で作成されたデータに基づく SCO の特許にのみ適用される。このライセンスは、癌の化学療法に関連した、あるいは関連付けられる医学研究目的に限定される。ここで使用される「医学の研究目的」という用語は、臨床試験外の患者の治療、あるいは、化合物の商用分</p>

<p>compounds. However, this license will apply only to [SCO] patents that rely upon data generated by DTP/NCI or DTP/NCI testing laboratories. This license shall be only for medical research purposes related to or connected with the therapy of cancer. The term "medical research purposes" as used herein shall not include treatment of patients outside of clinical trials or commercial distribution of the compounds.</p>	<p>譲を含まないものとする。</p>
<p>10) DTP/NCI will make a sincere effort to transfer any knowledge, expertise, and technology developed during such collaboration in the discovery and development process to [SCO], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology.</p>	<p>1 0) 特許保護される技術に関連した知的財産の保護のための互いに許容できる保証条項を条件として、DTP/NCI は、SCO に、発見と開発過程で行った共同作業で開発した知識、ノウハウ、技術を移転するために誠実な取り組みを行う。</p>
<p>11) All licenses granted on any patents arising from the collaboration conducted under the terms of this MOU shall contain a clause referring to this MOU and shall indicate that the licensee has been apprised of this MOU.</p>	<p>1 1) この MOU に関する諸条件で行われた共同研究から生ずるどのような特許についてのライセンス契約には、この MOU を参照する条項を含んでおり、ライセンシーがこの MOU の存在を通告されたことを示すものとする。</p>
<p>12) Should an NCI/NIH patent on an agent discovered under this collaboration eventually be licensed</p>	<p>1 2) この共同作業で発見された化合物に関する NCI/NIH の特許が、更なる生産と販売のために製薬会</p>

to a pharmaceutical company for production and marketing, DTP/NCI will request that NIH/OTT require the licensee to negotiate and enter into agreement(s) with [SCO] and/or an appropriate [Source Country] Government agency(ies) within twelve (12) months from the execution of said license. The agreement(s) will address the concern on the part of the [Source Country] government that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.

Such terms will apply equally to inventions directed to a direct isolate from a natural product material, a product structurally based upon an isolate from the natural product material, a synthetic material for which the natural product material provided a key development lead, a derivative of a synthetic compound provided by [Source Country] or [SCO], or a method of synthesis or use of any aforementioned isolate, product, material or derivative; though the percentage of royalties negotiated as payment might vary depending upon the relationship of the marketed drug to the originally isolated product. It is understood that the eventual development of a drug to the stage of marketing is a long term process which may require

社にライセンスされる場合、ライセンスの実行から 12 カ月以内に、SCO あるいは/または提供国政府の適切な代理者と交渉し協定関係に入るよう NIH/OTT がライセンシーに要求することを、DTP/NCI が要望する。提供国政府の一部として、適切な政府機関、研究所、そして/または、個人がロイヤリティとその他の形の補償を適宜受けるということとその協定は記載していなければならない。

そのような条項は、天然産物からの直接分離物、天然産物からの分離物の構造から派生した化合物、天然産物が開発リード化合物のもととなった合成化合物、提供国が SCO によって供給された合成化合物の派生物、合成方法、そのような化合物の使用法などに等しく適用される。ただし、市販される医薬品と最初に分離された化合物の関係により、ロイヤリティのパーセントは異なる。市場導入のための化合物の開発は、10-15 年を必要とする長期の過程であることが理解されなければならない。



10-15 years.	
<p>13) In obtaining licensees, DTP/NCI/NIH will require the applicant for license to seek as its first source of supply the natural products available from [Source Country]. If no appropriate licensee is found who will use natural products available from [Source Country], or if [SCO] or their suppliers cannot provide adequate quantities of raw materials at a mutually agreeable fair price, the licensee will be required to pay to the [Source Country] Government or [SCO] as appropriate, compensation (to be negotiated) to be used for expenses associated with cultivation of medicinal organisms that are endangered or for other appropriate conservation measures. These terms will also apply in the event that the licensee begins to market a synthetic material for which a material from [Source Country] provided a key development lead.</p>	<p>1 3) ライセンシーを取得することで、DTP/NCI/NIH は、ライセンス申請者に対して、提供国で利用可能な天然物質の最初の供給国するよう求める。提供国で利用可能な天然物質を使う適切なライセンシーが見つからない場合、または、提供国やその供給者が、相互に同意できる公正な価格で原料の十分な量を提供することはできない場合、ライセンシーは、提供国又は SCO の適切な方に、補償（交渉可能）を支払うことを要求される。補償は、危険にさらされた医療用生物の栽培とその他適切な保全措置に付随する費用に使われる。これらの条項は、ライセンシーが、提供国が供給した物質が主要な開発リードとなった合成化合物を市場で販売する場合にも適用される。</p>
<p>14) Article 13 shall not apply to organisms which are freely available from different countries (i.e., common weeds, agricultural crops, ornamental plants, fouling organisms) unless information indicating a particular use of the organism (e.g., medicinal,</p>	<p>1 4) 第 13 条は、生物がほかの国（例えば、ありふれた雑草、農産物、鑑賞用植物、汚損生物）でも自由に利用可能な場合は適用されない。ただし、その生物の特別の用途に関する情報が地域住民によって得られ、提供国のその生物を収集するガイドをしてくれ</p>

<p>pesticidal) was provided by local residents to guide the collection of such an organism from [Source Country], or unless other justification acceptable to both [SCO] and DTP/NCI is provided. In the case where an organism is freely available from different countries, but a phenotype producing an active agent is found only in [Source Country], Article 13 shall apply.</p>	<p>た場合や、SCO と DTP/NCI の両方に許容できる他の正当な理由が提供されない場合、第 13 条は適用される。生物が異なった国から自由に利用可能ですが、活性化化合物を生産する表現型が、提供国でしかみつけることができないときは、第 13 条は適用される。</p>
<p>15) Publication of data resulting from the collaboration under this MOU will be undertaken at times determined by agreement between [SCO] and DTP/NCI. Before either party submits a paper or abstract for publication, the other party shall have sixty (60) days to review and as necessary, file a patent application in accordance with Article 9.</p>	<p>1 5) この MOU の下に共同研究から生じるデータの公表は、SCO と DTP/NCI の間の申し合わせで決まった時に実施される。何れの当事者が公表のために論文か要約を提出する前に、他方は、レビューを行い、必要ならば第 9 条に従って、特許出願するための 60 日間を保持する。</p>
<p>16) It is the intention of NCI that [SCO] not be liable to DTP/NCI for any claims or damages arising from NCI's use of the material provided by [SCO]; however, no indemnification for any loss, damage, or liability is intended or provided by any party under this MOU. Each party shall be liable for any loss, claim, damage or liability, that said party incurs, as a result of said party's activities under this MOU, except that the NCI, as an</p>	<p>1 6) SCO によって供給された物質の NCI の使用から生ずるクレームや損害に対して SCO は DTP/NCI に責任を負わせるべきではないというのが NCI の意図である。しかしながら、どんな損失、損害のための補償や責任は、この MOU の下でどんな当事者によって意図するか、または提供されることはない。各当事者は、この MOU の下で行った活動の結果、それぞれの当事者が受けたどんな損失や負債、クレームや損害に責任をおうべきであ</p>

<p>agency of the United States, assumes liability only to the extent as provided under the Federal Tort Claim Act (28 U.S.C. § 171).</p>	<p>る。合衆国の政府機関のひとつとして、連邦政府の Tort Claim 条例(28 米国 C. § 171)に基づき、NCI の責任の範囲は限定される。</p>
<p>17) DTP/NCI and its relevant contractors will not distribute materials provided by [SCO] to other organizations without written authorization from [SCO]. However, should [SCO] wish to consider collaboration with organizations selected by NCI for distribution of materials acquired through NCI collection contracts, DTP/NCI will establish contact between such organizations and [SCO].</p>	<p>1 7) DTP/NCI とその委託契約者は、SCO 承認書なしで SCO から提供された材料を他の組織に分譲することはない。しかしながら、NCI の委託収集者を通じて入手した試料の分譲に関して、SCO が NCI によって選択された組織と共同研究を考慮することを望むならば、収集契約を通して入手された材料の分配のために NCI によって選択される組織との共同作業を考えたいなら、DTP/NCI は、そのような組織と SCO の間の接触を確立する。</p>
<p>18) [SCO] scientists and their collaborators may screen additional samples of the same materials for other biological activities and develop them for such purposes independently of this MOU.</p>	<p>1 8) SCO の研究者とその協力者は他の生物活性のために同じ材料に関する追加サンプルをスクリーニングして、この MOU の如何にかかわらず、他の目的のためにそれらを開発することができる。</p>
<p>19) With the exception of Articles 1-4 and 6, all other Articles shall survive the expiration of this Agreement or its termination by the [Source Country] or [SCO]. Subsequent compounds and/or extracts may be submitted under the appropriate DTP/NCI mechanism and agreement.</p>	<p>1 9) 第 1 から第 4 条と第 6 条を除いて、他のすべての条項はこの契約の満了した後でも、また、提供国か SCO によるこの契約の終了した後でも、有効である。適切な DTP/NCI メカニズムと協定に従って、その後の化合物、そして/または、抽出が提出されるかもしれない。</p>

<p>This MOU shall be valid as of the date of the final authorized signature below for an initial period of five (5) years, after which, it can be renewed by mutual agreement. It may be amended at any time subject to the written agreement of both parties. Copies of such amendments will be kept on file at both of the addresses indicated below. [SCO] and DTP/NCI are confident that this MOU will lay the basis for a mutually successful cooperation in discovering and developing new therapies in the treatment of cancer.</p>	<p>以下の最終的なご署名の日付付けで、このMOUは5年間の間、有効になる。その後、相互の合意により延長できる。本契約書は、双方の合意文書をもっていつでも修正できる。そのような修正文書のコピーは、以下で示されたアドレスにある両方の場所に保管される。SCOとDTP/NCIは、このMOUが癌治療で新しい療法を発見して、開発することへの相互の良好な協力の基礎を築くと確信している。</p>
<p><b>For the [SCO]:</b></p> <p><b>Name</b></p> <p><b>Date</b></p> <p>mailing and contact address:</p>	
<p><b>For the National Cancer Institute:</b></p> <p>Andrew C. von Eschenbach, M.D.</p> <p>Director, National Cancer Institute</p> <p>Date</p>	

mailing and contact address:

Technology Transfer Branch

National Cancer Institute at  
Frederick

NCI-Frederick

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米国癌研究所遺伝資源収集合意書

米国癌研究所遺伝資源収集合意書 (LOC)

米国国立癌研究所遺伝資源収集合意契約

LETTER OF COLLECTION AGREEMENT (LOC)

<p><b><u>Agreement Between</u></b> <b><u>[Source Country Organization,</u></b> <b><u>SCO]</u></b></p> <p><b><u>and</u></b></p> <p><b><u>the Developmental Therapeutics</u></b> <b><u>Program Division of Cancer</u></b> <b><u>Treatment and Diagnosis</u></b> <b><u>National Cancer Institute</u></b></p>	<p>[提供国機関]と米国国立衛生研究所癌研究所癌治療診断部門開発治療プログラムとの遺伝資源収集合意書</p>
<p>The Developmental Therapeutics Program (DTP), Division of Cancer Treatment and Diagnosis (‘DCTD’), National Cancer Institute (NCI) is currently investigating plants, micro-organisms, and marine macro-organisms as potential sources of novel anticancer drugs.</p>	<p>米国国立衛生研究所の国立がん研究所 (NCI) がん診断治療部治療開発プログラム (DTP-DCTD) は、新規抗がん医薬品の材料として、植物、微生物、海洋微生物を調査研究している。</p>
<p>The DTP is the drug discovery program of the NCI which is an Institute of the National Institutes of Health (NIH), an arm of the Department of Health and Human Services (DHHS) of the United States Government.</p>	<p>DTP は、米国政府の保健福祉省 (DHHS) の一部門である国立衛生研究所 (NIH) の、下部研究機関である国立がん研究所における化合物探索プログラムである。</p>
<p>While investigating the potential of natural products in drug discovery and development, NCI wishes to promote the conservation and sustainable utility of biological diversity, and recognizes</p>	<p>医薬品探索開発に自然産物の能力を探索するにあたり、[提供国]の国内で収集された生物から開発した医薬品の商用化の際には、[提供国]の組織や関係者への代償の必要性があ</p>

<p>the need to compensate [Source Country, SC] organizations and peoples in the event of commercialization of a drug developed from an organism collected within their country's borders.</p>	<p>ることを理解している。</p>
<p>As part of the drug discovery program, DTP has contracts with various organizations for the collection of plants, micro-organisms and marine macro-organisms worldwide.</p>	<p>創薬探索プログラムの一環として、DTP は世界の植物、微生物、海洋微生物の収集のために、様々な組織と契約を締結している。</p>
<p>DTP has an interest in investigating plants, micro-organisms and marine macro-organisms from [Source Country], and wishes to collaborate with the [Source Country Government (SCG) or Source Country Organization(s) (SCO)] as appropriate in this investigation.</p>	<p>DTP は[提供国]の植物、微生物、海洋微生物を探索することに興味を持っており、[提供国政府]あるいは[提供国の組織]と必要に応じて共同で調査をすることを望んでいる。</p>
<p>The collection of plants, micro-organisms and marine macro-organisms will be within the framework of the collection contract between the NCI and the NCI Contractor [Contractor] which will collaborate with the appropriate agency in the [SCG or SCO].</p>	<p>植物、微生物、海洋微生物の収集は、[提供国政府あるいは組織]の適切な当局と協力関係にある NCI の請負人と NCI の間の収集契約の枠組みの中で行われる。</p>
<p>The NCI will make sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to the [appropriate Source Country Organization (SCO)] in [Source Country] as the agent appointed by the [SCG or SCO], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with</p>	<p>NCI は、薬剤の発見と開発に関連する知識、ノウハウ、及び技術を、[提供国政府あるいは組織]の任命する代理人として、[提供国]の[提供国の適切な機関]に移転するために、誠意をもって努力する。ただし、特許化した技術に関連した知的財産の保護についての、相互に容認できる保証規定に従うことを条件とする。[提供国政府あるいは組織]は、同様に、自</p>

<p>any patented technology. The [SCG or SCO], in turn, desires to collaborate closely with the DTP/NCI in pursuit of the investigation of its plants, micro-organisms and marine macro-organisms, subject to the conditions and stipulations of this agreement.</p>	<p>国の植物、微生物、海洋微生物などの研究を追求する際に、本契約の条件と条項にしたがって、DTP/NCI と密に共同研究を行うことを希望する。</p>
<p>A. The role of DTP, DCTD, NCI in the collaboration will include the following:</p> <p>1) DTP/NCI will screen the extracts of all plants, micro-organisms and marine macro-organisms provided from [Source Country] for anticancer activity, and will provide the test results to [SCO] on an annual basis. Such results will be channeled via Contractor.</p>	<p>A. 本共同研究における DTP、DCTP、NCI の役割は、以下を含む：</p> <p>1) [提供国]から提供されたすべての植物、微生物、海洋微生物の抽出物について、抗がん作用をスクリーニングし、試験結果を[提供国機関]へ年に一度提供する。これらの結果は、請負人を通じて渡される。</p>
<p>2) The parties will keep the test results and subsequently-developed data confidential until approved for publication by the parties. Before either party submits a paper or abstract containing test results for publication, the other party shall have 60 days to review and, as necessary file a sole or joint patent application in accordance with Article 6.</p>	<p>2) 両当事者は、試験結果及びそこから明らかになるデータを、当事者による出版が承認されるまで秘密にしておかなければならない。一方当事者が試験結果を含む論文や抄録を出版のために投稿する前には、他の当事者は 60 日の間検討、及び必要に応じて第 6 条に従い単独あるいは共同での特許出願を申し立てることができる。</p>
<p>3) Any extracts exhibiting significant activity will be further studied by bioassay-guided fractionation in order to isolate the pure compounds(s) responsible for the observed activity. Since the relevant bioassays are only available at DTP/NCI, such fractionation will be carried out in</p>	<p>3) 有意な活性を示す抽出物はいずれも、観察された活性の原因となる純粋化合物を単離するために、さらなるバイオアッセイ（生物検定）による分別を行う。関連するバイオアッセイは DTP/NCI においてのみ可能なため、これらの分別は DTP/NCI の研究室で行われる。[提供国機関]</p>



<p>DTP/NCI laboratories. A suitably qualified scientist designated by [SCO] may participate in this process subject to the terms stated in Article 4. In addition, in the course of the contract period, DTP/NCI will assist the [SCO], thereby assisting the [Source Country], to develop the capacity to undertake drug discovery and development, including capabilities for the screening and isolation of active compounds from plants, micro-organisms and marine organisms.</p>	<p>の指定した、適切な資格を有する科学者が、第4条の条件に従って、本プロセスに参加することができる。さらに、契約期間中、DTP/NCIは、植物、微生物、海洋微生物から活性化化合物をスクリーニング及び単離する能力を含め、薬剤の発見や開発を行う能力の開発に際し、[提供国機関]を、よって[提供国]を支援する。</p>
<p>4) Subject to the provision that suitable laboratory space and other necessary resources are available, DTP/NCI agrees to invite a senior technician or scientist designated by [SCO] to work in the laboratories of DTP/NCI or, if the parties agree, in laboratories using technology which would be useful in furthering work under this agreement. The duration of such visits would not exceed one year except by prior agreement between [SCO] and DTP/NCI. The designated visiting scientist(s) will be subject to provisions usually governing Guest Researchers at NIH. Salary and other conditions of exchange will be negotiated in good faith. Costs and other conditions of visits will also be negotiated in good faith prior to the arrival of the visiting scientist(s).</p>	<p>4) 適切な研究室の場所及び他の必要な資源が入手可能であるという条項に従い、DTP/NCIは、[提供国機関]が指定する上級の技術者あるいは科学者がDTP/NCI内の研究室で、あるいはもし両当事者らが合意するのであれば、本契約に基づく作業を推し進めるのに役立つ技術を利用している研究室で働くため、招聘することに合意する。彼らの滞在期間は、[提供国機関]とDTP/NCIの間で事前の合意がある場合を除き、1年を超えないものとする。指定された招聘科学者(ら)は、NIHの、主に客員研究員のための規則に従う。給与及び他の交換条件は誠意をもって交渉する。費用及び招聘に係る他の条件についても、招聘研究者(ら)の到着前に、誠意をもって交渉する。</p>
<p>5) In the event of the isolation of a promising agent from a plant,</p>	<p>5) [提供国]で採取した植物、微生物、海洋微生物から有望な物質を単離し</p>

<p>micro-organism or marine macro-organism collected in [Source Country], further development of the agent will be undertaken by DTP/NCI in collaboration with [SCO]. Once an active agent is approved by the DTP/NCI for preclinical development, [SCO] and the DTP/NCI will discuss participation by SCO scientists in the development of the specific agent. The DTP/NCI will make a sincere effort to transfer any knowledge, expertise, and technology developed during such collaboration in the discovery and development process to [SCO], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology.</p>	<p>た際には、DTP/NCI は[提供国機関]と共同で、その物質のさらなる開発を行う。活性物質が前臨床開発のために DTP/NCI に承認された場合、[提供国機関]及び DTP/NCI は、特定の物質の開発における[提供国機関]の科学者の参加について話し合う。DTP/NCI は、発見と開発の過程において共同研究の間に開発された知識、ノウハウ、技術を、[提供国機関]に伝達するために誠実な努力をし、すべての特許化された技術に関連する知的財産の保護のための、相互に受け入れ可能な約束についての規定に従う。</p>
<p>6) DTP/NCI/NIH will, as appropriate, seek patent protection on all inventions developed under this agreement by DTP/NCI employees alone or by DTP/NCI and [SCG or SCO] employees jointly, and will seek appropriate protection abroad, including in [Source Country], if appropriate. All resulting patent applications and patents shall be assigned to the U.S. Department of Health and Human Services and managed by NIH. Under current NIH policy, all inventors of such assigned patents may receive royalties in accordance with said NIH policy for any royalty-bearing license(s) for these patent(s).</p>	<p>6) DTP/NCI/NIH は、DTP/NCI の職員のみが、あるいは DTP/NCI と [提供国政府あるいは提供国機関]の職員が共同で、本契約の下で開発したあらゆる発明についての知的財産に関し、必要に応じて保護を求める。そして、可能であれば、[提供国]も含めた海外での適切な保護も求める。結果として生じたすべての特許出願及び特許は、米国保健福祉省に帰属し、NIH によって管理される。現在の NIH の方針の下では、譲渡された特許の発明者はすべて、ロイヤルティが発生する特許については、当該 NIH 方針に従ってロイヤルティを受け取ることができる。</p>

<p>7) All licenses granted on any patents resulting from this collaboration shall contain a clause referring to this agreement and shall indicate that the licensee has been apprised of this agreement.</p>	<p>7) この共同研究によって生じた特許から得られたライセンスはすべて、本契約について言及した条項を含むこととし、ライセンシーは本契約について知らされていることを明示する。</p>
<p>8) Should an agent derived from an organism collected under the terms of this agreement eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI will request that NIH/OTT require the successful licensee to negotiate and enter into agreement(s) with the appropriate [SCG] agency(ies) or [SCO] within twelve (12) months from the execution of said license. This agreement(s) will address the concern on the part of the [SCG or SCO] that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.</p>	<p>8) 本契約の条項の下で採取された組織から生じた物質が製品化や市場出荷のために製薬会社にライセンスされた場合には、DTP/NCI は、NIH/OTT が成功を収めたライセンシーに対して、当該ライセンスの実施から（12）ヶ月以内に、[提供国政府]の適切な部局あるいは[提供国機関]と交渉し、契約を締結することを求めるよう、要求する。この契約は、[提供国政府あるいは提供国機関]の側で、関連する部局、機関及び／あるいは人々が、必要に応じてロイヤルティあるいは他の形での補償を受けるよう対応する。</p>
<p>9) The terms of Article 8 shall apply equally to inventions directed to a direct isolate from a natural product material, a product structurally based upon an isolate from the natural product material, a synthetic material for which the natural product material provided a key development lead, or a method of synthesis or use of any aforementioned isolate, product or material; though the percentage of royalties negotiated as payment might vary depending upon the relationship of the marketed drug to the originally</p>	<p>9) 第8条の条件は、天然生成物からの直接単離物、天然生成物からの単離物の構造的に基づく物質、天然生成物が開発の鍵となる合成物質、あるいは上述の単離物、生成物あるいは物質の合成方法や利用を対象とした発明に対しても、同様に適用される。ただし、支払いとして交渉されたロイヤルティの割合は、商品化された薬剤と元来の単離物質との関係によって異なる。薬剤の商品化の段階への最終的な開発には、10～15年という長期の過程が必要であることが認識されている。</p>

<p>isolated product. It is understood that the eventual development of a drug to the stage of marketing is a long term process which may require 10- 15 years.</p>	
<p>10) In obtaining licensees, the DTP/NCI/NIH will require the license applicant to seek as its first source of supply the natural products from [Source Country]. If no appropriate licensee is found that will use natural products available from [Source Country], or if the [SCG] or [SCO] as appropriate, or its suppliers cannot provide adequate amounts of raw materials at a mutually agreeable fair price, the licensee will be required to pay to the [SCG] or [SCO] as appropriate, compensation (to be negotiated) to be used for expenses associated with cultivation of medicinal organisms that are endangered or for other appropriate conservation measures. These terms will also apply in the event that the licensee begins to market a synthetic material for which a material from [Source Country] provided a key development lead.</p>	<p>10) ライセンシーを得る際には、DTP/NCI/NIH は申請者に対して、[提供国]からの天然生成物を一次的な供給源として求めることを要請する。[提供国]から入手可能な天然生成物を利用する適切なライセンシーが見つからない場合、あるいは[提供国政府]、[提供国機関]、またはその提供者が、相互に合意できる公正な価格で十分な量の原材料を供給できない場合、ライセンシーは、絶滅の危機にある薬用生物の培養のための経費、あるいは他の適切な保全手段のために用いる補償（交渉の余地あり）を、必要に応じて[提供国政府]あるいは[提供国機関]に支払うことが求められる。これらの条件は、ライセンシーが[提供国]由来の物質が開発主導の鍵となるような合成物質を市販し始めた時にも適用される。</p>
<p>11) Article 10 shall not apply to organisms which are freely available from different countries (i.e., common weeds, agricultural crops, ornamental plants, fouling organisms) unless information indicating a particular use of the organism (e.g., medicinal, pesticidal) was provided by local residents to guide the collection of such</p>	<p>11) 他の国々で自由に利用できる生物（すなわち、一般的な海藻、農作物、鑑賞植物、汚損生物）に対しては、[提供国]由来の当該生物の採取を指導した地元住民が、それらの生物の特定の利用法（例：医療用、殺虫用）を示すような情報を提供しない限り、あるいは[提供国政府]あるいは[提供国機関]及びDTP/NCIの両方</p>

<p>an organism from [Source Country], or unless other justification acceptable to both the [SCG or SCO] and the DTP/NCI is provided. In the case where an organism is freely available from different countries, but a phenotype producing an active agent is found only in [Source Country], Article 10 shall apply.</p>	<p>が受け入れ可能な他の理由がない限り、第 10 条の規定は適用されない。ある生物が他の国々で自由に利用できるが、活性物質を産生する表現型のもは[提供国]のみに存在する場合、第 10 条は適用される。</p>
<p>12) DTP/NCI will test any pure compounds independently submitted by the [SCG or SCO] scientists for antitumor activity, provided such compounds have not been tested previously in the DTP/NCI screens. If significant antitumor activity is detected, further development of the compound may, as appropriate, be undertaken by DTP/NCI in consultation with the [SCG or SCO]. Should an NCI/NIH patent on an agent derived from the submitted compound(s) eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI will request that NIH/OTT require the successful licensee to negotiate and enter into agreement(s) with the appropriate [SCG agency(ies) or SCO] within twelve (12) months from the execution of said license. This agreement will address the concern on the part of the [SCG or SCO] that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.</p>	<p>12) DTP/NCI は、[提供国政府あるいは提供国機関]の科学者から自主的に提出されたあらゆる純粋な化合物について、それらが過去に DTP/NCI によるスクリーニングを受けていない場合には、抗腫瘍作用についての試験を行う。有意な抗腫瘍作用が検出されたときには、[提供国政府あるいは提供国機関]と協議の上、必要に応じて DTP/NCI によって当該化合物の更なる開発が行われる。提出された化合物由来の物質の NCI/NIH の特許が、最終的に製品化や市場出荷のために製薬会社にライセンスされた場合には、DTP/NCI は、NIH/OTT が成功を収めたライセンシーに対して、当該ライセンスの実施から (12) ヶ月以内に、[提供国政府]の適切な部局あるいは[提供国機関]と交渉し、契約を締結することを求めるよう、要求する。この契約は、[提供国政府あるいは提供国機関]の側で、関連する部局、機関及び／あるいは人々が、必要に応じてロイヤルティあるいは他の形での補償を受けるよう対応する。</p>

<p>13) DTP/NCI may send selected samples to other organizations for investigation of their anti-cancer, anti-HIV or other therapeutic potential. Such samples will be restricted to those collected by NCI contractors unless specifically authorized by the [SCG or SCO]. Any organization receiving samples must agree to compensate the [SCG or SCO] and individuals, as appropriate, in the same fashion as described in Articles 8-10 above, notwithstanding anything to the contrary in Article 11.</p>	<p>13) DTP/NCI は、抗癌、抗 HIV、あるいは他の治療可能性についての調査のために、選抜されたサンプルを他の機関に送ることができる。これらのサンプルは[提供国政府あるいは提供国機関]に特に許可された場合を除き、NCI 請負人によって採取されたものに限られる。サンプルを受領した機関はいずれも、[提供国政府あるいは提供国機関]及び個人に対し、第 11 条の別段の定めにかかわらず、上記第 8～10 条で述べたのと同様の方法で補償をすることに同意する。</p>
<p>B. The role of the Source Country Government (‘SCG’) or Source Country Organization(s) (‘SCO’) in the collaboration will include the following:</p> <p>1) The appropriate agency in [SCG or SCO] will collaborate with Contractor in the collection of plants, microorganisms and marine macro-organisms, and will work with Contractor to arrange the necessary permits to ensure the timely collection and export of materials to DTP/NCI.</p>	<p>B. 本共同研究における提供国政府 (SCG) あるいは提供国機関 (SCO) の役割は、以下を含む：</p> <p>1) 植物、微生物、海洋微生物の採取において、[提供国政府あるいは提供国機関] の適切な部局が請負人と協力し、請負人とともに、時宜を得た資料の採取及び DTP/NCI への輸出を確実にするために必要な許可を手配する。</p>
<p>2) Should the appropriate agency in [SCG or SCO] have any knowledge of the medicinal use of any plants, microorganisms and marine macro-organisms by the local population or traditional healers, this information will be used to guide the collection of plants, micro-organisms or marine macro-organisms on a priority</p>	<p>2) [提供国政府あるいは提供国機関] の適切な部局が、植物、微生物、海洋微生物の医学的利用について何らかの知識を有している場合、その情報は植物、微生物、海洋微生物の採取指導のために、可能であれば優先的に利用する。適切な抽出物を作ることが可能にするのに適用可能であれば、伝統的なヒーラーの用いてい</p>

<p>basis where possible. Details of the methods of administration (e.g., hot infusion, etc.) used by the traditional healers will be provided where applicable to enable suitable extracts to be made. All such information will be kept confidential by DTP/NCI until both parties agree to publication. The permission of the traditional healer or community will be sought before publication of their information, and proper acknowledgment will be made of their contribution.</p>	<p>る投与方法の詳細（例：hot infusion 高温浸出？）についても提供される。これらの情報はすべて、両当事者が出版に合意するまで、DTP/NCIによって秘密が保持される。伝統的ヒーラーやコミュニティの情報について出版する際には、事前に彼らの許可を求め、彼らの貢献について適切に謝辞を述べるものとする。</p>
<p>4) In the event of large amounts of raw material being required for production, the appropriate agency of the [SCG or SCO] and Contractor will investigate the mass propagation of the material in [Source Country]. Consideration should also be given to sustainable harvest of the material while conserving the biological diversity of the region, and involvement of the local population in the planning and implementation stages.</p>	<p>4) 製品化のために大量の原材料が必要となった場合には、[提供国政府あるいは提供国機関]の適切な部局及び請負人は、当該材料の[提供国]内での大量繁殖について調査を行う。原料の持続的な収穫の一方で、当該地域の生物多様性の保全、及び実行段階における地元の人々との関与についても考慮しなければならない。</p>
<p>5) [SCG or SCG] and SCO scientists and their collaborators may screen additional samples of the same raw materials for other biological activities and develop them for such purposes independently of this agreement.</p>	<p>5) [提供国政府]及び[提供国機関]の科学者及び共同研究者は、同一の原料物質由来の追加の標本を、本契約から独立して、他の生物活性のスクリーニングやそのための開発に利用することができる。</p>
<p>This agreement shall be valid as of the date of the final authorized signature below for an initial period of five (5) years, after which it can be renewed by mutual agreement. It may be amended</p>	<p>本契約は、以下に最終的な正式の署名がなされた日に発効し、最初の期限は（5）年間、その後は相互の合意により更新される。両当事者の書面での合意により、いつでも修正が</p>

<p>at any time subject to the written agreement of both parties. Copies of such amendments will be kept on file at both of the addresses indicated below.</p>	<p>可能である。これら修正事項のコピーは、以下に示された両方の住所の下で保管する。</p>
<p>For the National Cancer Institute:  _____  Name (typed): _____  Director, National Cancer Institute  Date _____  mailing and contact address:  Technology Transfer Branch National Cancer Institute at Frederick, Fairview Center, Suite 502 1003 - W. 7th Street  Frederick, Maryland 21701-8512 U.S.A.  Telephone: 301-846-5465  Facsimile: 301-846-6820</p>	<p>国立癌研究所：  _____  氏名（タイプすること）：  _____  国立癌研究所所長  日時 _____  住所： 国立癌研究所技術移転部門  Frederick, Fairview Center, Suite 502 1003 - W. 7th Street  Frederick, Maryland 21701-8512 U.S.A.  電話番号： 301-846-5465  FAX 番号： 301-846-6820</p>
<p>For [SCI] or [SCO]:  Title: _____  Date _____  mailing and contact address: _____</p>	<p>[提供国政府]あるいは[提供国機関]  職位: _____  日時 _____  住所: _____</p>



**MEMORANDUM OF UNDERSTANDING BETWEEN THE  
GOVERNMENT OF SAMOA AND THE REGENTS OF THE  
UNIVERSITY OF CALIFORNIA, BERKELEY FOR DISPOSITION  
OF FUTURE REVENUE FROM LICENSING OF PROSTRATIN  
GENE SEQUENCES, AN ANTI-VIRAL MOLECULE**

(13 August 2004)

<p><b>I. Preamble</b></p> <p>This Memorandum of Understanding, effective as of the date of final signature, is undertaken by the government of Samoa (“Samoa”), a sovereign nation, and The Regents of the University of California, Berkeley acting through its Office of Technology Licensing at the University of California, Berkeley at 2150 Shattuck Ave., Suite 510, Berkeley, CA 94720-1620 (“UC Berkeley”).</p> <p>Samoa is an island nation whose people for thousands of years have faithfully accumulated and transmitted from generation to generation knowledge about the healing properties of their island plants. With permission of the Samoan government, the Chiefs and Orators of Falealupo village (such permission later formalized as the</p>	<p><b>I. 前文</b></p> <p>本覚書は、最終署名日に発効し、主権国家であるサモアの政府（以下、「サモア」とする）と、カリフォルニア大学バークレー校の理事（以下、「UCバークレー」とする）が、2150 Shattuck Ave., Suite 510, Berkeley, CA 94720-1620にある同校の技術移転事務所を介して取り交わされた。</p> <p>サモアは島国であり、人々は島の植物の治癒性についての知識を、数千年にわたって代々忠実に蓄積し、伝えてきた。1984年、ポール・アラン・コックス博士はサモア政府、ファレアルポ村の長及び演説家（、ヒーラーのEpenesa Mauigoa氏及びPela Lilo氏の許可を得て（ファレアルポによる許可は後に、ファレアルポ契約として正式化された）サモアの薬用植物の調査を開始し、サモアのママラの木 (<i>Homalanthus nutans</i>) から単離されたプロストラチンに抗ウィルス機能があることを発見した。先住民の知的財産及びママラ</p>
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<p>Falealupo Covenant), and healers Epenesa Mauigoa and Pela Lilo, in 1984 Paul Alan Cox, Ph.D. began research on Samoan medicinal plants, which culminated in the discovery of the anti-viral properties of prostratin, isolated from the Samoan <i>mamala tree</i>, <i>Homalanthus nutans</i>. Both the indigenous intellectual property and the genetic material of the mamala tree are part of the national sovereignty of Samoa, as recognized by Samoan custom, Samoan law, and the Convention on Biodiversity.</p> <p>UC Berkeley is one of the world's leading universities. For more than a century it has invested millions of dollars in laboratories, laboratory equipment, faculty recruitment, and the training of faculty and students, including that of Paul Alan Cox, Ph.D. who was a Miller Research Fellow at the Miller Institute for Basic Research in Science from 1981 - 1983. Part of the training Dr. Cox received at UC Berkeley helped prepare him to do ethnobotanical research and to identify the Samoan <i>mamala tree</i>, <i>Homalanthus nutans</i>, as of significant biological interest.</p> <p>This agreement sets forth an understanding between Samoa and UC Berkeley regarding the future distribution of revenue from UC</p>	<p>の木の遺伝物質は、いずれもサモアの習慣や法律、生物多様性条約によって認識されたサモアの主権的権利の一部である。</p> <p>UCバークレーは世界でも有名大学の一つである。一世紀以上にわたり、研究室やその設備、教員の採用、また1981～1983年の間ミラー基礎科学研究所の例サーチ・フェローであったポール・アラン・コックス博士を含む教員や生徒の研修に数百万ドルを投じてきた。コックス博士がUCバークレーで受けた研修の一部が、彼が民族植物学の研究を行い、重要な生物学的関心として、サモアのママラの木 (<i>Homalanthus nutans</i>) を特定する準備を促した。</p> <p>本契約は、UCバークレーのジェイ・D・キースリング教授の研究室で、サモア原産のママラの木の遺伝物質を利用して行われた研究から生じうる知的財産権の、UCバークレーのライセンス収入について、サモアとUCバークレーでの将来の配分について明記している。キースリング教授は、サモアとの共同研究において、商業的に実現可能な抗ウイルス治療法として、<i>Homalanthus nutans</i>及び他の植物の遺伝子から、プロストラチンや他の非腫瘍化を促進するホルボールエステル (及びその派生物) の生産に関わる遺伝子を特定し単離することを提案している。この共同研究は、商品化されたプロストラチンをライセンス化し</p>
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<p>Berkeley’s licensing of intellectual property rights that may arise from research performed at UC Berkeley in the laboratory of Professor Jay D. Keasling, using Samoa’s indigenous genetic material of the <i>mamala</i> tree. Professor Keasling proposes to identify and isolate the genes responsible in <i>Homalanthus nutans</i> and other plants to produce prostratin and other related non-tumor promoting phorbol esters (and their derivatives) as anti-viral remedies in a commercially viable manner, in collaboration with Samoa. This collaboration may result in new intellectual property rights that may be licensed to commercialize Prostratin.</p>	<p>うる知的財産権を生み出す可能性がある。</p>
<p><b>II. Contributions of the Samoan People to World Health</b></p> <p>Although prostratin had previously been isolated from plants in New Zealand and Australia, and although species of the genus <i>Homalanthus</i> occur throughout the South Pacific, it was Dr. Cox’s ethnobotanical study of traditional Samoan medicine which first caused the compound to be screened by the US National Cancer Institute for potential antiviral properties. Contributions of the Samoan people and their traditional medicinal practices relating to the discovery of the potential use of</p>	<p><b>II. 世界の健康に対する、サモアの人々の貢献</b></p> <p>プロストラチンは過去にニュージーランドとオーストラリアで植物から単離されたことがあり、<i>Homalanthus</i> 属の種は南太平洋全体に存在するが、潜在的な抗ウイルス機能について化合物を米国国立がん研究所で初めて検査させたのは、コックス博士によるサモアの伝統医学についての民族植物学的研究による。サモアの人々、そしてウイルス性疾患に対するプロストラチンの潜在的な利用法の発見に関する彼らの伝統医学の貢献は、効果的な抗ウイルス薬の探索において重要であったと認識されるべきである。</p>

<p>prostratin against viral illness should be recognized as important in the search for effective anti-viral drugs. The generosity of Samoan villages, chiefs, families, and healers in allowing plants used by healers to be collected should be reciprocated in the event that prostratin is marketed as an anti-viral remedy. Such reciprocation could be helpful in preserving existing rainforest land, furthering the mission of the Parks and Conservation Authority, and maintaining the healing traditions and health of the Samoan people.</p>	<p>サモアの村や首長、家族、ヒーラーが、ヒーラーの用いた植物の採取を許可してくれた寛大さに対し、プロストラチンが抗ウイルス治療として商品化された折には報いなければならない。そのような返礼は、現存する熱帯雨林の土地を保存し、公園と保全に関する権威者のミッションを促進し、サモアの人々の健康と医療の伝統を維持するのに役立つであろう。</p>
<p><b>III. Uncertainties of Drug Development</b></p> <p>UC Berkeley and its collaborating researchers and scientists cannot yet ascertain if prostratin will be useful in treating viral illness, nor can UC Berkeley assert that prostratin will be a viable commercial drug licensed the US Food and Drug Administration. Many steps remain in the testing and development process, steps that are out of the control, supervision, or influence of UC Berkeley. However, both UC Berkeley and Samoa deem it wise at this point to investigate genetic technology as a potential path to producing a stable supply of prostratin, should it be approved as an anti-viral remedy at some future date.</p>	<p><b>III. 薬剤開発の不確実性</b></p> <p>UCバークレーと共同研究者らは、プロストラチンがウイルス性の疾病の治療に役立つのか、未だ解明できていない。また、UCバークレーは、プロストラチンが米国食品医薬品局（FDA）の認可する実用可能な市販薬になるか断言することも出来ない。試験と開発の過程には、UCバークレーによる制御や監督、影響の及ばない幾つもの段階が残されている。しかし、UCバークレーとサモアはいずれも、プロストラチンが将来いつの日か抗ウイルス治療として認可されるのであれば、現時点では安定供給を生み出せる方法としての遺伝子技術を研究するのが賢明だと考えている。</p>

<p><b>IV. Research Collaboration</b></p> <p>Samoa and UC Berkeley agree to facilitate a research program to produce a stable supply of prostratin, with any income of these efforts to be allocated as shown in section V below. In this research, Samoa will:</p> <p>a. allow UC Berkeley researchers and their bona fide colleagues access to Samoa for research purposes with a minimum of delay or hindrance;</p> <p>b. allow import of all necessary research equipment, materials, and vehicles used by UC Berkeley and its researchers, without payment of tax or duty, as long as such research equipment, materials, and vehicles are clearly identified and declared to the Samoan government, and are exported from the country after their use;</p> <p>c. allow export from the country of living material and genetic collections of <i>Homalanthus nutans</i> and related plants without hindrance or delay, on the condition that UC Berkeley destroy or return to Samoa all seeds, propagules, cell cultures, or other propagative materials at the conclusion of this research, unless otherwise expressly permitted by the Samoan government.</p>	<p><b>IV. 共同研究</b></p> <p>サモアとUCバークレーはプロストラチンの安定供給を行う研究プログラムを促進することで合意しており、そこから生じるあらゆる収入の配分については、以下のセクションVで示す。本研究において、サモアは、</p> <p>a. UCバークレーの研究者とその真正な同僚に対し、最低限の遅延と障害で、研究目的でのサモアへのアクセスを許可する、</p> <p>b. UCバークレーの使用するすべての必要な研究機材、材料、車両を、これらの機材、材料、車両が明確に特定可能で、サモア政府に申告されており、利用後に持ち出す限り、税金あるいは他の義務なく持ち込むことを許可する、</p> <p>c. <i>Homalanthus nutans</i>生体材料及び遺伝コレクションの輸出及び関連植物を、UCバークレーが研究の完了時に、種子、繁殖体、細胞培養、あるいは他の繁殖物質を、サモア政府により明示的な許可がない限り破壊あるいはサモアに返還するという条件のもとで、遅延と障害なく輸出することを許可する。</p> <p>本研究において、UCバークレーは、</p> <p>a. サモアの本研究における知的貢献</p>
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<p>In this research, UC Berkeley will</p> <p>a. acknowledge the intellectual contribution of Samoa to this research in all press releases, press conferences, publications and oral presentations;</p> <p>b. obtain prior informed consent of villages or other landowners prior to collection of any living material or genetic material of <i>Homalanthus nutans</i> from their lands;</p> <p>c. name, wherever possible, any new gene, gene sequence, or gene product discovered during the research in such a way that the connection of the gene, gene sequence, or gene product to Samoa and Samoa's national sovereignty will be clear to other researchers;</p> <p>d. endeavor to protect by patent, copyright, or other legal mechanism all discoveries and products, arising directly from this research under the direction of Professor Jay D. Keasling at UC Berkeley or at Samoa that may have commercial value, with the understanding that UC Berkeley is not obligated to file patent applications unless it has a foreseeable mechanism for recovering the costs through licensing;</p>	<p>について、すべてのプレスリリース、記者会見、出版物、及び口頭発表において謝辞を述べる、</p> <p>b. 村や他の地主から、彼らの土地から <i>Homalanthus nutans</i> の生体材料あるいは遺伝材料を採取する前に、事前に取得する合意 (PIC) を取得する、</p> <p>c. 可能な限り、新しい遺伝子、遺伝子配列、あるいは遺伝子産物に対し、サモア及びサモアの主権的権利について、他の研究者に明らかになるような名前を付ける、</p> <p>d. ライセンシングの費用を回収できる予見可能な仕組みがない限り、UCバークレーは特許を申請する義務を負わないという了解のもとで、UCバークレーのジェイ・D・キースリング教授あるいはサモアの監督下にある本研究から直接生じるすべての発見と製品で、商品価値を持ちうるものについて、特許、著作権、あるいは他の法的仕組みによって保護するよう努める、</p> <p>e. 低価格での治療法を途上国においては無料で、実費で、あるいは最低限の利益で提供するというUCバークレーとサモアの共通のゴールを考慮し、このような特許や著作権を公共の利益のためにライセンスするための合理的な努力をする、</p> <p>f. 研究が行われている期間中、サモアの首相あるいは指定代理人に対し、</p>
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<p>e. exert reasonable efforts in licensing such patents or copyrights for public benefit, keeping in mind UC Berkeley's and Samoa's mutual goals of providing low cost therapies for free, at cost, or with minimal profit in the developing world;</p> <p>f. provide an annual report to the Samoan Prime Minister or his assignee of the scientific progress during the period that the research is being conducted including copies of all relevant scientific publications, a statement of patent, copyright, and licensing activity;</p> <p>g. share revenue with Samoa in accordance with Article V.</p>	<p>すべての関連する科学出版物、特許や著作権、他のライセンス活動についての文書のコピーを含め、科学的な進捗について年次報告書を提出する、</p> <p>g. 第V条に従い、サモアと収入を配分する。</p>
<p><b>V. Terms of Recognition of the Contribution of the Samoan Land and People to the Development of a Gene Product for Prostratin</b></p> <p>In consideration for the assistance of the Samoan people in bringing prostratin to the attention of researchers developing treatments for viral diseases, and in consideration for their preservation of genetic resources of <i>Homalanthus nutans</i> and related diseases, UC Berkeley agrees to the following terms as reciprocation for the public health benefits that the</p>	<p>V. プロストラチンの遺伝子産物の開発における、サモアの土地及び人々の貢献への認識に関する条項</p> <p>ウイルス性疾患の治療を開発する研究者たちがプロストラチンへ注意を向けるのを、サモアの人々が促したことを考慮して、また彼らが <i>Homalanthus nutans</i> や他の疾患の遺伝資源を保全してきたことを考慮して、UCバークレーは、サモアの人々が可能にした公衆衛生上の利益への返礼として、以下の条件に合意するものとする。すべてのライセンス、基準時における支払い、ロイヤルティ、技術、ジェイ・D・キースリング教授あるいは</p>

<p>Samoan people made possible. From the proceeds of all of licenses, benchmark payments, royalties, technologies and any other income that results from UC Berkeley’s licensing of intellectual property arising directly from this research under the direction of Professor Jay D. Keasling at UC Berkeley or at Samoa (after first reimbursing to UC Berkeley all reasonable and necessary patent costs, legal fees, and other necessary and reasonable costs pursuant to obtaining, maintaining, and protecting the intellectual property, and provided that all UC Berkeley inventors of a given patent application agree in writing to the following revenue distribution) UC Berkeley will provide 50% of such net revenue to Seacology, a non-profit Foundation incorporated under the laws of the United States, and with offices in Berkeley, California, which shall distribute their share of the royalties as follows:</p> <p>a. <b>50% to the Samoan government</b></p> <p>b. <b>33% to Falealupo village</b>, paid in trust for the benefit of Falealupo village and administered by Seacology, a non-profit Foundation incorporated under the laws of the United States, and with offices in</p>	<p>はサモアの監督下で直接生じた知的財産をUCバークレーがライセンスングした結果得られたその他のあらゆる収入による収益から、(当該特許申請に係るUCバークレーの発明者すべてが以下の利益配分について合意するという条件で、すべての合理的に必要な特許料、弁護士費用、知的財産の取得・維持・保護のために必要で合理的な費用をUCバークレーに最初に払い戻して以降)、UCバークレーは正味の歳入のうち50%を米国の法の下で設立された非営利財団で、カリフォルニア州バークレーに事務所を持つシーコロジーに提供し、彼らはロイヤルティを以下のように配分する：</p> <p>a. <b>サモア政府へ50%</b></p> <p>b. <b>ファレアルポ村へ33%</b>、ファレアルポ村の利益のために信託によって支払われ、を米国の法の下で設立された非営利財団で、カリフォルニア州バークレーに事務所を持つシーコロジーによって行われる、</p> <p>c. <b>サイピピ村へ2%</b>、サイピピ村の利益のために信託によって支払われ、を米国の法の下で設立された非営利財団で、カリフォルニア州バークレーに事務所を持つシーコロジーによって行われる、</p> <p>d. <b>タフア村へ2%</b>、タフア村の利益のために信託によって支払われ、を米国の法の下で設立された非営利財団</p>
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<p>Berkeley, California;</p> <p>c. <b>2% to Saipipi village</b>, paid in trust for the benefit of Saipipi village and administered by Seacology, a non-profit Foundation incorporated under the laws of the United States, and with offices in Berkeley, California;</p> <p>d. <b>2% to Tafua village</b>; paid in trust for the benefit of Tafua village and administered by Seacology, a non-profit Foundation incorporated under the laws of the United States, and with offices in Berkeley, California;</p> <p>e. <b>8% to other villages</b>; that will participate in this research by allowing access to genetic material in their forests, or who have begun growing commercial crops of <i>Homalanthus nutans</i> at the day of FDA approval of prostratin or its analogues as a drug, in a reasonable and equitable manner solely to be decided by Seacology, and paid in trust for the benefit of these villages and administered by Seacology, a non-profit Foundation incorporated under the laws of the United States, and with offices in Berkeley, California;</p> <p>f. <b>2% to the lineal descendents of</b></p>	<p>で、カリフォルニア州バークレーに事務所を持つシーコロジーによって行われる、</p> <p>e. <b>その他の村へ8%</b>、その村の森で遺伝資料へのアクセスを許可した、あるいはプロストラチンあるいはその類似物がFDAに薬剤として承認された日に<i>Homalanthus nutans</i>の商用作物を育成し始めたなどにより、本研究に参加した村に対し、シーコロジーが単独で決定した合理的で衡平な方法で、信託によって支払われ、を米国の法の下で設立された非営利財団で、カリフォルニア州バークレーに事務所を持つシーコロジーによって行われる、</p> <p>f. <b>Epenesa Mauigoaの直系子孫へ2%</b>、かつてのペセガ村で、ポール・コックス博士に対し、<i>Homalanthus nutans</i>のウィルス由来疾患に対する潜在的な活性を特定した最初のヒーラーであるとして、当該子孫の健康、教育、福祉のためにシーコロジーへ信託によって支払われ、を米国の法の下で設立された非営利財団で、カリフォルニア州バークレーに事務所を持つシーコロジーによって行われる、</p> <p>g. <b>Pela Liloの直系子孫へ2%</b>、かつてのファレアルポ村で、ポール・コックス博士に対し、<i>Homalanthus nutans</i>のウィルス由来疾患に対する潜在的な活性を特定した2番目のヒーラーであるとして、当該子孫の健康、教育、福祉のためにシーコロジーへ信</p>
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<p>Epenesa Mauigoa, late of Pesega village, being the first healer to identify for Dr. Paul Cox <i>Homalanthus nutans</i> as having potential activity against diseases of viral origin, to be paid in trust to Seacology for the health, education, and well-being of said descendants and administered by Seacology, a non-profit Foundation incorporated under the laws of the United States, and with offices in Berkeley, California;</p> <p>g. <b>2%</b> to the lineal descendents of Pela Lilo, late of Falealupo village, being the second healer to identify for Dr. Paul Cox <i>Homalanthus nutans</i> as having potential activity against diseases of viral origin, to be paid in trust to Seacology for the health, education, and well-being of said descendants and administered by Seacology, a non-profit Foundation incorporated under the laws of the United States, and with offices in Berkeley, California;</p> <p>h. (1%?)<b>0. 5%</b> to Seacology, a non-profit Foundation incorporated under the laws of the United States, and with offices in Berkeley, California; for its good offices in coordinating payments b through g.</p>	<p>託によって支払われ、を米国の法の下で設立された非営利財団で、カリフォルニア州バークレーに事務所を持つシーコロジーによって行われる、</p> <p>h. シーコロジーに対して0.5% (1%?)、米国の法の下で設立された非営利財団で、カリフォルニア州バークレーに事務所を持つ。bからgの支払いを取りまとめてくれたことに対し、支払う。</p>
<p><b>VI. Commercialization of Prostratin and Special</b></p>	<p>VI. プロストラチンの商品化と、発展途上国への特別な考慮</p>

<p><b>Considerations for Developing Countries</b></p> <p>Samoa and UC Berkeley intend to license their respective intellectual property rights so that prostratin (if it is approved as an anti HIV-AIDS therapy) is made available to developing nations at minimal cost. UC Berkeley shall use reasonable efforts in negotiating with any third party licensee to include terms for the distribution of the drug in developing nations at a minimal profit. In addition Professor Jay D. Keasling shall emphasize the generosity of the Samoan people, the dignity of the Samoa culture, and the contribution made to public health by the indigenous medicine practiced by Samoan healers in all presentations and publications in which the collaborative work is described. Professor Keasling will also work to see that Samoa receives the diplomatic credit it deserves in furthering the distribution of prostratin (if approved) to those developing nations hit hard by HIV/AIDS but who would be burdened by payments substantially driven by profit.</p>	<p>サモア及びUCバークレーは、それぞれの知的財産権をライセンスする予定である。それによって、プロストラチンは（もし抗HIV/AIDS治療薬として認可されれば）、発展途上国は最低限の費用で入手できる。UCバークレーは第三者のライセンシーとの交渉において、発展途上国に対し、最低限の利益で薬剤を配布する条件を含めることについて合理的な努力を行う。さらにジェイ・D・キースリング教授は、サモアの人々の寛大さを強調、サモアの文化の尊厳、サモアのヒーラーが行う伝統医学の公衆衛生への貢献に関し、共同研究に言及するすべてのプレゼンテーションや出版物において強調することとする。キースリング教授はさらに、サモアが然るべき外交上の信頼を得られるよう努める。それはHIV/AIDSにより大きな打撃を受ける発展途上国へのプロストラチン（もし承認されれば）の配布を促進することで得られるが、同時に、利益によって実質的に決定される支払いが負担となる。</p>
<p><b>V. Complete Agreement between the Parties</b></p> <p>Both the government of Samoa and</p>	<p><b>V. 当事者間での完全な合意</b></p> <p>サモア政府とUCバークレーはいずれも、本覚書が当事者間の完全な了解事</p>

<p>UC Berkeley agree that this Memorandum states the entire understanding between the parties, and that no other promises- written, oral, or implied- shall govern the terms of this agreement. No parol evidence of any kind shall be used in construing the meaning of the terms of this agreement.</p>	<p>項について述べていることに合意しており、(書面、口頭、黙示による)いかなる約束も本契約には影響しない。いかなる種類の口頭証拠も、本契約の文言の解釈に用いない。</p>
<p><b>VI. Dispute, Controversy, Resolution</b></p> <p>Both parties enter into this agreement in the spirit of mutual respect and gratitude. Should disputes arise under this agreement, either party may demand nonbinding arbitration. Any arbitration shall include one arbitrator chosen by Samoa, one arbitrator chosen by UC Berkeley, and one arbitrator chosen jointly by the other two arbitrators. Any arbitration shall take place at a place acceptable to both parties. Likewise, either party may demand an audit of costs and revenues covered in this agreement, no more than once a year, by an auditor acceptable to both parties. The requesting party shall bear the cost of the audit. The agreement shall be construed according to the laws of the state of California in the United States.</p>	<p><b>VI. 紛争、論争、解決</b></p> <p>両当事者は、互いに尊敬と感謝の精神のもと、本契約を締結するものとする。本契約下で紛争が生じた場合、いずれかの当事者が、拘束力のない仲裁を要求することができる。いかなる仲裁においても、サモアが選定する調停人を1名、UCバークレーが選定する調停人を1名、その2名が合同で選定する調停人を1名含める。同様に、各当事者は本契約の範囲での費用及び収益について、1年に1回限り、両当事者の認めた監査人による監査を要求することができる。本契約は、米国カリフォルニア州の法律に従って解釈されるものとする。</p>

This agreement does not expressly or by implication affect the rights of either party in any intellectual property except as expressly provided herein.

本契約は、ここに明示的に記述されている場合を除き、両当事者のいかなる知的財産に、明示的にも暗示的にも影響しない。

Signed and agreed to this 13th day of August, 2004.

2004年8月13日、合意し署名した。

**For the Government of Samoa**  
サモア政府

**For the Regents of the  
University of California,  
Berkeley**  
カリフォルニア大学バークレー校

\_\_\_\_\_  
—  
Its Prime Minister, Tuilaepa Sailele  
Malielegaoi  
トゥイラエパ・サイレ・マリエレガ  
オイ首相

\_\_\_\_\_  
—  
Its Vice Chancellor for Research,  
Beth Burnside, Ph.D.  
研究副総長、ベス・バーンサイド博士

Date

Date

\_\_\_\_\_  
—  
日時

\_\_\_\_\_  
—  
日時

**For Seacology**  
シーコロジ

**Read and understood by  
Regents' employee:**  
理事会職員が把握し理解した

\_\_\_\_\_  
—  
Its Chairman, Paul Alan Cox, Ph.D.  
委員長、ポール・アラン・コックス博

\_\_\_\_\_  
—  
Jay D. Keasling, Ph.D., Professor

士

ジェイ・D・キースリング博士

Date

Date

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日時

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日時

米国国立公園生物資源標準アクセスと利益配分契約

米国国立公園生物資源標準アクセスと利益配分契約

<p style="text-align: center;"><b>GENERAL CONDITIONS</b> <b>For</b> <b>SCIENTIFIC RESEARCH AND</b> <b>COLLECTING PERMIT</b></p> <p style="text-align: center;"><b>United States Department of the</b> <b>Interior</b> <b>National Park Service</b></p>	<p>米国国立公園生物資源標準アクセスと利益配分契約</p> <p>米国内務省 国立公園局</p>
<p><b>1. Authority</b> - The permittee is granted privileges covered under this permit subject to the supervision of the superintendent or a designee, and shall comply with all applicable laws and regulations of the National Park System area and other federal and state laws. A National Park Service (NPS) representative may accompany the permittee in the field to ensure compliance with regulations.</p>	<p><b>1. 権限</b> — 許可証を受けた者は、管理者又は指定を受けた者の監督に従った許可証の下で特権を与えられ、国立公園制度についてのすべての適用法令及び他の連邦法や州法に従う。国立公園局（NPS）の代表者は、被許可者が規則に従っていることを確認するため、現場に同行することができる。</p>
<p><b>2. Responsibility</b> - The permittee is responsible for ensuring that all persons working on the project adhere to permit conditions and applicable NPS regulations.</p>	<p><b>2. 責任</b> — 許可証を受けた者は、当該プロジェクト内で働く者が皆、許可条件及び適用されるNPSの規則を忠実に守ることを保証することにつき、責任を負う。</p>
<p><b>3. False information</b> - The permittee is prohibited from giving false information that is used to issue this permit. To do so will be considered a breach of conditions and be grounds for revocation of this permit and other applicable penalties.</p>	<p><b>3. 虚偽の情報</b> — 許可証を受けた者は、許可証を得るために、虚偽の情報を提供してはならない。そのような行動は条件違反とみなされ、許可の取り消しや他の適用可能な罰則の根拠となる。</p>

<p>4. <b>Assignment</b> - This permit may not be transferred or assigned. Additional investigators and field assistants are to be coordinated by the person(s) named in the permit and should carry a copy of the permit while they are working in the park. The principal investigator shall notify the park's Research and Collecting Permit Office when there are desired changes in the approved study protocols or methods, changes in the affiliation or status of the principal investigator, or modification of the name of any project member.</p>	<p>4. <b>譲渡</b> - 許可証の移転及び譲渡を禁止する。研究員や現場アシスタントの追加は許可証に氏名のある者が調整して行い、公園内で作業をする間は許可証のコピーを携行しなければならない。主任の研究員は、承認された研究手続きや方法を変更したい場合や、主任研究員の所属や肩書に変更があった場合、あるいはプロジェクトメンバーの氏名が変更した場合には、研究・採取許可事務所 (Research and Collecting Permit Office) に通知しなければならない。</p>
<p>5. <b>Revocation</b> - This permit may be terminated for breach of any condition. The permittee may consult with the appropriate NPS Regional Science Advisor to clarify issues resulting in a revoked permit and the potential for reinstatement by the park superintendent or a designee.</p>	<p>5. <b>取り消し</b> - この許可証は、いかなる条件の違反によっても取り消されうる。許可を受けた者は、許可証取り消しの結果を招いた問題や、公園の管理者又は指定を受けた者による許可証回復の可能性について明らかにするため、適切な NPS 地域科学アドバイザーに相談することができる。</p>
<p>6. <b>Collection of specimens (including materials)</b> - No specimens (including materials) may be collected unless authorized on the Scientific Research and Collecting permit.</p> <p>The general conditions for specimen collections are:</p> <ul style="list-style-type: none"> <li>• Collection of archeological materials without a valid Federal Archeology</li> </ul>	<p>6. <b>標本 (素材を含む) の採取</b> - いかなる標本 (素材を含む) も、科学研究及び採取許可証によって認められない限り、採取することができない。</p> <p>標本採取の一般的な条件とは：</p> <ul style="list-style-type: none"> <li>• 考古学的な素材を、有効な連邦考古学許可証なしに採取することは禁じられている。</li> <li>• 連邦政府が絶滅の危機に瀕しているとリストした種を、米国魚類野</li> </ul>



<p>Permit is prohibited.</p> <ul style="list-style-type: none"> <li>• Collection of federally listed threatened or endangered species without a valid U.S. Fish and Wildlife Service endangered species permit is prohibited.</li> <li>• Collection methods shall not attract undue attention or cause unapproved damage, depletion, or disturbance to the environment and other park resources, such as historic sites.</li> <li>• New specimens must be reported to the NPS annually or more frequently if required by the park issuing the permit. Minimum information for annual reporting includes specimen classification, number of specimens collected, location collected, specimen status (e.g., herbarium sheet, preserved in alcohol/formalin, tanned and mounted, dried and boxed, etc.), and current location.</li> <li>• Collected specimens that are not consumed in analysis or discarded after scientific analysis remain federal property. The NPS reserves the right to designate the repositories of all specimens removed from the park and to approve or restrict reassignment of specimens from one repository to another. Because specimens are Federal property, they shall not be destroyed or discarded without prior</li> </ul>	<p>生生物局の絶滅危惧種に関する有効な許可証なしに採取することは禁じられている。</p> <ul style="list-style-type: none"> <li>• 採取方法は過度の注目を集めず、あるいは環境や他の公園内の資源（史跡など）に対して望ましくない損傷や喪失、混乱を与えないものでなければならない。</li> <li>• 新たな標本については年に1回、または許可証を発行した公園からの要求があればより頻繁に、NPSに報告しなければならない。年に1度最低限報告すべき情報は、標本の分類、採取した標本の数、採取された場所、標本の状態（例：乾燥標本シート、アルコール/ホルマリン漬け、タンニン処理された状態、乾燥し箱詰めされた状態、など）、及び現在の場所を含む。</li> <li>• 採取された標本のうち、分析時に消費されたり、科学分析後に廃棄されたりしないものは、連邦政府の資産となる。NPSは、公園から移動させたすべての標本の保管場所の指定、ある保管場所から他への配置転換に対する承認や制限について権利を有する。標本は連邦政府の資産なので、NPSの事前の許可なく破壊や廃棄はできない。</li> <li>• 永久的に保存される各標本（あるいはグループとしてラベル表示されたひとまとまりの標本）は、NPSのラベルを貼付し、NPS国内目録に登録し、掲載されなけれ</li> </ul>
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<p>NPS authorization.</p> <ul style="list-style-type: none"> <li>• Each specimen (or groups of specimens labeled as a group) that is retained permanently must bear NPS labels and must be accessioned and cataloged in the NPS National Catalog. Unless exempted by additional park-specific stipulations, the permittee will complete the labels and catalog records and will provide accession information. It is the permittee's responsibility to contact the park for cataloging instructions and specimen labels as well as instructions on repository designation for the specimens.</li> <li>• Collected specimens may be used for scientific or educational purposes only, and shall be dedicated to public benefit and be accessible to the public in accordance with NPS policies and procedures.</li> <li>• Any specimens collected under this permit, any components of any specimens (including but not limited to natural organisms, enzymes or other bioactive molecules, genetic materials, or seeds), and research results derived from collected specimens are to be used for scientific or educational purposes only, and may not be used for commercial or other revenue-generating purposes unless the permittee has entered into a Cooperative Research And</li> </ul>	<p>ばならない。公園独自の追加の規定により免除された場合を除き、許可を受けた者は、ラベル及び目録の記録を完成させ、登録情報を提供するものとする。許可を受けた者は、登録のための説明と標本のラベル、及び標本の保管場所を指定する説明に関して公園と連絡を取ることにつき責任を負う。</p> <ul style="list-style-type: none"> <li>• 採取された標本は科学あるいは教育目的のみで利用可能であり、公共の利益のために捧げられ、NPS のポリシー及び手続きに従って一般人が利用できる。</li> <li>• 本許可証のもとで採取された標本、標本の構成成分（天然生物、酵素あるいは他の生理活性分子、遺伝物質、種子を含むがこれに限定されるものではない）、及び採取された標本から生じた研究結果は科学あるいは教育目的のみで利用可能であり、許可を受けた者が、協力的研究開発契約（CRADA）あるいは他の承認された利益配分契約を NPS と締結していない限り、商用その他収入を生み出す目的では利用できない。採取された研究標本の売却、あるいは第三者への許可なき移転は禁止されている。さらに、許可を得た者が採取した標本やその構成成分、標本や構成成分から開発した製品あるいは研究結果を、CRADA や他の利益配分契約を NPS と締結せずに売却、あるいは移転した場合には、許可を得</li> </ul>
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<p>Development Agreement (CRADA) or other approved benefit-sharing agreement with the NPS. The sale of collected research specimens or other unauthorized transfers to third parties is prohibited. Furthermore, if the permittee sells or otherwise transfers collected specimens, any components thereof, or any products or research results developed from such specimens or their components without a CRADA or other approved benefit-sharing agreement with NPS, permittee will pay the NPS a royalty rate of twenty percent (20%) of gross revenue from such sales or other revenues. In addition to such royalty, the NPS may seek other damages to which the NPS may be entitled including but not limited to injunctive relief against the permittee.</p>	<p>た者は NPS に対し、売価あるいは収入の粗利益の 20%の割合でロイヤルティを支払わなければならない。このロイヤルティに加えて、NPS は許可を受けた者に対し、他の損害、例えば差止めによる救済を含むがこれに限定されるものではない、を与える権利を有する。</p>
<p><b>7. Reports</b> - The permittee is required to submit an Investigator's Annual Report and copies of final reports, publications, and other materials resulting from the study. Instructions for how and when to submit an annual report will be provided by NPS staff. Park research coordinators will analyze study proposals to determine whether copies of field notes, databases, maps, photos, and/or other materials may also be requested. The permittee is responsible for the content of reports and data provided to the National Park</p>	<p><b>7. 報告</b> - 許可を受けた者は、調査者による年次報告書、最終報告書のコピー、出版物、本研究から生じたその他一切を提出しなければならない。年次報告書の提出時期及び方法については、NPS の職員から説明がされる。公園の研究コーディネーターが研究計画を分析し、野帳のコピー、データベース、地図、写真及び／あるいはその他の物が必要か否かを決定する。許可を受けた者は、NPS に提供された報告書の内容及びデータについて責任を負う。</p>

Service.	
8. <b>Confidentiality</b> - The permittee agrees to keep the specific location of sensitive park resources confidential. Sensitive resources include threatened species, endangered species, and rare species, archeological sites, caves, fossil sites, minerals, commercially valuable resources, and sacred ceremonial sites.	8. <b>守秘義務</b> - 許可を受けた者は、公園の慎重に扱うべき資源の特定の位置について、秘密を保持しなければならない。慎重に扱うべき資源とは、絶滅危惧種、稀少種、考古学的な遺跡、洞窟、化石の発掘現場、鉱物、商業的に価値のある資源、神聖な儀式の場所を含む。
9. <b>Methods of travel</b> - Travel within the park is restricted to only those methods that are available to the general public unless otherwise specified in additional stipulations associated with this permit.	9. <b>移動手段</b> - 公園内の移動は、本許可証に関連した追加の規定で特別の定めがない限り、一般人が可能な方法に限られるものとする。
10. <b>Other permits</b> - The permittee must obtain all other required permit(s) to conduct the specified project.	10. <b>その他の許可</b> - 許可を受けた者は、特定のプロジェクトを遂行するために必要な他のすべての許可を取得しなければならない。
11. <b>Insurance</b> - If liability insurance is required by the NPS for this project, then documentation must be provided that it has been obtained and is current in all respects before this permit is considered valid.	11. <b>保険</b> - 本プロジェクトに対し、NPS から損害賠償保険が求められたときは、許可証が有効とみなされる前に、保険は取得済みで、全ての点で最新状態であることを書面化して提供しなければならない。
12. <b>Mechanized equipment</b> - No use of mechanized equipment in designated, proposed, or potential wilderness areas is allowed unless authorized by the superintendent or a designee in additional specific conditions associated with this permit.	12. <b>機械設備</b> - 管理者又は指定された者が、本許可証に関連した追加の特別の条件にもとづいて許可を与えた場合を除き、指定された、提案された、あるいは潜在的な自然保護区域内で機械設備を利用してはならない。
13. <b>NPS participation</b> - The permittee should not anticipate assistance from the NPS unless specific	13. <b>NPS の参加</b> - 許可を受けた者は、本許可証に付随した追加の規則あるいは別途書面での合意に基づい

arrangements are made and documented in either an additional stipulation attached to this permit or in other separate written agreements.	て、特別の取り決めがなされ、かつ文書化された場合を除き、NPSからの援助を見込むことはできない。
<b>14. Permanent markers and field equipment</b> - The permittee is required to remove all markers or equipment from the field after the completion of the study or prior to the expiration date of this permit. The superintendent or a designee may modify this requirement through additional park specific conditions that may be attached to this permit. Additional conditions regarding the positioning and identification of markers and field equipment may be issued by staff at individual parks.	<b>14. 油性マーカー及び現場機器</b> - 許可を受けた者は、研究完了後、あるいは許可証の有効期限までに、すべてのマーカーあるいは機器を現場から取り除かなければならない。管理者又は指定を受けた者は、本許可証に付随する公園特有の追加条件により、この要求を変更することができる。マーカー及び現場機器の位置決めや特定に関する追加条件は、個々の公園で職員が発令することもできる。
<b>15. Access to park and restricted areas</b> - Approval for any activity is contingent on the park being open and staffed for required operations. No entry into restricted areas is allowed unless authorized in additional park specific stipulations attached to this permit.	<b>15. 公園及び規制区域へのアクセス</b> - あらゆる活動への承認は、公園が開園しており、必要な運営のための人員が配備されていることを条件とする。また、本許可証に付随した公園の特定の規定に基づく追加の許可がない限り、規制区域に立ち入ってはならない。
<b>16. Notification</b> - The permittee is required to contact the park's Research and Collecting Permit Office (or other offices if indicated in the stipulations associated with this permit) prior to initiating any fieldwork authorized by this permit. Ideally this contact should occur at least one week prior to the initial visit to the park.	<b>16. 通知</b> - 許可を受けた者は、許可証で認められているフィールドワークを開始する前に、公園の研究・採取許可事務所（あるいは許可証に関連する規定に示された他の事務所）に連絡を取る必要がある。理想的には、この連絡は、公園への最初に訪問する少なくとも1週間前に行うのが望ましい。
<b>17. Expiration date</b> - Permits expire	<b>17. 有効期限</b> - 許可証は、記載され

<p>on the date listed. Nothing in this permit shall be construed as granting any exclusive research privileges or automatic right to continue, extend, or renew this or any other line of research under new permit(s).</p>	<p>た日時に失効する。本許可証は、独占的に研究する権利や、それらの権利あるいは新たな許可証の下での他の一連の研究を行う権利を自動的に継続、延長、更新するものではない。</p>
<p><b>18. Other stipulations</b> - This permit includes by reference all stipulations listed in the application materials or in additional attachments to this permit provided by the superintendent or a designee. Breach of any of the terms of this permit will be grounds for revocation of this permit and denial of future permits.</p>	<p><b>18. その他の規定</b> - 本許可証は、申請書に記載された、あるいは管理者又は指定を受けた者から追加で添付して提供された規定をすべて含める。これらの条件に違反することは、許可の取り消しや将来的な申請却下の根拠となる。</p>

米国国立癌研究所 Maxygen 共同研究開発契約

Cooperative Research and Development Agreement - National Cancer Institute and Maxygen Inc.(Feb 24, 2000)

## PUBLIC HEALTH SERVICE

### COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

This Cooperative Research and Development Agreement, hereinafter referred to as the "CRADA," consists of this Cover Page, an attached Agreement, and various Appendices referenced in the Agreement. This Cover Page serves to identify the Parties to this CRADA:

(1) the following Bureau(s), Institute(s), Center(s) or Division(s) of the National Institutes of Health ("NIH"), the Food and Drug Administration ("FDA"), and the Centers for Disease Control and Prevention ("CDC"):

The National Cancer Institute hereinafter singly or collectively referred to as the Public Health Service ("PHS"); and

(2) Maxygen, Incorporated, which has offices at 515 Galveston Drive, Redwood City, California, 94063 hereinafter referred to as the "Collaborator."

THE SYMBOL "\*\*\*\*\*" IS USED TO INDICATE THAT A PORTION OF THE EXHIBIT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

## Article 1. Introduction

This Cooperative Research and Development Agreement (CRADA) between PHS and the Collaborator will be effective when signed by all Parties. The research and development activities which will be undertaken by each of the Parties in the course of this CRADA are detailed in the Research Plan (RP) which is attached as Appendix A. The funding and staffing commitments of the Parties are set forth in Appendix B. Any exceptions or changes to the CRADA are set forth in Appendix C. This CRADA is made under the authority of the Federal Technology Transfer Act, 15 U.S.C. (S)3710a and is governed by its terms.

## Article 2. Definitions

As used in this CRADA, the following terms shall have the indicated meanings:

2.1 "Affiliate" means any corporation or other business entity controlled by, controlling, or under common control with Collaborator. For this purpose, A "control" means direct or indirect beneficial ownership of at least fifty (50) percent of the voting stock or at least fifty (50) percent interest in the income of such corporation or other business.

2.2 "Cooperative Research and Development Agreement" or "CRADA" means this Agreement, entered into by PHS pursuant to the Federal Technology Transfer Act of 1986, as amended, 15 U.S.C. 3710a et seq. and Executive Order 12591 ----- of October 10, 1987.

2.3 "Government" means the Government of the United States as represented through the PHS agency that is a Party to this agreement.

2.4 "IP" means intellectual property.



2.5 "Invention" means any invention or discovery which is or may be patentable or otherwise protected under title 35, United States Code, or any novel variety or plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

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2.6 "Principal Investigator(s)" or "PIs" means the persons designated respectively by the Parties to this CRADA who will be responsible for the scientific and technical conduct of the RP.

2.7 "Proprietary/Confidential Information" means confidential scientific, business, or financial information provided that such information does not include:

2.7.1. information that is publicly known or available from other sources who are not under a confidentiality obligation to the source of the information;

2.7.2. information which has been made available by its owners to others without a confidentiality obligation;

2.7.3. information which is already known by or available to the receiving Party without a confidentiality obligation; or

2.7.4. information which relates to potential hazards or cautionary warnings associated with the production, handling or use of the subject matter of the Research Plan of this CRADA.

2.8 "Research Materials" means all tangible materials other than Subject Data first produced in the performance of this CRADA.

2.9 "Research Plan" or "RP" means the statement in Appendix A of the respective research and development commitments of the Parties to this CRADA.

2.10 "Subject Invention" means any Invention of the Parties, conceived or first actually reduced to practice in the performance of the Research Plan of this CRADA.

2.11 "Subject Data" means all recorded information first produced in the performance of this CRADA by the Parties.

### Article 3. Cooperative Research

3.1 Principal Investigators. PHS research work under this CRADA will be performed by the PHS laboratory identified in the RP, and the PHS Principal Investigator (PI) designated in the RP will be responsible for the scientific and technical conduct of this project on behalf of PHS. Also designated in the RP is the Collaborator PI who will be responsible for the scientific and technical conduct of this project on behalf of the Collaborator.

3.2 Research Plan Change. The RP may be modified by mutual written consent of the Principal Investigators. Substantial changes in the scope of the RP will be treated as amendments under Article 13.6.

### Article 4. Reports

4.1 Interim Reports. The Parties shall exchange formal written interim progress reports on a schedule agreed to by the PIs, but at least within twelve (12) months after this CRADA becomes effective and at least within every twelve (12) months thereafter. Such reports shall set forth the technical progress made, identifying such problems as may have been encountered and establishing goals and objectives requiring further effort, any modifications to the Research Plan pursuant to Article 3.2, and all

CRADA-related patent applications filed.

4.2 Final Reports. The Parties shall exchange final reports of their results within four (4) months after completing the projects described in the RP or after the expiration or termination of this CRADA.

## Article 5. Financial and Staffing Obligations

5.1 PHS and Collaborator Contributions. The contributions of the Parties, including payment schedules, if applicable, are set forth in Appendix B.

PHS shall not be obligated to perform any of the research specified herein or to take any other action required by this CRADA if the funding is not provided as set forth in Appendix B. PHS shall return excess funds to the Collaborator when it sends its final fiscal report pursuant to Article 5.2, except for staffing support pursuant to Article 10.3. Collaborator acknowledges that the U.S. Government will have the authority to retain and expend any excess funds for up to one (1) year subsequent to the expiration or termination of the CRADA to cover any costs incurred during the term of the CRADA in undertaking the work set forth in the RP.

5.2 Accounting Records. PHS shall maintain separate and distinct current accounts, records, and other evidence supporting all its obligations under this CRADA, and shall provide the Collaborator a final fiscal report pursuant to Article 4.2.

5.3 Capital Equipment. Equipment purchased by PHS with funds provided by the Collaborator shall be the property of PHS. All capital equipment provided under this CRADA by one party for the use of another Party remains the property of the providing Party unless other disposition is mutually agreed upon by in writing by the Parties. If title to this equipment remains with the providing Party, that Party is responsible for maintenance of the equipment and the costs of its transportation to and from the site where it will be used.

## Article 6. Intellectual Property Rights and Patent Applications

6.1 Reporting. The Parties shall promptly report to each other in writing each Subject Invention resulting from the research conducted under this CRADA that is reported to them by their respective employees. Each Party shall report all Subject Inventions to the other Party in sufficient detail to determine inventorship. Such reports shall be treated as Proprietary/Confidential Information in accordance with Article 8.4.

6.2 Collaborator Employee Inventions. If the Collaborator does not elect to retain its IP rights, the Collaborator shall offer to assign these IP rights to the Subject Invention to PHS pursuant to Article 6.5. If PHS declines such assignment, the Collaborator may release its IP rights as it may determine.

6.3 PHS Employee Inventions. PHS on behalf of the U.S. Government may elect to retain IP rights to each Subject Invention made solely by PHS employees. If PHS does not elect to retain IP rights, PHS shall offer to assign these IP rights to such Subject Invention to the Collaborator pursuant to Article 6.5. If the Collaborator declines such assignment, PHS may release IP rights in such Subject Invention to its employee inventors pursuant to Article 6.6.

6.4 Joint Inventions. Each Subject Invention made jointly by PHS and Collaborator employees shall be jointly owned by PHS and the Collaborator. The Collaborator may elect to file the joint patent or other IP application(s) thereon and shall notify PHS promptly upon making this election. If the Collaborator decides to file such applications, it shall do so in a timely manner and at its own expense. If the Collaborator does not elect to file such application(s), PHS on behalf of the U.S. Government shall have the right to file the joint application(s) in a timely manner and at its own expense. If either Party decides not to retain its IP rights to a jointly owned Subject Invention, it shall offer to assign such rights to the other Party

pursuant to Article 6.5. If the other Party declines such assignment, the offering Party may release its IP rights as provided in Articles 6.2, 6.3, and 6.6.

6.5 Filing of Patent Applications. With respect to Subject Inventions made by the Collaborator as described in Article 6.2, or by PHS as described in Article 6.3, a Party exercising its right to elect to retain IP rights to a Subject Invention agrees to file patent or other IP applications in a timely manner and at its own expense and after consultation with the other Party. The Party shall notify the other Party of its decision regarding filing in countries other than the United States in a timely manner. The Party may elect not to file a patent or other IP application thereon in any particular country or countries provided it so advises the other Party ninety (90) days prior to the expiration of any applicable filing deadline, priority period or statutory bar date, and hereby agrees to assign its IP right, title and interest in such country or countries to the Subject Invention to the other Party and to cooperate in the preparation and filing of a patent or other IP applications. In any countries in which title to patent or other IP rights is transferred to the Collaborator, the Collaborator agrees that PHS inventors will share in any royalty distribution that the Collaborator pays to its own inventors.

6.6 Release to Inventors. In the event neither of the Parties to this CRADA elects to file a patent or other IP application on a Subject Invention, either or both (if a joint invention) may retain or release their IP rights in accordance with their respective policies and procedures. However, the Government shall retain a nonexclusive, non-transferable, irrevocable, royalty-free license to practice any such Subject Invention or have it practiced throughout the world by or on behalf of the Government.

6.7 Patent Expenses. The expenses attendant to the filing of patent or other IP applications generally shall be paid by the Party filing such application. If an exclusive license to any Subject Invention is granted to the Collaborator, the Collaborator shall be responsible for all past and future out-of-pocket expenses in connection with the preparation, filing,

prosecution and maintenance of any applications claiming such exclusively-licensed inventions and any patents or other IP grants that may issue on such applications. The Collaborator may waive its exclusive license rights on any application, patent or other IP grant at any time, and incur no subsequent compensation obligation for that application, patent or IP grant.

6.8 Prosecution of Intellectual Property Applications. Within one month of receipt or filing, each Party shall provide the other Party with copies of the applications and all documents received from or filed with the relevant patent or other IP office in connection with the prosecution of such applications. Each Party shall also provide the other Party with the power to inspect and make copies of all documents retained in the patent or other IP application files by the applicable patent or other IP office. Where licensing is contemplated by Collaborator, the Parties agree to consult with each other with respect to the prosecution of applications for PHS Subject Inventions described in Article 6.3 and joint Subject Inventions described in Article 6.4. If the Collaborator elects to file and prosecute IP applications on joint Subject Inventions pursuant to Article 6.4, PHS will be granted an associate power of attorney (or its equivalent) on such IP applications.

## Article 7. Licensing

7.1 Option for Commercialization License. With respect to Government IP rights to any Subject Invention not made solely by the Collaborator's employees for which a patent or other IP application is filed, PHS hereby grants to the Collaborator an exclusive option to elect an exclusive or nonexclusive commercialization license, which is substantially in the form of the appropriate model PHS license agreement. This option does not apply to Subject Inventions conceived prior to the effective date of this CRADA that are reduced to practice under this CRADA, if prior to that reduction to practice, PHS has filed a patent application on the invention and has licensed it or offered to license it to a third party. The terms of the license will fairly reflect the nature of the invention,

the relative contributions of the Parties to the invention and the CRADA, the risks incurred by the Collaborator and the costs of subsequent research and development needed to bring the invention to the marketplace. The field of use of the license will be commensurate with the scope of the RP.

7.2 Exercise of License Option. The option of Article 7.1 must be exercised by written notice mailed within three (3) months after either (i) Collaborator receives written notice from PHS that the patent or other IP application has been filed; or (ii) the date Collaborator files such IP application. Exercise of this option by the Collaborator initiates a negotiation period that expires nine (9) months after the exercise of the option. If the last proposal by the Collaborator has not been responded to in writing by PHS within this nine (9) month period, the negotiation period shall be extended to expire one (1) month after PHS so responds, during which month the Collaborator may accept in writing the final license proposal of PHS. In the absence of such acceptance, or an extension of the time limits by PHS, PHS will be free to license such IP rights to others. In the event that the Collaborator elects the option for an exclusive license, but no such license is executed during the negotiation period, PHS agrees not to make an offer for an exclusive license on more favorable terms to a third party for a period of six (6) months without first offering Collaborator those more favorable terms. These times may be extended at the sole discretion of PHS upon good cause shown in writing by the Collaborator.

7.3 License for PHS Employee Inventions and Joint Inventions. Pursuant to 15 U.S.C. (S) 3710a(b)(1)(A), for Subject Inventions made under this CRADA by a PHS employee(s) or jointly by such employee(s) and employees of the Collaborator pursuant to Articles 6.3 and 6.4 and licensed pursuant to the option of Article 7.1, the Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C.

552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party.

7.4 License in Collaborator Inventions. Pursuant to 15 U.S.C. (S) 3710a(b)(2), for inventions made solely by Collaborator employees under this CRADA pursuant to Article 6.2, the Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.

7.5 Third Party License. Pursuant to 15 U.S.C. (S) 3710a(b)(1)(B), if PHS grants an exclusive license to a Subject Invention made wholly by PHS employees or jointly with a Collaborator under this CRADA, pursuant to Articles 6.3 and 6.4, the Government shall retain the right to require the Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the invention in Collaborator's licensed field of use on terms that are reasonable under the circumstances; or if the Collaborator fails to grant such a license, to grant the license itself. The exercise of such rights by the Government shall only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Collaborator, (ii) the action is necessary to meet requirements for public use specified by Federal regulations, and such requirements are not reasonably satisfied by the Collaborator; or (iii) the Collaborator has failed to comply with an agreement containing provisions described in 15 U.S.C. 3710a(c)(4)(B). The determination made by the Government under this Article is subject to administrative appeal and judicial review under 35 U.S.C. 203(2).

7.6 Joint Inventions Not Exclusively Licensed. In the event that the Collaborator does not acquire an exclusive commercialization license to IP rights in all fields in joint Subject Inventions described in Article 6.4, then each Party shall have the right to use the joint Subject Invention and to license its use to others in all fields not exclusively licensed to Collaborator. The Parties may agree to a joint licensing approach for such



IP rights.

## Article 8. Proprietary Rights and Publication

8.1 Right of Access. PHS and the Collaborator agree to exchange all Subject Data produced in the course of research under this CRADA. Research Materials will be shared equally by the Parties to the CRADA unless other disposition is agreed to by the Parties. All Parties to this CRADA will be free to utilize Subject Data and Research Materials for their own purposes, consistent with their obligations under this CRADA.

8.2 Ownership of Subject Data and Research Materials. Subject to the sharing requirements of Paragraph 8.1 and the regulatory filing requirements of Paragraph 8.3, the producing Party will retain ownership of and title to all Subject Inventions, all Subject Data and all Research Materials produced solely by their investigators. Jointly developed Subject Inventions, Subject Data and Research Materials will be jointly owned.

8.3 Dissemination of Subject Data and Research Materials. To the extent permitted by law, the Collaborator and PHS agree to use reasonable efforts to keep Subject Data and Research Materials confidential until published or until corresponding patent applications are filed. Any information that would identify human subjects of research or patients will always be maintained confidentially. To the extent permitted by law, the Collaborator shall have the exclusive right to use any and all CRADA Subject Data in and for any regulatory filing by or on behalf of Collaborator, except that PHS shall have the exclusive right to use Subject Data for that purpose, and authorize others to do so, if the CRADA is terminated or if Collaborator abandons its commercialization efforts.

8.4 Proprietary/Confidential Information. Each Party agrees to limit its disclosure of Proprietary/Confidential Information to the amount necessary to carry out the Research Plan of this CRADA, and shall place a confidentiality notice on all such information. Confidential oral communications shall be reduced to writing within 30 days by the disclosing

Party. Each Party receiving Proprietary/Confidential Information agrees that any information so designated shall be used by it only for the purposes described in the attached Research Plan. Any Party may object to the designation of information as Proprietary/Confidential Information by another Party. Subject Data and Research Materials developed solely by the Collaborator may be designated as Proprietary/Confidential Information when they are wholly separable from the Subject Data and Research Materials developed jointly with PHS investigators, and advance designation of such data and material categories is set forth in the RP. The exchange of other confidential information, e.g., patient-identifying data, should be similarly limited and treated. Jointly developed Subject Data and Research Material derived from the Research Plan may be disclosed by Collaborator to a third party under a confidentiality agreement for the purpose of possible sublicensing pursuant to the Licensing Agreement and subject to Article 8.7.

#### 8.5 Protection of Proprietary/Confidential Information.

Proprietary/Confidential Information shall not be disclosed, copied, reproduced or otherwise made available to any other person or entity without the consent of the owning Party except as required under court order or the Freedom of Information Act (5 U.S.C. ' 552). Each Party agrees to use its best efforts to maintain the confidentiality of Proprietary/Confidential Information. Each Party agrees that the other Party is not liable for the disclosure of Proprietary/Confidential Information which, after notice to and consultation with the concerned Party, the other Party in possession of the Proprietary/Confidential Information determines may not be lawfully withheld, provided the concerned Party has been given an opportunity to seek a court order to enjoin disclosure.

8.6 Duration of Confidentiality Obligation. The obligation to maintain the confidentiality of Proprietary/Confidential Information shall expire at the earlier of the date when the information is no longer Proprietary Information as defined in Article 2.7 or three (3) years after the expiration or termination date of this CRADA. The Collaborator may

request an extension to this term when necessary to protect Proprietary/Confidential Information relating to products not yet commercialized.

8.7 Publication. The Parties are encouraged to make publicly available the results of their research. Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about a Subject Invention, Subject Data or Research Materials, the other Party shall be provided thirty (30) days to review the proposed publication or disclosure to assure that Proprietary/Confidential Information is protected. The publication or other disclosure shall be delayed for up to thirty (30) additional days upon written request by any Party as necessary to preserve U.S. or foreign patent or other IP rights.

## Article 9. Representations and Warranties

9.1 Representations and Warranties of PHS. PHS hereby represents and warrants to the Collaborator that the official signing this CRADA has authority to do so.

### 9.2 Representations and Warranties of the Collaborator.

9.2.1. The Collaborator hereby represents and warrants to PHS that the Collaborator has the requisite power and authority to enter into this CRADA and to perform according to its terms, and that the Collaborator's official signing this CRADA has authority to do so. The Collaborator further represents that it is financially able to satisfy any funding commitments made in Appendix B.

9.2.2. The Collaborator certifies that the statements herein are true, complete, and accurate to the best of its knowledge. The Collaborator is aware that any false, fictitious, or fraudulent statements or claims may subject it to criminal, civil, or administrative penalties.

## Article 10. Termination

10.1 Termination By Mutual Consent. PHS and the Collaborator may terminate this CRADA, or portions thereof, at any time by mutual written consent. In such event the Parties shall specify the disposition of all property, inventions, patent or other IP applications and other results of work accomplished or in progress, arising from or performed under this CRADA, all in accordance with the rights granted to the Parties under the terms of this Agreement.

10.2 Unilateral Termination. Either PHS or the Collaborator may unilaterally terminate this entire CRADA at any time by giving written notice at least thirty (30) days prior to the desired termination date, and any rights accrued in property, patents or other IP rights shall be disposed of as provided in paragraph 10.1.

10.3 Staffing. If this CRADA is mutually or unilaterally terminated prior to its expiration, funds will nevertheless remain available to PHS for continuing any staffing commitment made by the Collaborator pursuant to Article 5.1 above and Appendix B, if applicable, for a period of six (6) months after such termination. If there are insufficient funds to cover this expense, the Collaborator agrees to pay the difference.

10.4 New Commitments. No Party shall make new commitments related to this CRADA after a mutual termination or notice of a unilateral termination and shall, to the extent feasible, cancel all outstanding commitments and contracts by the termination date.

10.5 Termination Costs. Concurrently with the exchange of final reports pursuant to Articles 4.2 and 5.2, PHS shall submit to the Collaborator for payment a statement of all costs incurred prior to the date of termination and for all reasonable termination costs including the cost of returning Collaborator property or removal of abandoned property, for which

Collaborator shall be responsible.

## Article 11. Disputes

11.1 Settlement. Any dispute arising under this CRADA which is not disposed of by agreement of the Principal Investigators shall be submitted jointly to the signatories of this CRADA. If the signatories are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the Assistant Secretary for Health (or his/her designee or successor) shall propose a resolution. Nothing in this Article shall prevent any Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies.

11.2 Continuation of Work. Pending the resolution of any dispute or claim pursuant to this Article, the Parties agree that performance of all obligations shall be pursued diligently in accordance with the direction of the PHS signatory.

## Article 12. Liability

12.1 Property. The U.S. Government shall not be responsible for damages to any Collaborator property provided to PHS, where Collaborator retains title to the property, or any property acquired by Collaborator for its own use pursuant to this CRADA.

12.2 NO WARRANTIES. EXCEPT AS SPECIFICALLY STATED IN ARTICLE 9, THE PARTIES MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO ANY MATTER WHATSOEVER, INCLUDING THE CONDITIONS OF THE RESEARCH OR ANY INVENTION OR PRODUCT, WHETHER TANGIBLE OR INTANGIBLE, MADE, OR DEVELOPED UNDER THIS CRADA, OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY

## INVENTION OR PRODUCT.

12.3 Indemnification. The Collaborator agrees to hold the U.S. Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of the use by the Collaborator for any purpose of the Subject Data, Research Materials and/or Subject Inventions produced in whole or part by PHS employees under this CRADA, unless due to the negligence or willful misconduct of PHS, its employees, or agents. The Collaborator shall be liable for any claims or damages it incurs in connection with this CRADA. PHS has no authority to indemnify the Collaborator.

12.4 Force Majeure. Neither Party shall be liable for any unforeseeable event beyond its reasonable control not caused by the fault or negligence of such Party, which causes such Party to be unable to perform its obligations under this CRADA, and which it has been unable to overcome by the exercise of due diligence. In the event of the occurrence of such a force majeure event, the Party unable to perform shall promptly notify the other Party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the force majeure event.

## Article 13. Miscellaneous

13.1 Governing Law. The construction, validity, performance and effect of this CRADA shall be governed by Federal law, as applied by the Federal Courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this CRADA.

13.2 Entire Agreement. This CRADA constitutes the entire agreement between the Parties concerning the subject matter of this CRADA and supersedes any prior understanding or written or oral agreement.

13.3 Headings. Titles and headings of the articles and subarticles of this CRADA are for convenient reference only, do not form a part of this CRADA, and shall in no way affect its interpretation. The PHS component that is the Party for all purposes of this CRADA is the Bureau(s), Institute(s), Center(s) or Division(s) listed on the Cover Page herein.

13.4 Waivers. None of the provisions of this CRADA shall be considered waived by any Party unless such waiver is given in writing to the other Party. The failure of a Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any rights of any Party.

13.5 Severability. The illegality or invalidity of any provisions of this CRADA shall not impair, affect, or invalidate the other provisions of this CRADA.

13.6 Amendments. If either Party desires a modification to this CRADA, the Parties shall, upon reasonable notice of the proposed modification or extension by the Party desiring the change, confer in good faith to determine the desirability of such modification or extension. Such modification shall not be effective until a written amendment is signed by the signatories to this CRADA or by their representatives duly authorized to execute such amendment.

13.7 Assignment. Neither this CRADA nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party.

13.8 Notices. All notices pertaining to or required by this CRADA shall be in writing and shall be signed by an authorized representative and shall be delivered by hand or sent by certified mail, return receipt requested, with postage prepaid, to the addresses indicated on the signature page for each Party. Notices regarding the exercise of license options shall be made pursuant to Article 7.2. Any Party may change such address by notice given

to the other Party in the manner set forth above.

13.9 Independent Contractors. The relationship of the Parties to this CRADA is that of independent contractors and not agents of each other or joint venturers or partners. Each Party shall maintain sole and exclusive control over its personnel and operations. Collaborator employees who will be working at PHS facilities may be asked to sign a Guest Researcher or Special Volunteer Agreement appropriately modified in view of the terms of this CRADA.

13.10 Use of Name or Endorsements. By entering into this CRADA, PHS does not directly or indirectly endorse any product or service provided, or to be provided, whether directly or indirectly related to either this CRADA or to any patent or other IP license or agreement which implements this CRADA by its successors, assignees, or licensees. The Collaborator shall not in any way state or imply that this CRADA is an endorsement of any such product or service by the U.S. Government or any of its organizational units or employees. Collaborator issued press releases that reference or rely upon the work of PHS under this CRADA shall be made available to PHS at least 7 days prior to publication for review and comment.

13.11 Exceptions to this CRADA. Any exceptions or modifications to this CRADA that are agreed to by the Parties prior to their execution of this CRADA are set forth in Appendix C.

13.12 Reasonable Consent. Whenever a Party's consent or permission is required under this CRADA, such consent or permission shall not be unreasonably withheld.

#### Article 14. Duration of Agreement

14.1 Duration. It is mutually recognized that the duration of this project cannot be rigidly defined in advance, and that the contemplated time periods



for various phases of the RP are only good faith guidelines subject to adjustment by mutual agreement to fit circumstances as the RP proceeds. In no case will the term of this CRADA extend beyond the term indicated in the RP unless it is revised in accordance with Article 13.6.

14.2 Survivability. The provisions of Articles 4.2, 5-8, 10.3-10.5, 11.1, 12.2-12.4, 13.1, 13.10 and 14.2 shall survive the termination of this CRADA.

SIGNATURES BEGIN ON THE NEXT PAGE

FOR PHS:

/s/ Alan Rabson

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Alan Rabson, M.D.  
Deputy Director, NCI

-----  
Date

Mailing Address for Notices:

National Cancer Institute  
Technology Development & Commercialization Branch  
NCI-FCRDC  
1003 West Seventh Street, Fairview Center, Suite 502  
Frederick, MD 21701  
phone: 301-846-5465  
fax: 301-8466820

FOR THE COLLABORATOR:

/s/ Russell J. Howard

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Russell J. Howard, Ph.D.  
CEO and President

Date

Mailing Address for Notices:

Maxygen, Inc.  
515 Galveston Drive  
Redwood City, CA 94063  
phone: 650-298-5300  
fax: 650-364-2715

Appendix A: RESEARCH PLAN

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Title: Shuffling of \*\*\*\*\*.

National Cancer Institute (NCI) Principal Investigators:

\*\*\*\*\*

\*\*\*\*\*

Collaborator Principal Investigator:

\*\*\*\*\*

Term of CRADA: 3 years from execution of this CRADA.

A Letter of Intent (LOI) for this CRADA was executed by and between the

Parties on 10/13/99.

#### GOALS OF THE CRADA:

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This CRADA Research Plan (RP) describes a collaboration between the NCI-Developmental Therapeutics Program (DTP) and Maxygen. The CRADA collaboration leverages the NCI research on \*\*\*\*\* and Maxygen's proprietary Shuffling Technology which can rapidly evolve and select improved versions of natural and synthetic \*\*\*\*\*. The major activity of this CRADA is for the DTP and Maxygen to collaborate to screen and characterize \*\*\*\*\* provided by Maxygen. The major goal of this CRADA is to maximize the chemotherapeutic potential of \*\*\*\*\*.

Goal A of this CRADA is to screen and optimize evolved \*\*\*\*\* synergize with that of the commercially-available, tubulin inhibitor, \*\*\*\*\*, on breast cancer cell lines.

The \*\*\*\*\* provided by Maxygen for screening and optimization under this CRADA will be targeted toward one or the other of the following improved cytotoxicity and antigenic profiles:

- (1) An evolved, \*\*\*\*\*.
- (2) An evolved derivative of the \*\*\*\*\*.

One of the great attractions of \*\*\*\*\* as anti-tumor agents is that they act by mechanisms that are insensitive to mutations in \*\*\*\*\*. Additionally, they synergize with the activity of DNA damaging agents such as \*\*\*\*\* in some, but not all, cell lines [32]. The Shuffled \*\*\*\*\* may be expressed as fusions to targeting domains such as \*\*\*\*\*.

Goal B: Implement an in vivo mouse model program to identify clinical candidates from the optimized evolved \*\*\*\*\*.

Candidate molecules selected for improved activity from the efforts as described in Goal A are to be screened by the NCI-Biological Testing Branch (BTB) in \*\*\*\*\* animal models containing \*\*\*\*\*.

## SCIENTIFIC BACKGROUND

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### Maxygen's Shuffling Technology:

Maxygen's Shuffling Technology: Maxygen's Shuffling Technology consists of proprietary techniques, methodologies, processes, materials and/or instrumentation useful for the recombination, rearrangement, and/or mutation of genetic material for the creation of genetic diversity, and subsequent techniques useful for the high-throughput (HTP) screening of the resultant genetic material to identify potentially useful genes. Shuffling, as practiced in the laboratory, mirrors the process of natural evolution by which the tremendous diversity of all life forms may have been created. In nature, the accumulation of mutations and the process of sexual reproduction creates genetic diversity. This genetic diversity is subjected to natural selection pressures such that only some of the genetic diversity survives. Humans have used the enormous amount of existing genetic diversity to their advantage by breeding domestic dogs, horses, cattle, cats, vegetables, fruits, and cereals from wild breeding stocks. Breeders select whatever characteristics they desire from within existing species and breed them together, regardless of whether the resulting animal or plant would ever survive (i.e. be useful) in nature. In just a few generations of breeding, substantial variation and novel properties can be achieved.

Shuffling is, in essence, the application of classical breeding principles to sub-genomic sequences. This approach to sequence evolution generalizes concepts from classical genetics, allowing one to selectively breed DNA

sequences in the test tube. Maxygen begins with the natural diversity already present in a gene family or creates it by mutagenesis, and then rapidly shuffles the diversity to create a large pool of novel genes. Their process involves fragmenting the genes into pieces and reassembling them in a homology-dependent fashion. Those genes that encode proteins with the desired novel properties are then selected using high-throughput (HTP) screening assays. As with traditional breeding, Maxygen's technology does not require a rational understanding of the genes involved in order to engineer novel properties. This technology provides a powerful tool for rapidly evolving single genes, operons and whole viruses for desired properties, and has many advantages relative to random mutation or rational sequence design.

\*\*\*\*\*

RELATED PATENT APPLICATIONS AND PATENTS, OTHER AGREEMENTS:

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The Parties hereby modify their rights under the following prior agreements:

Confidential Disclosure Agreement: Two-way agreement # 3-60778-99;

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and the Parties agree that the materials and/or information provided thereunder are now governed by the terms of this CRADA in accordance with Article 13.2, except that the obligations of the parties with regard to

confidentiality shall remain retroactive to December 14, 1998.

Letter of Intent: A Letter of Intent (LOI) for this CRADA was executed by and ----- between the Parties on 10/13/99. With this exception, there are no other existing CRADAs between NIH and Maxygen.

Related Patents/Patent Applications of NCI:  
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Note: Maxygen has decided not to apply for a license at this time for the NIH Intellectual Property listed below. Maxygen would prefer to wait for results obtained from the Research Plan of this CRADA before applying for a license. Nothing herein is a commitment by NIH not to license this patent(s) to others who may apply for a license pursuant to 37CFR 404 in the interim.

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## APPENDIX B

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### FINANCIAL AND STAFFING CONTRIBUTIONS OF THE PARTIES

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Maxygen Staffing: (total of 0.\*\*\*\*\* person-years for 1st year of CRADA. Staffing in subsequent years 2-3 will be contingent on the results obtained in the initial year). Changes in staffing levels will be documented by written amendment.

Maxygen will provide scientific staff and other support as necessary to conduct the research outlined in Appendix A, Research Plan. Staffing for the first year will be as follows:

Name	Position / title	% of time devoted to CRADA Research
------	------------------	-------------------------------------

Plan

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\*\*\*\*\* Principal Investigator \*\*\*\*\*

Duties: Direct the research described in the CRADA goals and provide scientific staff and other support as necessary to conduct the Research Plan as outlined in Appendix A.

\*\*\*\*\* Manager, Business Development \*\*\*\*\*

Duties: Assess commercial progress and opportunities, and provide on-going business support for Research Plan activities.

\*\*\*\*\* Maxygen \*\*\*\*\*

Duties: Creation of Shuffled \*\*\*\*\* at Maxygen, and scale-up of expression.

\*\*\*\*\* Maxygen \*\*\*\*\*

Duties: Expression and HTP screening of \*\*\*\*\*.

The above assignments and time allocations are approximate. During the term of the CRADA, these staffing assignments and percentages of time devoted to CRADA research are likely to vary from the information provided above.

Maxygen Financial Support: No funding will be provided to the National Cancer Institute for collaborative research and development pursuant to this CRADA.

National Cancer Institute Staffing: (total of \*\*\*\*\* person-years/year).

Name	Position / title	% time devoted to CRADA Research
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*****	NCI, Principal Investigator	*****
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Duties: To direct the research described in the CRADA goals and provide scientific staff and other support as necessary to conduct the Research Plan as outlined in Appendix A.

*****	Principal Investigator	*****
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Duties: To direct the research described in the CRADA goals and provide scientific staff and other support as necessary to conduct the Research Plan as outlined in Appendix A.

*****,	SAIC Investigator	*****
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Duties: Supervise SAIC personnel on project and conduct in vitro assays.

*****	NCI/DTP / LDDR	*****
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Duties: Conduct in vitro assays.

*****	NCI/DTP Investigator	*****
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Duties: Conduct in vitro assays



\*\*\*\*\* NCI/DTP Investigator \*\*\*\*\*

Duties: Conduct in vivo assays

\*\*\*\*\* SAIC Research Technician \*\*\*\*\*

Duties: Conduct in vivo assays

NCI Financial Support:

NCI will provide no funding to the Collaborator for collaborative research and development pursuant to this CRADA inasmuch as financial contributions by the U.S. government to non-Federal parties under a CRADA are not authorized under the Federal Technology Transfer Act [15 U.S.C. (S) 3710a(d)(1)].

APPENDIX C

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EXCEPTIONS OR MODIFICATIONS TO THIS CRADA

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The PHS Model CRADA is replaced in its entirety by the following in which additional terms are underlined, while deletions are struck-out.

PUBLIC HEALTH SERVICE

COOPERATIVE RESEARCH AND DEVELOPMENT

AGREEMENT

This Cooperative Research and Development Agreement, hereinafter referred to as the CRADA, consists of this Cover Page, an attached Agreement, and various Appendices referenced in the Agreement.

This Cover Page serves to identify the Parties to this CRADA:

(1) the following Bureau(s), Institute(s), Center(s) or Division(s) of the National Institutes of Health ('NIH'), The National Cancer Institute ('NCI'), hereinafter referred to as the National Institutes of Health ('NIH'); and

(2) Maxygen, Inc. which has offices at 515 Galveston Drive, Redwood City, California 94063, hereinafter referred to as the 'Collaborator'.

## COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

### Article 1. Introduction

This Cooperative Research and Development Agreement (CRADA) between NIH and the Collaborator will be effective when signed by all Parties. The research and development activities which will be undertaken by each of the Parties in the course of this CRADA are detailed in the Research Plan which is attached as Appendix A. The funding and staffing commitments of the Parties are set forth in Appendix B. Any exceptions or changes to the CRADA are set forth in Appendix C. This CRADA is made under the authority of the Federal Technology Transfer Act, 15 U.S.C. (S)3710a and is governed by its terms.

### Article 2. Definitions

As used in this CRADA, the following terms shall have the indicated meanings:

2.1 "Affiliate" means any corporation or other business entity controlled by, controlling, or under common control with Collaborator. For this purpose, A "control" means direct or indirect beneficial ownership of at least fifty (50) percent of the voting stock or at least fifty (50) percent interest in the income of such corporation or other business.

2.2 "Cooperative Research and Development Agreement" or "CRADA" means this Agreement, entered into by NIH pursuant to the Federal Technology Transfer Act of 1986, as amended, 15 U.S.C. 3710a et seq. and Executive Order 12591 of October 10, 1987.

2.3 "Government" means the Government of the United States as represented through the NIH agency that is a Party to this agreement.

2.4 "IP" means intellectual property.

2.5 "Invention" means any invention or discovery which is or may be patentable or otherwise protected under title 35, United States Code, or any novel variety or plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

2.6 "Principal Investigator(s)" or "PIs" means the persons designated respectively by the Parties to this CRADA who will be responsible for the scientific and technical conduct of the Research Plan.

2.7 "Proprietary/Confidential Information" means confidential scientific, business, or financial information provided that such information does not include:

2.7.1. information that is publicly known or available from other sources who are not under a confidentiality obligation to the source of the information;

2.7.2. information which has been made available by its owners to others without a confidentiality obligation;

2.7.3. information which is already known by or available to the receiving Party without a confidentiality obligation; or

2.7.4. information which relates to potential hazards or cautionary warnings associated with the production, handling or use of the subject matter of the Research Plan of this CRADA.

2.8 "Research Materials" means all tangible materials other than Subject Data first produced in the performance of the Research Plan of this CRADA.

2.9 "Research Plan" means the statement in Appendix A of the respective research and development commitments of the Parties to this CRADA.

2.10 "Subject Invention" means any Invention of the Parties, conceived or first actually reduced to practice in the performance of the Research Plan of this CRADA.

2.11 "Subject Data" means all recorded information first produced in the performance of the Research Plan of this CRADA by the Parties.

2.12 "Steering Committee" means the joint NIH Collaborator research and development team whose composition and responsibilities with regard to the studies performed under this CRADA are described in Article 3.3 of this CRADA.

2.13 "Shuffling" means the systems set up by man to use high speed recombination and/or rearrangement and/or mutation of genetic material for the creation of genetic diversity.

2.14 "Shuffling Technology" means techniques, methodologies, processes, materials and/or instrumentation useful for Shuffling, and the screening of genetic material resulting from Shuffling to identify potential useful genes.

### Article 3. Cooperative Research

3.1 Principal Investigators. NIH research work under this CRADA will be performed by the NIH laboratory identified in the Research Plan, and the NIH Principal Investigator (PI) designated in the Research Plan will be responsible for the scientific and technical conduct of this project on behalf of NIH. Also designated in the Research Plan is the Collaborator PI who will be responsible for the scientific and technical conduct of this project on behalf of the Collaborator.

3.2 Research Plan Change. The Research Plan may be modified by mutual written consent of the Principal Investigators. Substantial changes in the scope of the Research Plan will be treated as amendments under Article 13.6. If the results from the Research Plan are promising, NIH and Collaborator shall discuss, in good faith, plans to support and to submit proposals for further research in a separate clinical CRADA. If the Research Plan is amended to include the participation of any extramural grantee investigators, NIH shall urge the grantee investigators to cooperate exclusively with the Collaborator. However, such urging shall not constitute a condition of any grant award.

3.3 Steering Committee and CRADA Research. The Parties agree to establish a Steering Committee comprising at least the Principal Investigators designated pursuant to Article 3.1 to conduct and monitor the research in accordance with the Research Plan, review Subject Inventions disclosures and to review proposed publications and data. Details of the research and development as set forth in the Research Plan shall be formulated, reviewed and/or approved in Steering Committee meetings before implementation of any resource-intensive study. Notwithstanding the

forgoing, Collaborator has the option to sponsor its own pre-clinical studies outside the scope of this CRADA.

3.4 Composition of Steering Committee. Collaborator and NIH shall have equal voice in decisions of the Steering Committee. The initial composition of the Steering Committee shall be voting members on behalf of NIH and two voting members on behalf of Collaborator. A Steering Committee member representing NIH will co-chair the Steering committee with the Steering Committee member representing Collaborator. The membership of the Steering Committee may be changed from time to time as mutually agreed by NIH and Collaborator in writing.

3.5 Meetings. The Steering Committee shall meet within one month of the execution of this CRADA, and then regularly once a quarter thereafter or as appropriate. The Steering Committee shall be the forum for discussion of issues for which differences in opinion may arise and shall be the initial forum to attempt to resolve any disputes arising therefrom. In the event, resolution of such dispute(s) is not achieved in the Steering Committee, the dispute resolution mechanism of Article 11 herein shall be implemented. The Principal Investigators shall report regularly to the Steering Committee on the progress of the research and development efforts covered by this CRADA, but not less than once a quarter, unless mutually agreed. Attendance at the Steering Committee meetings shall be limited to members of the Steering Committee and invited participants, as mutually agreed to by the Parties. Invited participants shall be non-voting members of the Steering Committee.

3.6 Written Record. The Steering Committee shall appoint one of its members to act as the Committee Secretary for each meeting, such appointment alternately between the parties from meeting to meeting. The Secretary shall prepare, for Committee approval and signature, written summaries of each Steering Committee meeting within two weeks of each Steering Committee meeting. These summaries shall include information about Steering Committee deliberations and describe issues addressed and decisions reached. Written materials created by the Steering Committee shall be treated as described in subarticle 3.7 below. The written summary

shall be deemed to be approved by the Committee if no comments are received within two weeks of receipt thereof. Upon incorporation of modifications in accordance with such comments, the revised summary shall be transmitted to Committee members of signature, but will be deemed approved within two weeks of receipt thereof.

3.7 Treatment of Steering Committee Proprietary Information. Except as required by law and subject to Article 8 of this CRADA, the Parties agree that Proprietary/Confidential Information including disclosures of such data in discussions and information exchanged at meetings of the Steering Committee, and in written summaries of Steering Committee meetings, shall be maintained as confidential to the Parties, and shall not be disclosed to any third parties without the consultation and written agreement within the Steering Committee.

#### Article 4. Reports

4.1 Interim Reports. The Parties shall exchange formal written interim progress reports on a schedule agreed to by the PIs, but at least within twelve (12) months after this CRADA becomes effective and at least within every twelve (12) months thereafter. Such reports shall set forth the technical progress made, identifying such problems as may have been encountered and establishing goals and objectives requiring further effort, any modifications to the Research Plan pursuant to Article 3.2, and all CRADA-related patent applications filed. Steering Committee reports or copies of annual reports updating the progress of the CRADA research shall satisfy the minimum reporting requirements under this Article 4.1.

4.2 Final Reports. The Parties shall exchange final reports of their results within four (4) months after completing the projects described in the Research Plan or after the expiration or termination of this CRADA.

#### Article 5. Financial and Staffing Obligations

5.1 NIH and Collaborator Contributions. The contributions of the Parties, including payment schedules, if applicable, are set forth in Appendix B. NIH shall not be obligated to perform any of the research specified herein or to take any other action required by this CRADA if the funding is not provided as set forth in Appendix B. NIH shall return excess funds to the Collaborator when it sends its final fiscal report pursuant to Article 5.2, except for staffing support pursuant to Article 10.3. Collaborator acknowledges that the U.S. Government will have the authority to retain and expend any excess funds for up to one (1) year subsequent to the expiration or termination of the CRADA to cover any costs incurred during the term of the CRADA in undertaking the work set forth in the Research Plan.

5.2 Accounting Records. NIH shall maintain separate and distinct current accounts, records, and other evidence supporting all its obligations under this CRADA, and shall provide the Collaborator a final fiscal report pursuant to Article 4.2.

5.3 Capital Equipment. Equipment purchased by NIH with funds provided by the Collaborator shall be the property of NIH. All capital equipment provided under this CRADA by one party for the use of another Party remains the property of the providing Party unless other disposition is mutually agreed upon by in writing by the Parties. If title to this equipment remains with the providing Party, that Party is responsible for maintenance of the equipment and the costs of its transportation to and from the site where it will be used.

## Article 6. Intellectual Property Rights and Patent Applications

6.1 Reporting. The Parties shall promptly report to each other in writing each Subject Invention resulting from the research conducted under this CRADA that is reported to them by their respective employees. Each Party shall report all Subject Inventions to the other Party in sufficient detail to determine inventorship. Such reports shall be treated as



Proprietary/Confidential Information in accordance with Article 8.4.

6.2 Collaborator Employee Inventions. If the Collaborator does not elect to retain title to its IP rights in a Subject Invention, the Collaborator shall offer to assign these IP rights to the Subject Invention to NIH pursuant to Article 6.5. If NIH declines such assignment, the Collaborator may release title to its IP rights as it may determine.

6.3 NIH Employee Inventions. NIH on behalf of the U.S. Government may elect to retain title to its IP rights to each Subject Invention made solely by NIH employees. If NIH does not elect to retain title to its IP rights, NIH shall offer to assign these IP rights to such Subject Invention to the Collaborator pursuant to Article 6.5. If the Collaborator declines such assignment, NIH may release title to its IP rights in such Subject Invention to its employee inventors pursuant to Article 6.6.

6.4 Joint Inventions. Each Subject Invention made jointly by NIH and Collaborator employees shall be jointly owned by NIH and the Collaborator. If NIH and Collaborator both agree that a patent application should be filed on a jointly owned Subject Invention, then the parties shall consult about the best manner to proceed in filing and prosecuting the jointly owned patent application. If NIH and Collaborator elect to file jointly, then each shall bear one-half the costs of such filing and prosecution. However, NIH only has authority to reimburse such costs directly to law firms under contract to NIH. Alternatively, the Collaborator may elect to file the joint patent or other IP application(s) thereon and shall notify NIH promptly upon making this election. If the Collaborator decides to file such applications, it shall do so in a timely manner and at its own expense. If the Collaborator does not elect to file such application(s), NIH on behalf of the U.S. Government shall have the right to file the joint application(s) in a timely manner and at its own expense. If either Party decides not to retain title to its IP rights to a jointly owned Subject Invention, it shall offer to assign such rights to the other Party pursuant to Article 6.5. If the other Party declines such assignment, the offering Party may release title to its IP rights as provided in Articles 6.2, 6.3, and 6.6.

6.5 Filing of Patent Applications. With respect to Subject Inventions made by the Collaborator as described in Article 6.2, or by NIH as described in Article 6.3, a Party exercising its right to elect to retain title to its IP rights to a Subject Invention agrees to file patent or other IP applications in a timely manner and at its own expense and after consultation with the other Party. The Party shall notify the other Party of its decision regarding filing in countries other than the United States in a timely manner. The Party may elect not to file a patent or other IP application thereon in any particular country or countries provided it so advises the other Party ninety (90) days prior to the expiration of any applicable filing deadline, priority period or statutory bar date, and hereby agrees to assign its IP right, title and interest in the Subject Invention in such country or countries to the Subject Invention to the other Party and to cooperate in the preparation and filing of a patent or other IP applications. In any countries in which title to patent or other IP rights for Subject Inventions is transferred to the Collaborator, the Collaborator agrees that NIH inventors will share in any royalty distribution that the Collaborator pays to its own inventors.

6.6 Release to Inventors. In the event neither of the Parties to this CRADA elects to file a patent or other IP application on a Subject Invention, either or both (if a joint invention) may retain or release titles to their IP rights in accordance with their respective policies and procedures. If NIH elects not to retain title to its IP rights in and to any such Subject Invention made solely or jointly by NIH, the Government shall retain a nonexclusive, non-transferable, irrevocable, royalty-free license to practice any such Subject Invention, or have it practiced throughout the world by or on behalf of the Government. Similarly, if Collaborator elects not to retain title to any IP rights to Subject Inventions made jointly or solely by its employees and, pursuant to Article 6.2 herein, offers such rights to NIH which waives such rights, then Collaborator shall be free to release such rights to its employee inventors subject to the Government retaining a nonexclusive, non-transferable, irrevocable, royalty-free license to practice, or have such Subject Invention(s) practiced throughout the world by or on behalf of the Government.

6.7 Patent Expenses. The expenses attendant to the filing of patent or other IP applications generally shall be paid by the Party filing such application unless agreed otherwise in connection with jointly owned patent applications. If an exclusive license to any Subject Invention is granted to the Collaborator, the Collaborator shall be responsible for all past and future out-of-pocket expenses in connection with the preparation, filing, prosecution and maintenance of any applications claiming such exclusively- licensed inventions and any patents or other IP grants that may issue on such applications. The Collaborator may waive its exclusive license rights on any application, patent or other IP grant at any time, and incur no subsequent compensation obligation for that application, patent or IP grant.

6.8 Prosecution of Intellectual Property Applications. Within one month of receipt or filing, each Party shall provide the other Party with copies of the applications and all documents received from or filed with the relevant patent or other IP office in connection with the prosecution of such applications. Each Party shall also provide the other Party with the power to inspect and make copies of all documents retained in the patent or other IP application files by the applicable patent or other IP office. Where licensing is contemplated by Collaborator, the Parties agree to consult with each other with respect to the prosecution of applications for NIH Subject Inventions described in Article 6.3 and joint Subject Inventions described in Article 6.4. If the one party elects to file and prosecute IP applications on joint Subject Inventions pursuant to Article 6.4, the other party will be granted an associate power of attorney (or its equivalent) on such IP applications. Patent counsel for each party shall cooperate with patent counsel for the other party in connection with the filing, prosecution and maintenance of patent applications claiming joint Subject Inventions. Associate power of Attorney will not be used by either party to make any submissions to the USPTO without consulting with the other party.

## Article 7. Licensing

7.1 Option for Commercialization License. With respect to Government IP

rights to any Subject Invention not made solely by the Collaborator's employees for which a patent or other IP application is filed, NIH hereby grants to the Collaborator an exclusive option to elect an exclusive or nonexclusive commercialization license, which is substantially in the form of the appropriate model NIH license agreement. This option does not apply to Subject Inventions conceived prior to the effective date of this CRADA that are reduced to practice under this CRADA, if prior to that reduction to practice, NIH has filed a patent application on the invention and has licensed it or offered to license it to a third party. The terms of the license will fairly reflect the nature of the invention, the relative contributions of the Parties to the invention and the CRADA, the risks incurred by the Collaborator and the costs of subsequent research and development needed to bring the invention to the marketplace. The field of use of the license will be commensurate with the scope of the Research Plan. The Collaborator shall have the right to sublicense the license rights granted hereunder, provided that the Collaborator obtains the prior written consent of NIH for the sublicensing of its non-exclusive license rights, such consent to be reasonably given in situations where Collaborator sublicenses its exclusive rights in one or more Subject Invention(s) to sublicensee(s) and requests to sublicense its non-exclusive rights in Subject Invention(s) to the same sublicensee(s); and any such sublicensee shall be bound by the terms of this license.

**7.2 Exercise of License Option.** The option of Article 7.1 must be exercised with respect to a particular Subject Invention by written notice mailed within three (3) months after either (i) Collaborator receives written notice from NIH that the patent or other IP application has been filed; or (ii) the date Collaborator files such IP application. Exercise of this option by the Collaborator initiates a negotiation period that expires nine (9) months after the exercise of the option. If the last proposal by the Collaborator has not been responded to in writing by NIH within this nine (9) month period, the negotiation period shall be extended to expire one (1) month after NIH so responds, during which month the Collaborator may accept in writing the final license proposal of NIH. In the absence of such acceptance, or an extension of the time limits by NIH, NIH will be free to license its rights in such Subject Invention to others. In the event that the Collaborator elects

the option for an exclusive license, but no such license is executed during the negotiation period, NIH agrees not to make an offer for an exclusive license on more favorable terms to a third party for a period of twelve (12) months without first offering Collaborator those more favorable terms. These times may be extended at the sole discretion of NIH upon good cause shown in writing by the Collaborator.

7.3 License for NIH Employee Inventions and Joint Inventions. Pursuant to 15 U.S.C. (S) 3710a(b)(1)(A), for Subject Inventions made under this CRADA by a NIH employee(s) or jointly by such employee(s) and employees of the Collaborator pursuant to Articles 6.3 and 6.4 and licensed pursuant to the option of Article 7.1, the Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. 552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party. The retained non-exclusive Government licenses described in this Article 7, and elsewhere herein, are intended by the NIH to be invoked by the NIH in circumstances consistent with the legislative history of the Stevenson-Wydler Technology Innovation Act, as amended, that provide for such licenses.

7.4 License in Collaborator Inventions. Pursuant to 15 U.S.C. (S) 3710a(b)(2), for inventions made solely by Collaborator employees under this CRADA pursuant to Article 6.2, (1) NIH hereby ensures Collaborator that Collaborator shall retain title in such Subject Inventions, and (2) the Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the Subject invention or have the Subject Invention practiced throughout the world by or on behalf of the Government for research or other Government purposes. As stated in the Research Plan, during the course and in the performance of this CRADA, the Collaborator will only use Shuffling Technology that Collaborator has developed or develops outside the course and performance of the CRADA

program. If the progress of the CRADA research would benefit by the development of inventive Shuffling Technology subject matter during the course of the CRADA, Collaborator will attempt to develop such inventive subject matter outside the scope, course and performance of the present CRADA. Such inventive Shuffling Technology subject matter shall not be considered to comprise a Subject Invention as defined herein. However, selected Shuffled \*\*\*\*\* and their corresponding DNA clones are considered Research Materials of the CRADA and fall under the scope of the CRADA Research Plan.

7.5 Third Party License. Pursuant to 15 U.S.C. (S) 3710a(b)(1)(B), if NIH grants an exclusive license to a Subject Invention made wholly by NIH employees or jointly with a Collaborator under this CRADA, pursuant to Articles 6.3 and 6.4, the Government shall retain the right to require the Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the invention in Collaborator's licensed field of use on terms that are reasonable under the circumstances; or if the Collaborator fails to grant such a license, to grant the license itself. The exercise of such rights by the Government shall only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Collaborator, (ii) the action is necessary to meet requirements for public use specified by Federal regulations, and such requirements are not reasonably satisfied by the Collaborator; or (iii) the Collaborator has failed to comply with an agreement containing provisions described in 15 U.S.C. 3710a(c)(4)(B). The determination made by the Government under this Article is subject to administrative appeal and judicial review under 35 U.S.C. 203(2).

7.6 Joint Inventions Not Exclusively Licensed. In the event that the Collaborator does not acquire an exclusive commercialization license to IP rights in all fields in joint Subject Inventions described in Article 6.4, then each Party shall have the right to use the joint Subject Invention and to license its use to others in all fields not exclusively licensed to Collaborator. The Parties may agree to a joint licensing approach for such IP rights.

## Article 8. Proprietary Rights and Publication

8.1 Right of Access. NIH and the Collaborator agree to exchange all Subject Data produced in the course of research under this CRADA. Research Materials will be shared equally by the Parties to the CRADA unless other disposition is agreed to by the Parties. All Parties to this CRADA will be free to utilize Subject Data and Research Materials for their own purposes, consistent with their obligations under this CRADA provided that NIH shall not have direct access to and/or direct use of Collaborator's proprietary Shuffling Technology in the performance of the CRADA.

8.2 Ownership of Subject Data and Research Materials. Subject to the sharing requirements of Paragraph 8.1 and the regulatory filing requirements of Paragraph 8.3, the producing Party will retain ownership of and title to all Subject Inventions, all Subject Data and all Research Materials produced solely by their investigators. Jointly developed Subject Inventions, Subject Data and Research Materials will be jointly owned.

8.3 Dissemination of Subject Data and Research Materials. To the extent permitted by law, the Collaborator and NIH agree to use reasonable efforts to keep Subject Data and Research Materials confidential until published or until corresponding patent applications are filed. Any information that would identify human subjects of research or patients will always be maintained confidentially. To the extent permitted by law, the Collaborator shall have the exclusive right to use any and all CRADA Subject Data in and for any regulatory filing by or on behalf of Collaborator, except that NIH shall have the exclusive right to use Subject Data for that purpose, and authorize others to do so, if Collaborator abandons its commercialization efforts.

8.4 Proprietary/Confidential Information. Each Party agrees to limit its disclosure of Proprietary/Confidential Information to the other Party hereunder to the amount necessary CRADA #00880 to carry out the

Research Plan of this CRADA, and shall place a confidentiality notice on all such information. Confidential oral communications shall be reduced to writing within 30 days by the disclosing Party. Each Party receiving Proprietary/Confidential Information of the other Party pursuant to this CRADA agrees that any information so designated shall be used by it only for the purposes described in the attached Research Plan. Any Party may object to the designation of information as Proprietary/Confidential Information by another Party. Subject Data and Research Materials developed solely by the Collaborator may be designated as Proprietary/Confidential Information when they are wholly separable from the Subject Data and Research Materials developed jointly with NIH investigators, and advance designation of such data and material categories is set forth in the Research Plan. The exchange of other confidential information, e.g., patient-identifying data, should be similarly limited and treated. Jointly developed Subject Data and Research Material derived from the Research Plan may be disclosed by Collaborator to a third party under a confidentiality agreement for the purpose of possible sublicensing pursuant to any licensing agreement of Subject Inventions or such purposes as Collaborator considers appropriate to pursue its commercial interests including, but not limited to, disclosures to manufacturing subcontractors, clinical or preclinical laboratories, medical or scientific consultants, quality control, quality assurance or analytical laboratories, or government regulatory agencies.

#### 8.5 Protection of Proprietary/Confidential Information.

Proprietary/Confidential Information shall not be disclosed, copied, reproduced or otherwise made available to any other person or entity without the consent of the owning Party except as required under court order or the Freedom of Information Act (5 U.S.C. (S) 552). Each Party agrees to use its best efforts to maintain the confidentiality of Proprietary/Confidential Information. Each Party agrees that the other Party is not liable for the disclosure of Proprietary/Confidential Information which, after notice to and consultation with the concerned Party, the other Party in possession of the Proprietary/Confidential Information determines may not be lawfully withheld, provided the concerned Party has been given an opportunity to seek a court order to enjoin disclosure.



8.6 Duration of Confidentiality Obligation. The obligation to maintain the confidentiality of Proprietary/Confidential Information shall expire at the earlier of the date when the information is no longer Proprietary Information as defined in Article 2.7 or three (3) years after the expiration or termination date of this CRADA unless, after the said three (3) years, any Party informs the other Party that the Confidential Information is still secret and confidential, in which case the obligation shall extend for a further successive periods of two (2) years. The Collaborator may request an extension to these terms when necessary to protect Proprietary/Confidential Information relating to products not yet commercialized.

8.7 Publication. The Parties are encouraged to make publicly available the results of their research. Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about a Subject Invention, Subject Data or Research Materials, or any other confidential information concerning this CRADA, the submitting Party shall first submit a draft of the proposed disclosure to the Steering Committee for review at least 30 days prior to any submission for publication or other public disclosure. As defined under Article 8.4, if such proposed disclosure contains Proprietary/Confidential Information of a Party, such Party may require that such Confidential Information be deleted or modified from the proposed disclosure in accordance with Article 8.5. The Steering Committee shall provide advisory review and comments prior to submission of proposed disclosures for publication and/or public presentation. The submitting party will seriously consider the suggested modifications of the Steering Committee. To avoid loss of patent rights as a result of premature public disclosure of patentable information, the reviewing Party shall notify the submitting Party in writing within 30 days after receipt of such proposed disclosure whether the reviewing Party desires that a patent application be filed on any invention disclosed in such proposed disclosure. In the event that the reviewing Party desires such filing, the submitting Party shall withhold publication or disclosure of such proposed disclosure until the earlier of: (i) the date a patent application is filed thereon, or (ii) the date the

Parties determine after consultation that no patentable invention exists, or (iii) 60 days after receipt by the submitting Party of the reviewing Party's written notice of its desire to file such patent application.

## Article 9. Representations and Warranties

9.1 Representations and Warranties of NIH. NIH hereby represents and warrants to the Collaborator that the official signing this CRADA has authority to do so.

9.2 Representations and Warranties of the Collaborator.

(a) The Collaborator hereby represents and warrants to NIH that the Collaborator has the requisite power and authority to enter into this CRADA and to perform according to its terms, and that the Collaborator's official signing this CRADA has authority to do so. The Collaborator further represents that it is financially able to satisfy any funding commitments made in Appendix B.

(b) The Collaborator certifies that the statements herein are true, complete, and accurate to the best of its knowledge. The Collaborator is aware that any false, fictitious, or fraudulent statements or claims may subject it to criminal, civil, or administrative penalties.

9.3 NIH Disclosure of Third Party Rights. NIH hereby acknowledges that Research Materials provided to Collaborator during the course of the CRADA research may be subject to third party patent and other rights. NIH will exercise its best efforts to provide Collaborator with all non-privileged and non-confidential information its PI and NIH have in their possession, or of which they are aware, identifying third party rights in and to Research Materials supplied by NIH to Collaborator under this CRADA.

## Article 10. Termination

10.1 Termination By Mutual Consent. NIH and the Collaborator may terminate this CRADA, or portions thereof, at any time by mutual written consent. In such event the Parties shall specify the disposition of all property, inventions, patent or other IP applications and other results of work accomplished or in progress, arising from or performed under this CRADA, all in accordance with the rights granted to the Parties under the terms of this Agreement.

10.2 Unilateral Termination. Either NIH or the Collaborator may unilaterally terminate this entire CRADA at any time by giving written notice at least thirty (30) days prior to the desired termination date, and any rights accrued in property, patents or other IP rights shall be disposed of as provided in paragraph 10.1, provided that, if either Party unilaterally terminates this CRADA for reasons other than for cause including, but not limited to, lack of interest, unwillingness or inability of either Party to contribute resources to the continuation of the CRADA research, and decides not to retain title to its IP rights to Subject Inventions, then pursuant to Articles 6.2, 6.3 and 6.4, such Party shall offer to assign these IP rights to such Subject Inventions to the other Party.

10.3 Staffing. If this CRADA is mutually or unilaterally terminated by Collaborator prior to its expiration, funds will nevertheless remain available to NIH for continuing any staffing commitment made by the Collaborator pursuant to Article 5.1 above and Appendix B, if applicable, for a period of six (6) months after such termination. If there are insufficient funds to cover this expense, the Collaborator agrees to pay the difference.

10.4 New Commitments. No Party shall make new commitments related to this CRADA after a mutual termination or notice of a unilateral termination and shall, to the extent feasible, cancel all outstanding commitments and contracts by the termination date.

10.5 Termination Costs.

Collaborator shall not be responsible to NIH for any termination costs.

## Article 11. Disputes

11.1 Settlement. Any dispute arising under this CRADA which is not disposed of by agreement of the Principal Investigators shall be submitted jointly to the signatories of this CRADA. If the signatories are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the Assistant Secretary for Health (or his/her designee or successor) shall propose a resolution. Nothing in this Article shall prevent any Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies.

11.2 Continuation of Work. Pending the resolution of any dispute or claim pursuant to this Article, the Parties agree that performance of all non-disputed obligations shall be pursued diligently in accordance with the direction of the NIH signatory. Disputed obligations shall be pursued diligently by each Party in accordance with their best judgment and subject to their obligation to mitigate any damages resulting from their actions.

## Article 12. Liability

12.1 Property. The U.S. Government shall not be responsible for damages to any Collaborator property provided to NIH, where Collaborator retains title to the property, or any property acquired by Collaborator for its own use pursuant to this CRADA.

12.2 NO WARRANTIES. EXCEPT AS SPECIFICALLY STATED IN ARTICLE 9, THE PARTIES MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO ANY MATTER WHATSOEVER, INCLUDING THE CONDITIONS OF THE RESEARCH OR ANY INVENTION OR PRODUCT,

WHETHER TANGIBLE OR INTANGIBLE, MADE, OR DEVELOPED UNDER THIS CRADA, OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY INVENTION OR PRODUCT.

12.3 Indemnification. The Collaborator agrees to hold the U.S. Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of the use by the Collaborator for any purpose of the Subject Data, Research Materials and/or Subject Inventions produced in whole or part by NIH employees under this CRADA, unless due to the negligence or willful misconduct or willful misrepresentation of NIH, its employees, or agents. The Collaborator shall be liable for any claims or damages arising from the liable acts of the Collaborator in connection with this CRADA. NIH has no authority to indemnify the Collaborator.

12.4 Force Majeure. Neither Party shall be liable for any unforeseeable event beyond its reasonable control not caused by the fault or negligence of such Party, which causes such Party to be unable to perform its obligations under this CRADA, and which it has been unable to overcome by the exercise of due diligence. In the event of the occurrence of such a force majeure event, the Party unable to perform shall promptly notify the other Party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the force majeure event.

#### Article 13. Miscellaneous

13.1 Governing Law. The construction, validity, performance and effect of this CRADA shall be governed by Federal law, as applied by the Federal Courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this CRADA.

13.2 Entire Agreement. This CRADA constitutes the entire agreement

between the Parties concerning the subject matter of this CRADA and supersedes any prior understanding or written or oral agreement.

The Parties hereby modify their rights under the following prior agreement(s):

Confidential Disclosure Agreement: Two-way agreement # 3-60778-99:

\*\*\*\*\*

Effective date: December 14, 1998

Material Transfer Agreement: # 2-50178

Provider: Maxygen; Recipient: NCI, DTP

\*\*\*\*\*

Executed: October xx, 1999; expiration date: October xx, 2002.

and the Parties agree that the information provided thereunder is now governed by the terms of this CRADA.

13.3 Headings. Titles and headings of the articles and subarticles of this CRADA are for convenient reference only, do not form a part of this CRADA, and shall in no way affect its interpretation. The NIH component that is the Party for all purposes of this CRADA is the Bureau(s), Institute(s), Center(s) or Division(s) listed on the Cover Page herein.

13.4 Waivers. None of the provisions of this CRADA shall be considered waived by any Party unless such waiver is given in writing to the other Party.

The failure of a Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any rights of any Party.

13.5 Severability. The illegality or invalidity of any provisions of this CRADA shall not impair, affect, or invalidate the other provisions of this CRADA.

13.6 Amendments. If either Party desires a modification to this CRADA, the Parties shall, upon reasonable notice of the proposed modification or extension by the Party desiring the change, confer in good faith to determine the desirability of such modification or extension. Such modification shall not be effective until a written amendment is signed by the signatories to this CRADA or by their representatives duly authorized to execute such amendment.

13.7 Assignment. Neither this CRADA nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party, provided that a Party may assign its rights and obligations under this CRADA without such consent to an Affiliate or a third party that succeeds to substantially all of the business or assets of the assigning Party, by way of merger, sale of assets or otherwise.

13.8 Notices. All notices pertaining to or required by this CRADA shall be in writing and shall be signed by an authorized representative and shall be delivered by hand or sent by certified mail, return receipt requested, with postage prepaid, to the addresses indicated on the signature page for each Party. Notices regarding the exercise of license options shall be made pursuant to Article 7.2. Any Party may change such address by notice given to the other Party in the manner set forth above.

13.9 Independent Contractors. The relationship of the Parties to this CRADA is that of independent contractors and not agents of each other or joint venturers or partners. Each Party shall maintain sole and exclusive control

over its personnel and operations. Collaborator employees who will be working at NIH facilities may be asked to sign a Guest Researcher or Special Volunteer Agreement appropriately modified in view of the terms of this CRADA.

13.10 Use of Name or Endorsements. By entering into this CRADA, NIH does not directly or indirectly endorse any product or service provided, or to be provided, whether directly or indirectly related to either this CRADA or to any patent or other IP license or agreement which implements this CRADA by its successors, assignees, or licensees. The Collaborator shall not in any way state or imply that this CRADA is an endorsement of any such product or service by the U.S. Government or any of its organizational units or employees. Collaborator issued press releases that reference or rely upon the work of NIH under this CRADA shall be made available to NIH at least 7 days prior to publication for review and comment.

13.11 Exceptions to this CRADA. Any exceptions or modifications to this CRADA that are agreed to by the Parties prior to their execution of this CRADA are set forth in Appendix C.

13.12 Reasonable Consent. Whenever a Party's consent or permission is required under this CRADA, such consent or permission shall not be unreasonably withheld.

#### Article 14. Duration of Agreement

14.1 Duration. It is mutually recognized that the duration of this project cannot be rigidly defined in advance, and that the contemplated time periods for various phases of the Research Plan are only good faith guidelines subject to adjustment by mutual agreement to fit circumstances as the Research Plan proceeds. In no case will the term of this CRADA extend beyond the term indicated in the Research Plan unless it is revised in accordance with Article 13.6.



14.2 Survivability. The provisions of Articles 4.2, 5-8, 10.3-10.5, 11.1, 12.2-12.4, 13.1, 13.10 and 14.2 shall survive the termination of this CRADA.

SIGNATURES BEGIN ON THE NEXT PAGE

FOR NIH:

\_\_\_\_\_  
Date: \_\_\_\_\_

Alan Rabson, M.D.

Deputy Director, NCI

Mailing Address for Notices:

National Cancer Institute

Technology Development & Commercialization Branch

NCI-FCRDC

1003 West Seventh Street,

Fairview Center, Suite 502

Frederick, MD 21701

Phone: 301-846-5465

Fax: 301-8466820

FOR THE COLLABORATOR:

\_\_\_\_\_  
Date: \_\_\_\_\_

\_\_\_\_\_

Mailing Address for Notices:

\_\_\_\_\_

米国ハーバード大学商用専有実施権ライセンス契約

米国ハーバード大学商用専有実施権ライセンス契約

Exclusive License Agreement (sample) - Harvard College, USA

前提

**Subject matter** BIOLOGICAL MATERIALS: the materials supplied by HARVARD (identified in Appendix B) together with any progeny, mutants, or derivatives thereof supplied by HARVARD or created by LICENSEE.

**Summary of use(s)** An exclusive commercial license under PATENT RIGHTS, and a license to use BIOLOGICAL MATERIALS to make and have made, to use and have used, to sell and have sold the LICENSED PRODUCTS, and to practice the LICENSED PROCESSES, for the life of the PATENT RIGHTS.

**Purpose or background** LICENSEE is desirous of obtaining an exclusive license in the TERRITORY in order to practice the above-referenced invention covered by PATENT RIGHTS in the United States and in certain foreign countries, and to manufacture, use and sell in the commercial market the products made in accordance therewith, and HARVARD is desirous of granting such a license to LICENSEE in accordance with the terms of this Agreement.

**Contact details** Harvard University Office for Technology and Trademark Licensing, Holyoke Center 727, 1350 Massachusetts Avenue, Cambridge, MA 02138, United States of America.

E-mail: [otti@harvard.edu](mailto:otti@harvard.edu)

Telephone: (617) 495 3067; Fax: (617) 495 9568..

*Template revised September 2002*

契約本文

Exclusive Licensing Agreement

Effective as of [date]

Re: Harvard Case [case number(s)]

In consideration of the mutual promises and covenants set forth below, the parties hereto agree as follows:

## **ARTICLE I DEFINITIONS**

As used in this Agreement, the following terms shall have the following meanings:

1.1 **AFFILIATE:** any company, corporation, or business in which LICENSEE owns or controls at least fifty percent (50%) of the voting stock or other ownership. Unless otherwise specified, the term LICENSEE includes AFFILIATES.

1.2 **BIOLOGICAL MATERIALS:** the materials supplied by HARVARD (identified in Appendix B) together with any progeny, mutants, or derivatives thereof supplied by HARVARD or created by LICENSEE.

1.3 **FIELD:** [field].

1.4 **HARVARD:** President and Fellows of Harvard College, a nonprofit Massachusetts educational corporation having offices at the Office for Technology and Trademark Licensing, Holyoke Center, Suite 727, 1350 Massachusetts Avenue, Cambridge, Massachusetts 02138.

1.5 LICENSED PROCESSES: the processes covered by PATENT RIGHTS or processes utilizing BIOLOGICAL MATERIALS or some portion thereof.

1.6 LICENSED PRODUCTS: products covered by PATENT RIGHTS or products made or services provided in accordance with or by means of LICENSED PROCESSES or products made or services provided utilizing BIOLOGICAL MATERIALS or incorporating some portion of BIOLOGICAL MATERIALS.

1.7 LICENSEE: [company], a corporation organized under the laws of [state] having its principal offices at [address].

1.8 NET SALES: the amount billed, invoiced, or received (whichever occurs first) for sales, leases, or other transfers of LICENSED PRODUCTS, less:

(a) customary trade, quantity or cash discounts and non-affiliated brokers' or agents' commissions actually allowed and taken;

(b) amounts repaid or credited by reason of rejection or return;

(c) to the extent separately stated on purchase orders, invoices, or other documents of sale, taxes levied on and/or other governmental charges made as to production, sale, transportation, delivery or use and paid by or on behalf of LICENSEE or sublicensees; and

(d) reasonable charges for delivery or transportation provided by third parties, if separately stated.

NET SALES also includes the fair market value of any non-cash consideration received by LICENSEE or sublicensees for the sale, lease, or transfer of LICENSED PRODUCTS.

1.9 NON-COMMERCIAL RESEARCH PURPOSES: use of PATENT RIGHTS and/or BIOLOGICAL MATERIALS for academic research or other not-for-profit scholarly purposes which are undertaken at a non-profit or governmental institution that does not use the PATENT RIGHTS and/or

BIOLOGICAL MATERIALS in the production or manufacture of products for sale or the performance of services for a fee.

1.10 NON-ROYALTY SUBLICENSE INCOME: Sublicense issue fees, sublicense maintenance fees, sublicense milestone payments, and similar non-royalty payments made by sublicensees to LICENSEE on account of sublicenses pursuant to this Agreement.

1.11 PATENT RIGHTS: United States patent application [serial number] filed [filing date], the inventions described and claimed therein, and any divisions, continuations, continuations-in-part to the extent the claims are directed to subject matter specifically described in USSN [serial number] and are dominated by the claims of the existing PATENT RIGHTS, patents issuing thereon or reissues thereof, and any and all foreign patents and patent applications corresponding thereto, all to the extent owned or controlled by HARVARD.

1.12 TERRITORY: [territory].

1.13 The terms "Public Law 96-517" and "Public Law 98-620" include all amendments to those statutes.

1.14 The terms "sold" and "sell" include, without limitation, leases and other transfers and similar transactions.

## **ARTICLE II REPRESENTATIONS**

2.1 HARVARD is owner by assignment from inventor(s)] of [his/her/their] entire right, title and interest in United States Patent Application [serial number] filed [filing date] entitled [invention] (Harvard Case [case number]), in the foreign patent applications corresponding thereto, and in the inventions described and claimed therein.

2.2 HARVARD has the authority to issue licenses under PATENT RIGHTS.

2.3 HARVARD is committed to the policy that ideas or creative works produced at HARVARD should be used for the greatest possible public benefit, and believes that every reasonable incentive should be provided for the prompt introduction of such ideas into public use, all in a manner consistent with the public interest.

2.4 LICENSEE is prepared and intends to diligently develop the invention and to bring products to market which are subject to this Agreement.

2.5 LICENSEE is desirous of obtaining an exclusive license in the TERRITORY in order to practice the above-referenced invention covered by PATENT RIGHTS in the United States and in certain foreign countries, and to manufacture, use and sell in the commercial market the products made in accordance therewith, and HARVARD is desirous of granting such a license to LICENSEE in accordance with the terms of this Agreement.

### **ARTICLE III GRANT OF RIGHTS**

3.1 HARVARD hereby grants to LICENSEE and LICENSEE accepts, subject to the terms and conditions hereof, in the TERRITORY and in the FIELD:

(a) an exclusive commercial license under PATENT RIGHTS, and

(b) a license to use BIOLOGICAL MATERIALS

to make and have made, to use and have used, to sell and have sold the LICENSED PRODUCTS, and to practice the LICENSED PROCESSES, for the life of the PATENT RIGHTS. Such licenses shall include the right to grant sublicenses, subject to HARVARD's approval, which approval shall not be unreasonably withheld. In order to provide LICENSEE with commercial exclusivity for so long as the license under PATENT RIGHTS remains exclusive, HARVARD agrees that it will not grant licenses under PATENT RIGHTS to others except as required by HARVARD's obligations in paragraph 3.2(a) or as permitted in paragraph 3.2(b) and that it will not provide BIOLOGICAL MATERIALS to others for any commercial purpose.

3.2 The granting and exercise of this license is subject to the following conditions:

(a) HARVARD's "Statement of Policy in Regard to Inventions, Patents and Copyrights," dated August 10, 1998, Public Law 96-517, Public Law 98-620, and HARVARD's obligations under agreements with other sponsors of research. Any right granted in this Agreement greater than that permitted under Public Law 96-517, or Public Law 98-620, shall be subject to modification as may be required to conform to the provisions of those statutes.

(b) HARVARD reserves the right to

(i) make, use, and provide the BIOLOGICAL MATERIALS to others on a non-exclusive basis, and grant others non-exclusive licenses to make and use the BIOLOGICAL MATERIALS, all for NON-COMMERCIAL RESEARCH PURPOSES; and

(ii) make and use, and grant to others non-exclusive licenses to make and use for NON-COMMERCIAL RESEARCH PURPOSES the subject matter described and claimed in PATENT RIGHTS.

(c) LICENSEE shall use diligent efforts to effect introduction of the LICENSED PRODUCTS into the commercial market as soon as practicable, consistent with sound and reasonable business practice and judgment; thereafter, until the expiration of this Agreement, LICENSEE shall endeavor to keep LICENSED PRODUCTS reasonably available to the public.

(d) At any time after [number] years from the effective date of this Agreement, HARVARD may terminate or render this license non-exclusive if, in HARVARD's reasonable judgment, the Progress Reports furnished by LICENSEE do not demonstrate that LICENSEE:

(i) has put the licensed subject matter into commercial use in the country or countries hereby licensed, directly or through a sublicense, and is keeping the licensed subject matter reasonably available to the public, or



(ii) is engaged in research, development, manufacturing, marketing or sublicensing activity appropriate to achieving 3.2(d)(i).

[Specific performance milestones should be inserted here.]

(e) In all sublicenses granted by LICENSEE hereunder, LICENSEE shall include a requirement that the sublicensee use its best efforts to bring the subject matter of the sublicense into commercial use as quickly as is reasonably possible. LICENSEE shall further provide in such sublicenses that such sublicenses are subject and subordinate to the terms and conditions of this Agreement, except: (i) the sublicensee may not further sublicense; and (ii) the rate of royalty on NET SALES paid by the sublicensee to the LICENSEE. Copies of all sublicense agreements shall be provided promptly to HARVARD.

(f) If LICENSEE is unable or unwilling to grant sublicenses, either as suggested by HARVARD or by a potential sublicensee or otherwise, then HARVARD may directly license such potential sublicensee unless, in Harvard's reasonable judgment, such license would be contrary to sound and reasonable business practice and the granting of such license would not materially increase the availability to the public of LICENSED PRODUCTS.

(g) A license in any other territory or field of use in addition to the TERRITORY and/or FIELD shall be the subject of a separate agreement and shall require LICENSEE's submission of evidence, satisfactory to HARVARD, demonstrating LICENSEE's willingness and ability to develop and commercialize in such other territory and/or field of use the kinds of products or processes likely to be encompassed in such other territory and/or field.

(h) During the period of exclusivity of this license in the United States, LICENSEE shall cause any LICENSED PRODUCT produced for sale in the United States to be manufactured substantially in the United States.

3.3 All rights reserved to the United States Government and others under Public Law 96-517, and Public Law 98-620, shall remain and shall in no way be affected by this Agreement.

## **ARTICLE IV ROYALTIES**

4.1 LICENSEE shall pay to HARVARD a non-refundable license royalty fee in the sum of [amount] dollars (\$[amount]) upon execution of this Agreement [and the sum of [amount] dollars (\$[amount]) upon issuance of the first U.S. patent in PATENT RIGHTS].

4.2

(a) LICENSEE shall pay to HARVARD during the term of this Agreement a royalty of (number) percent ([number]%) of NET SALES by LICENSEE and sublicensees. In the case of sublicenses, LICENSEE shall also pay to HARVARD a royalty of [number] percent ([number]%) of NON-ROYALTY SUBLICENSE INCOME.

(b) If the license pursuant to this Agreement is converted to a non-exclusive one and if other non-exclusive licenses in the same field and territory are granted, the above royalties shall not exceed the royalty rate to be paid by other licensees in the same field and territory during the term of the non-exclusive license.

(c) On sales between LICENSEE and its AFFILIATES or sublicensees for resale, the royalty shall be paid on the NET SALES of the AFFILIATE or sublicensee.

4.3 No later than January 1 of each calendar year after the effective date of this Agreement, LICENSEE shall pay to HARVARD the following non-refundable license maintenance royalty and/or advance on royalties. Such payments may be credited against running royalties due for that calendar year and Royalty Reports shall reflect such a credit. Such payments shall not be credited against milestone payments (if any) nor against royalties due for any subsequent calendar year.

**January 1, [year]**  
**January 1, [year]**

January 1, [year]  
each year thereafter      \$[amount]  
\$[amount]  
\$[amount]  
\$[amount]

## ARTICLE V REPORTING

5.1 Prior to signing this Agreement, LICENSEE has provided to HARVARD a written research and development plan under which LICENSEE intends to bring the subject matter of the licenses granted hereunder into commercial use upon execution of this Agreement. Such plan includes projections of sales and proposed marketing efforts.

5.2 No later than sixty (60) days after June 30 of each calendar year, LICENSEE shall provide to HARVARD a written annual Progress Report describing progress on research and development, regulatory approvals, manufacturing, sublicensing, marketing and sales during the most recent twelve (12) month period ending June 30 and plans for the forthcoming year. If multiple technologies are covered by the license granted hereunder, the Progress Report shall provide the information set forth above for each technology. If progress differs from that anticipated in the plan required under Paragraph 5.1, LICENSEE shall explain the reasons for the difference and propose a modified research and development plan for HARVARD's review and approval. LICENSEE shall also provide any reasonable additional data HARVARD requires to evaluate LICENSEE's performance.

5.3 LICENSEE shall report to HARVARD the date of first sale of LICENSED PRODUCTS (or results of LICENSED PROCESSES) in each country within thirty (30) days of occurrence.

5.4

(a) LICENSEE shall submit to HARVARD within sixty (60) days after each calendar half year ending June 30 and December 31, a Royalty Report setting forth for such half year at least the following information:

(i) the number of LICENSED PRODUCTS sold by LICENSEE, its AFFILIATES and sublicensees in each country;

(ii) total billings for such LICENSED PRODUCTS;

(iii) an accounting for all LICENSED PROCESSES used or sold; (iv) deductions applicable to determine the NET SALES thereof;

(v) the amount of NON-ROYALTY SUBLICENSE INCOME received by LICENSEE; and

(vi) the amount of royalty due thereon, or, if no royalties are due to HARVARD for any reporting period, the statement that no royalties are due.

Such report shall be certified as correct by an officer of LICENSEE and shall include a detailed listing of all deductions from royalties.

(b) LICENSEE shall pay to HARVARD with each such Royalty Report the amount of royalty due with respect to such half year. If multiple technologies are covered by the license granted hereunder, LICENSEE shall specify which PATENT RIGHTS and BIOLOGICAL MATERIALS are utilized for each LICENSED PRODUCT and LICENSED PROCESS included in the Royalty Report.

(c) All payments due hereunder shall be deemed received when funds are credited to Harvard's bank account and shall be payable by check or wire transfer in United States dollars. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate existing in the United States (as reported in the New York Times or the Wall Street Journal) on the last working day of each royalty period. No transfer, exchange, collection or other charges shall be deducted from such payments.

(d) All such reports shall be maintained in confidence by HARVARD except as required by law; however, HARVARD may include in its usual reports annual amounts of royalties paid.

(e) Late payments shall be subject to a charge of one and one half percent (1 1/2%) per month, or \$250, whichever is greater.

5.5 In the event of acquisition, merger, change of corporate name, or change of make-up, organization, or identity, LICENSEE shall notify HARVARD in writing within thirty (30) days of such event.

5.6 If LICENSEE or any AFFILIATE or sublicensee (or optionee) does not qualify as a "small entity" as provided by the United States Patent and Trademark Office, LICENSEE must notify HARVARD immediately.

## **ARTICLE VI RECORD KEEPING**

6.1 LICENSEE shall keep, and shall require its AFFILIATES and sublicensees to keep, accurate records (together with supporting documentation) of LICENSED PRODUCTS made, used or sold under this Agreement, appropriate to determine the amount of royalties due to HARVARD hereunder. Such records shall be retained for at least three (3) years following the end of the reporting period to which they relate. They shall be available during normal business hours for examination by an accountant selected by HARVARD, for the sole purpose of verifying reports and payments hereunder. In conducting examinations pursuant to this paragraph, HARVARD's accountant shall have access to all records which HARVARD reasonably believes to be relevant to the calculation of royalties under Article IV.

6.2 HARVARD's accountant shall not disclose to HARVARD any information other than information relating to the accuracy of reports and payments made hereunder.

6.3 Such examination by HARVARD's accountant shall be at HARVARD's expense, except that if such examination shows an underreporting or

underpayment in excess of five percent (5%) for any twelve (12) month period, then LICENSEE shall pay the cost of such examination as well as any additional sum that would have been payable to HARVARD had the LICENSEE reported correctly, plus interest on said sum at the rate of one and one half per cent (1 1/2%) per month.

## **ARTICLE VII DOMESTIC AND FOREIGN PATENT FILING AND MAINTENANCE**

7.1 Upon execution of this Agreement, LICENSEE shall reimburse HARVARD for all reasonable expenses HARVARD has incurred for the preparation, filing, prosecution and maintenance of PATENT RIGHTS. Thereafter, LICENSEE shall reimburse HARVARD for all such future expenses upon receipt of invoices from HARVARD. Late payment of these invoices shall be subject to interest charges of one and one-half percent (1 1/2%) per month. HARVARD shall, in its sole discretion, be responsible for the preparation, filing, prosecution and maintenance of any and all patent applications and patents included in PATENT RIGHTS. HARVARD shall consult with LICENSEE as to the preparation, filing, prosecution and maintenance of such patent applications and patents and shall furnish to LICENSEE copies of documents relevant to any such preparation, filing, prosecution or maintenance.

7.2 HARVARD and LICENSEE shall cooperate fully in the preparation, filing, prosecution and maintenance of PATENT RIGHTS and of all patents and patent applications licensed to LICENSEE hereunder, executing all papers and instruments or requiring members of HARVARD to execute such papers and instruments so as to enable HARVARD to apply for, to prosecute and to maintain patent applications and patents in HARVARD's name in any country. Each party shall provide to the other prompt notice as to all matters which come to its attention and which may affect the preparation, filing, prosecution or maintenance of any such patent applications or patents. In particular, LICENSEE must immediately notify HARVARD if LICENSEE or any AFFILIATE or sublicensee (or optionee) does not qualify

as a "small entity" as provided by the United States Patent and Trademark Office.

7.3 LICENSEE may elect to surrender its PATENT RIGHTS in any country upon sixty (60) days written notice to HARVARD. Such notice shall not relieve LICENSEE from responsibility to reimburse HARVARD for patent-related expenses incurred prior to the expiration of the (60)-day notice period (or such longer period specified in LICENSEE's notice).

## **ARTICLE VIII INFRINGEMENT**

8.1 With respect to any PATENT RIGHTS that are exclusively licensed to LICENSEE pursuant to this Agreement, LICENSEE shall have the right to prosecute in its own name and at its own expense any infringement of such patent, so long as such license is exclusive at the time of the commencement of such action. HARVARD agrees to notify LICENSEE promptly of each infringement of such patents of which HARVARD is or becomes aware. Before LICENSEE commences an action with respect to any infringement of such patents, LICENSEE shall give careful consideration to the views of HARVARD and to potential effects on the public interest in making its decision whether or not to sue.

8.2

(a) If LICENSEE elects to commence an action as described above, Harvard may, to the extent permitted by law, elect to join as a party in that action. Regardless of whether HARVARD elects to join as a party, HARVARD shall cooperate fully with LICENSEE in connection with any such action.

(b) If HARVARD elects to join as a party pursuant to subparagraph (a), HARVARD shall jointly control the action with LICENSEE.

(c) LICENSEE shall reimburse HARVARD for any costs HARVARD incurs, including reasonable attorneys' fees, as part of an action brought by LICENSEE, irrespective of whether HARVARD becomes a co-plaintiff.

8.3 If LICENSEE elects to commence an action as described above, LICENSEE may deduct from its royalty payments to HARVARD with respect to the patent(s) subject to suit an amount not exceeding fifty percent (50%) of LICENSEE's expenses and costs of such action, including reasonable attorneys' fees; provided, however, that such reduction shall not exceed fifty percent (50%) of the total royalty due to HARVARD with respect to the patent(s) subject to suit for each calendar year. If such fifty percent (50%) of LICENSEE's expenses and costs exceeds the amount of royalties deducted by LICENSEE for any calendar year, LICENSEE may to that extent reduce the royalties due to HARVARD from LICENSEE in succeeding calendar years, but never by more than fifty percent (50%) of the total royalty due in any one year with respect to the patent(s) subject to suit.

8.4 No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of HARVARD, which consent shall not be unreasonably withheld.

8.5 Recoveries or reimbursements from actions commenced pursuant to this Article shall first be applied to reimburse LICENSEE and HARVARD for litigation costs not paid from royalties and then to reimburse HARVARD for royalties deducted by LICENSEE pursuant to paragraph 8.3. Any remaining recoveries or reimbursements shall be shared equally by LICENSEE and HARVARD.

8.6 If LICENSEE elects not to exercise its right to prosecute an infringement of the PATENT RIGHTS pursuant to this Article, HARVARD may do so at its own expense, controlling such action and retaining all recoveries therefrom. LICENSEE shall cooperate fully with HARVARD in connection with any such action.

8.7 Without limiting the generality of paragraph 8.6, HARVARD may, at its election and by notice to LICENSEE, establish a time limit of sixty (60) days for LICENSEE to decide whether to prosecute any infringement of which HARVARD is or becomes aware. If, by the end of such sixty (60)-day period, LICENSEE has not commenced such an action, HARVARD may prosecute such an infringement at its own expense, controlling such action and



retaining all recoveries therefrom. With respect to any such infringement action prosecuted by HARVARD in good faith, LICENSEE shall pay over to Harvard any payments (whether or not designated as "royalties") made by the alleged infringer to LICENSEE under any existing or future sublicense authorizing LICENSED PRODUCTS, up to the amount of HARVARD's unreimbursed litigation expenses (including, but not limited to, reasonable attorneys' fees).

8.8 If a declaratory judgment action is brought naming LICENSEE as a defendant and alleging invalidity of any of the PATENT RIGHTS, HARVARD may elect to take over the sole defense of the action at its own expense. LICENSEE shall cooperate fully with HARVARD in connection with any such action.

## **ARTICLE IX TERMINATION OF AGREEMENT**

9.1 This Agreement, unless terminated as provided herein, shall remain in effect until the last patent or patent application in PATENT RIGHTS has expired or been abandoned.

9.2 HARVARD may terminate this Agreement as follows:

(a) If LICENSEE does not make a payment due hereunder and fails to cure such non-payment (including the payment of interest in accordance with paragraph 5.4(e)) within forty-five (45) days after the date of notice in writing of such non-payment by HARVARD.

(b) If LICENSEE defaults in its obligations under paragraph 10.4(c) and 10.4(d) to procure and maintain insurance.

(c) If, at any time after three years from the date of this Agreement, HARVARD determines that the Agreement should be terminated pursuant to paragraph 3.2(d).

(d) If LICENSEE shall become insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against

it. Such termination shall be effective immediately upon HARVARD giving written to LICENSEE.

(e) If an examination by Harvard's accountant pursuant to Article VI shows an underreporting or underpayment by LICENSEE in excess of 20% for any twelve (12) month period.

(f) If LICENSEE is convicted of a felony relating to the manufacture, use, or sale of LICENSED PRODUCTS.

(g) Except as provided in subparagraphs (a), (b), (c), (d), (e) and (f) above, if LICENSEE defaults in the performance of any obligations under this Agreement and the default has not been remedied within ninety (90) days after the date of notice in writing of such default by HARVARD.

9.3 LICENSEE shall provide, in all sublicenses granted by it under this Agreement, that LICENSEE's interest in such sublicenses shall at HARVARD's option terminate or be assigned to HARVARD upon termination of this Agreement.

9.4 LICENSEE may terminate this Agreement by giving ninety (90) days advance written notice of termination to HARVARD and paying a termination fee of [amount] dollars (\$[amount]). Upon termination, LICENSEE shall submit a final Royalty Report to HARVARD and any royalty payments and unreimbursed patent expenses invoiced by HARVARD shall become immediately payable.

9.5 Upon termination pursuant to Paragraph 9.2, whether by HARVARD or by LICENSEE, LICENSEE shall cease all use of the BIOLOGICAL MATERIALS and shall, upon request, return or destroy (at Harvard's option) all BIOLOGICAL MATERIALS under its control or in its possession.

9.6 Paragraphs 6.1, 6.2, 6.3, 7.1, 8.5, 9.4, 9.5, 9.6, 10.2, 10.3, 10.5, 10.6, 10.8 and 10.9 of this Agreement shall survive termination.

## **ARTICLE X GENERAL**

10.1 HARVARD does not warrant the validity of the PATENT RIGHTS licensed hereunder and makes no representations whatsoever with regard to the scope of the licensed PATENT RIGHTS or that such PATENT RIGHTS or BIOLOGICAL MATERIALS may be exploited by LICENSEE, an AFFILIATE, or sublicensee without infringing other patents.

10.2 HARVARD EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED OR EXPRESS WARRANTIES AND MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OF THE PATENT RIGHTS, BIOLOGICAL MATERIALS, OR INFORMATION SUPPLIED BY HARVARD, LICENSED PROCESSES OR LICENSED PRODUCTS CONTEMPLATED BY THIS AGREEMENT. Further HARVARD has made no investigation and makes no representation that the BIOLOGICAL MATERIALS supplied by it or the methods used in making or using such materials are free from liability for patent infringement.

10.3 IN NO EVENT SHALL HARVARD BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR EXPECTED SAVINGS OR OTHER ECONOMIC LOSSES, OR FOR INJURY TO PERSONS OR PROPERTY) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS WHETHER HARVARD KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES. HARVARD'S AGGREGATE LIABILITY FOR ALL DAMAGES OF ANY KIND RELATING TO THIS AGREEMENT OR ITS SUBJECT MATTER SHALL NOT EXCEED THE AMOUNT PAID BY LICENSEE TO HARVARD UNDER THIS AGREEMENT. The foregoing exclusions and limitations shall apply to all claims and actions of any kind, whether based on contract, tort (including but not limited to negligence), or any other grounds.

10.4 LICENSEE shall not distribute or release the BIOLOGICAL MATERIALS to others except to further the purposes of this Agreement. LICENSEE shall protect the BIOLOGICAL MATERIALS at least as well as it protects its own valuable tangible personal property and shall take

measures to protect the BIOLOGICAL MATERIALS from any claims by third parties including creditors and trustees in bankruptcy.

## 10.5

(a) LICENSEE shall indemnify, defend and hold harmless HARVARD and its current or former directors, governing board members, trustees, officers, faculty, medical and professional staff, employees, students, and agents and their respective successors, heirs and assigns (collectively, the "INDEMNITEES"), from and against any claim, liability, cost, expense, damage, deficiency, loss or obligation of any kind or nature (including, without limitation, reasonable attorney's fees and other costs and expenses of litigation) (collectively, "Claims"), based upon, arising out of, or otherwise relating to this Agreement, including without limitation any cause of action relating to product liability concerning any product, process, or service made, used or sold pursuant to any right or license granted under this Agreement.

(b) LICENSEE shall, at its own expense, provide attorneys reasonably acceptable to HARVARD to defend against any actions brought or filed against any Indemnitee hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

(c) Beginning at the time any such product, process or service is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by LICENSEE or by a sublicensee, AFFILIATE or agent of LICENSEE, LICENSEE shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than \$2,000,000 per incident and \$2,000,000 annual aggregate and naming the Indemnitees as additional insureds. During clinical trials of any such product, process or service, LICENSEE shall, at its sole cost and expense, procure and maintain commercial general liability insurance in such equal or lesser amount as HARVARD shall require, naming the Indemnitees as additional insureds. Such commercial general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for LICENSEE's indemnification under this Agreement. If LICENSEE elects to self-insure all or part of the limits described above

(including deductibles or retentions which are in excess of \$250,000 annual aggregate) such self-insurance program must be acceptable to HARVARD and the Risk Management Foundation of the Harvard Medical Institutions, Inc. in their sole discretion. The minimum amounts of insurance coverage required shall not be construed to create a limit of LICENSEE's liability with respect to its indemnification under this Agreement.

(d) LICENSEE shall provide HARVARD with written evidence of such insurance upon request of HARVARD. LICENSEE shall provide HARVARD with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance; if LICENSEE does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, HARVARD shall have the right to terminate this Agreement effective at the end of such fifteen (15) day period without notice or any additional waiting periods.

(e) LICENSEE shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold by LICENSEE or by a sublicensee, AFFILIATE or agent of LICENSEE and (ii) a reasonable period after the period referred to in (e)(i) above which in no event shall be less than fifteen (15) years.

10.6 LICENSEE shall not use HARVARD's name or insignia, or any adaptation of them, or the name of any of HARVARD's inventors in any advertising, promotional or sales literature without the prior written approval of HARVARD.

10.7 Without the prior written approval of HARVARD in each instance, neither this Agreement nor the rights granted hereunder shall be transferred or assigned in whole or in part by LICENSEE to any person whether voluntarily or involuntarily, by operation of law or otherwise. This Agreement shall be binding upon the respective successors, legal representatives and assignees of HARVARD and LICENSEE.

10.8 The interpretation and application of the provisions of this Agreement shall be governed by the laws of the Commonwealth of Massachusetts.

10.9 LICENSEE shall comply with all applicable laws and regulations. In particular, it is understood and acknowledged that the transfer of certain commodities and technical data is subject to United States laws and regulations controlling the export of such commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce. These laws and regulations among other things, prohibit or require a license for the export of certain types of technical data to certain specified countries. LICENSEE hereby agrees and gives written assurance that it will comply with all United States laws and regulations controlling the export of commodities and technical data, that it will be solely responsible for any violation of such by LICENSEE or its AFFILIATES or sublicensees, and that it will defend and hold HARVARD harmless in the event of any legal action of any nature occasioned by such violation.

10.10 LICENSEE agrees (i) to obtain all regulatory approvals required for the manufacture and sale of LICENSED PRODUCTS and LICENSED PROCESSES and (ii) to utilize appropriate patent marking on such LICENSED PRODUCTS. LICENSEE also agrees to register or record this Agreement as is required by law or regulation in any country where the license is in effect.

10.11 Any notices to be given hereunder shall be sufficient if signed by the party (or party's attorney) giving same and either (a) delivered in person, or (b) mailed certified mail return receipt requested, or (c) faxed to other party if the sender has evidence of successful transmission and if the sender promptly sends the original by ordinary mail, in any event to the following addresses:

If to LICENSEE:

[company]

[address]

[fax number]

If to HARVARD:

Office for Technology and Trademark Licensing  
Harvard University  
Holyoke Center, Suite 727  
1350 Massachusetts Avenue  
Cambridge, MA 02138  
Fax: (617) 495-9568

By such notice either party may change their address for future notices.

Notices delivered in person shall be deemed given on the date delivered. Notices sent by fax shall be deemed given on the date faxed. Notices mailed shall be deemed given on the date postmarked on the envelope.

10.12 Should a court of competent jurisdiction later hold any provision of this Agreement to be invalid, illegal, or unenforceable, and such holding is not reversed on appeal, it shall be considered severed from this Agreement. All other provisions, rights and obligations shall continue without regard to the severed provision, provided that the remaining provisions of this Agreement are in accordance with the intention of the parties.

10.13 In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the breach thereof, the parties shall try to settle such conflict amicably between themselves. Subject to the limitation stated in the final sentence of this section, any such conflict which the parties are unable to resolve promptly shall be settled through arbitration conducted in accordance with the rules of the American Arbitration Association. The demand for arbitration shall be filed within a reasonable time after the controversy or claim has arisen, and in no event after the date upon which institution of legal proceedings based on such controversy or claim would be barred by the applicable statute of limitation. Such arbitration shall be held in Boston, Massachusetts. The award through arbitration shall be final and binding. Either party may enter any such award in a court having jurisdiction or may make application to such court for judicial acceptance of the award and an order of enforcement, as the case

may be. Notwithstanding the foregoing, either party may, without recourse to arbitration, assert against the other party a third-party claim or cross-claim in any action brought by a third party, to which the subject matter of this Agreement may be relevant.

10.14 This Agreement constitutes the entire understanding between the parties and neither party shall be obligated by any condition or representation other than those expressly stated herein or as may be subsequently agreed to by the parties hereto in writing.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives.

**PRESIDENT AND FELLOWS OF HARVARD COLLEGE**

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**Joyce Brinton, Director**  
**Office for Technology and Trademark Licensing**

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**Date**

**COMPANY**

-----  
**Signature**

-----  
**Name**



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**Title**

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**Date**

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**APPENDIX A**

The following comprise PATENT RIGHTS:

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**APPENDIX B**

The following comprise BIOLOGICAL MATERIALS supplied by HARVARD: