Access and Benefit Sharing: Illustrated Procedures for the Collection and Importation of Biological Materials

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ABSTRACT

The Convention on Biological Diversity (CBD) contains rules that clarify the rights and responsibilities of parties accessing biological resources from member nations. One aspect of the convention addresses the system that governs access to genetic resources and how the benefits arising from their use are shared. This legislation is commonly called the Access and Benefit-Sharing (ABS) program. Anyone pursuing collection activities, whether of tangible materials or intangible information, may be subject to these new regulations. Especially targeted are scientists and researchers who make significant use of proprietary genetic resources, biological matter, and related information, such as traditional knowledge and farming know-how. Therefore, it is important for all potential collectors to be familiar with the fundamental principles of ABS law as well as the procedures that must be followed in order to be fully compliant with the rules and regulations of the countries where collecting occurs. Well in advance of any collection activities, researchers should review the ABS situation, determine who could best answer questions about ABS, find authorized partners in the country of interest, locate relevant information on the specific ABS regime, and, most importantly, execute the documents, letters and agreements necessary to proceed with collection activities.

1. INTRODUCTION

According to the Convention on Biological Diversity (CBD), the rights to biological resources belong to the state in whose territory the resource is found. In order to prevent biopiracy and create a climate of mutual trust, the global community undertook to regulate the handling of genetic resources in the CBD, a binding international agreement.

The goals of the CBD are to conserve biological diversity, promote its sustainable use, and ensure the fair and equitable sharing of benefits arising from its use. Responsibility for implementing the agreement is given to the state in whose territory the biological material is found. The CBD, however, contains rules that clarify the rights and responsibilities of all of the contracting parties. One relatively recent addition to the convention addresses the system governing access to genetic resources and the sharing of the benefits arising from their use: Access and Benefit Sharing (ABS). With this new legislation, a new world system for the use of biological matter now exists that has changed the nature of public and private sector R&D efforts.

Anyone pursuing collection activities, whether of tangible materials or intangible information, may be subject to the new regulations. Especially targeted are scientists and researchers who make significant use of proprietary genetic resources, biological matter, and related information, such as traditional knowledge and farming know-how. Such knowledge may, in national legislation, be considered intellectual property (IP) or trade secrets, and as such not in the public domain or available for unauthorized appropriation.

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Violation of the new access and benefit-sharing law, for example, by scientists conducting unauthorized collection activities, can result in fines, imprisonment, and the denial of future visits. Violation may also increase the transaction time needed to obtain a formal access permit. Therefore, it is essential not only to know the relevant policies, principles and laws, but also to have a practical understanding of the various potential ABS scenarios and the agreements, documents, applications, and other required procedural steps necessary for full compliance.

2. FOUR ABS SCENARIOS

We provide here the basics of ABS law, following four categories suggested in a recent publication by the Swiss Academy of Science,[1] providing some examples of agreements currently or soon to be in effect. Please note that on the Internet you may find thousands of examples of letters of intent, research permits, prior informed consent/mutually agreed terms (PIC/MAT) agreements, material transfer agreements (MTAs), and confidentiality agreements. To find out which type of agreement fits your project best, please consult the legal department at your university or college.

2.1 *No ABS situation*

For some projects, research does not involve any access to genetic resources for which ABS contracts are necessary. However, other research permits may be required. A research permit request may ask for more details than necessary in this situation. Possible situations might include:

- **research performed on human biological resources; human biological resources and genetic material are not covered by CBD.** You would need, instead, a research permit and approval by an ethical committee. Therefore, make appropriate contact with local academic partners and/or the national center for medical research.
- **research performed locally on national biological resources, without any involvement of indigenous people.** If you are employed by a national academic institution, normally a research and work permit is necessary. Contact a local academic colleague.
- **using Sweden as an illustrative example, research in Sweden, on Swedish material, or on material introduced before 1992.** If animals are included, an ethical committee permit is needed. Research that includes collection of red listed species necessitates a permit from Swedish regional authorities (called *Länsstyrelse* in Swedish).

2.2 *Simple ABS situation*

In the simplest scenario in which access and benefit sharing are relevant to research involves the collection and transfer (including export) of samples for an inventory. A (standardized) MTA is normally sufficient. In some countries this could be done with a standard research permit application that includes the MTA (see section 3.2 dealing with the research permit).

Other situations will require different actions:

- No standard research permit is available; the researcher/collectors will need to find a national colleague and formulate both a PIC and a MTA.
- When working with genetic resources deposited at the institutes of the Consultative Group on International Agricultural Research (CGIAR), standardized agreements are often available. This is, however, only the case for certain species used as crop plants.
- If the collection necessitates cooperation with indigenous people, a separate contract must be signed and the situation is more complex.
- If humans or animals are included in the research, a permit from the national ethical committee will need to be obtained.

2.3 *ABS situation*

A third scenario involves a situation in which the export of samples is required for further analysis and study in a laboratory abroad. No further exploitation is planned. In this scenario, PIC, MAT, and MTA are all necessary. For the most part, completion of the documents mentioned in the

simple ABS situations described in Section 2.2 is sufficient; however, each document will be more extensive. In the more-elaborate research permit applications, these additional documents are included. Confidentiality agreements also might be requested.

2.4 *Complex ABS situation*

The most complex scenario involving access and benefit sharing is a situation in which proposed research involves several steps, including research for commercial purposes and possible use of traditional knowledge. Initially, confidentiality agreements and letters of intent could be signed, followed by PIC, MAT, and MTA. In the MAT, issues concerning benefits have to be elucidated and agreed upon. Terms like interest, profit, and return, as well as payment times, have to be discussed and jointly interpreted by all stakeholders.

3. ILLUSTRATIVE EXAMPLES AND TEMPLATE AGREEMENTS

In order to better assist the reader of this chapter in understanding the various ABS scenarios and the documents, letters, and agreements that might be applicable, we present examples of:

1. Letter of intent
2. Research permit
3. PIC
4. MAT
5. Template MTA
6. Confidentiality agreement

In addition, we also provide examples of ABS legal principles in various countries, along with useful online links where information can be obtained. It should be noted that the examples of template contracts or agreements presented below are for illustrative purposes only and in no way refer to specific existing agreements. The examples are meant to provide input for the development of real documents, which will need to be adapted to each specific circumstance.

3.1 *Letter of intent*

The letter of intent is a document in which the partners in the project describe their intentions. It is not legally binding as are the PIC and the MTA. It is mainly useful as a vehicle by which the parties can convey to one another their expectations and anticipated degree of involvement. A letter of intent could be used later as a basis for a PIC. A project could be financed through a planning grant, based on a letter of intent, and signed by all cooperating partners and stakeholders. The planning grant should finance the negotiations resulting in a PIC, MAT, and MTA. Planning grants have to be prepared three to four months before the deadline for submitting project proposals.

The examples given here (Boxes 1A–1D; all Boxes are at the end of this chapter) are hypothetical but use features from the real world. It describes a study in a developing country where local scientists and indigenous people working together study herbs used for malaria and vector control. Stakeholders in the project could be the National Government (represented by the University of Vientiane and the Ministry of Environment and the Ministry of Health), local authorities in the province, national park officials where the study is performed, and indigenous people (represented by village representatives and individual healers).

3.2 *Research permit*

To be able to research in several foreign countries outside the E.U., you will need a research permit. In some countries, this is easy to obtain using a standard procedure with standard fees. In other cases, it can only be obtained in cooperation with a national partner or through prior informed consent contracts. For an example, see Box 2.

3.3 *Prior informed consent*

PIC is a description of the project signed by all stakeholders and other concerned parties. It can be difficult to determine who exactly is affected by the project; another problem is financing the information and negotiations. It can also be problematic to have to devote all the work and generate expectations for a project that does not have any guaranteed financing. The prior informed consent is normally written to fit a commercial

bioprospecting project. But how does it work with a basic noncommercial program?

Near-term, medium-term, and long-term benefits should be considered, including up-front payments, milestone payments, and royalties. The benefit-sharing time frame should be definitively stipulated. Furthermore, the balance between near-term, medium-term, and long-term benefits should be considered on a case-by-case basis.

The prior informed consent includes:

- conditions for export of biological material and related information
- conditions for use of the material and related knowledge
- conditions for how and what to make public
- patents and country of origin
- how and where to solve disputes

Prior informed consent means that everyone concerned has to be informed about the project and its terms before the project starts. If indigenous people are concerned, they must be informed so they understand the project. It may be necessary to translate the project into native languages or make a clear presentation with pictures. If the indigenous people do not give their consent, the project cannot start.

A letter of intent could be used to introduce the project and start negotiations, even before the project is financed. When the project is financed, the letter of intent could be integrated into the PIC. Remember that most academic organizations are not familiar with using letters of intent. Also, it is also important to identify and understand the respective roles of the legal entities involved:

- The scientist who is collecting should sign, in addition to the director of the institute, unless he has delegated the right to sign. The government, in the country where the collection is performed, could be represented by the ministry responsible for natural resources or another delegated unit. The government is legally considered the owner of the rights to the genetic material.
- If the project is performed in cooperation with a local university or institute, a local legal representative from the university should sign. In some countries, cooperation with a local university is a prerequisite for a project to be accepted. Depending on local laws, a cooperating scientist is sometimes expected to sign.
- If the project is performed within a national park, park authorities have to sign. This could also make the collection easier.
- If indigenous people are involved, their local representatives have to sign. This can be a complicated task, as several local communities may be involved and sometimes it is not clear who is a legal representative. A local community can also refuse to sign, and that will prevent the project from being performed in their legally defined area.
- If local individuals contribute to the project, they also are considered concerned parties. This may be the most complicated part to determine, as it is not easy to judge who will contribute prior to the project start. In Sweden, the scientist, if not otherwise stated in his or her contract, has the right to his or her inventions and intellectual property, which should then also be regulated in the PIC.

The above concerns and others are addressed and discussed in the following examples (Boxes 4A–4E) and their analysis.

The PIC should always set a time schedule. The duration could be a couple of months, for a specific collection, to up to five years or so if the project includes a Ph.D. program. The PIC must also define what happens with material and results after the time schedule has ended (see Box 4C).

Geographical area or areas shall also be defined realistically. This could be the whole nation or a local area. It is better to include any areas that could be of interest, rather than make it necessary to start new PIC negotiations, since these take a lot of time. An area could also be defined as a certain biotope in different geographical areas (see the examples in Box 4D).

Scientists often specialize in collecting genetic resources within a certain family or selected genera. However, often material also is collected

for colleagues interested in other species. If this is the case, it should be mentioned in the PIC, which should also state if the material will be given to a third party, how it will be used, and by whom. The genetic resources can be living or dead specimens, and also parts of specimens, such as genes, enzymes, or specified chemicals or extracts. Whole material from families or material from several genera can be included. The PIC can also include new derivatives made from the collected material. Questions to ask include: Why is the collection being made? How shall results be used? Is material to be taken out of the country? What information can be published? What species/samples can be transferred to a third party? What research methods may be involved? Have these provisions been set out in your project proposal for financing? Does publication of material obtained from indigenous people necessitate their consent? Is the project classified as commercial or as noncommercial? Box 4E offers several relevant examples.

3.4 *Mutually agreed terms*

In accordance with Article 15, Paragraph 7, of the Convention on Biological Diversity, each contracting party shall "*take legislative, administrative or policy measures, as appropriate [...] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.*" It is therefore important to assist parties and stakeholders in the development of mutually agreed terms to ensure the fair and equitable sharing of benefits.

3.4.1 *Basic requirements*

Everyone signing PICs and MTAs should understand the content, consequences, and meaning of certain terms. Mutually agreed terms take into account the different capacities and needs of those involved, including governments, indigenous and local communities, holders of ex situ collections, and the intended user organizations. This approach will contribute to fair negotiations and equitable shared benefits. Mutually agreed terms facilitate:

- legal certainty and clarity
- minimization of transaction costs
- inclusion of provisions on user and provider obligations
- development of different contractual agreements (for example, template agreements)
- different uses: taxonomy, collection, research, commercialization
- negotiated efficiently, within a reasonable period of time
- codification of written agreements

The following principles or basic requirements could be considered for the development of mutually agreed terms:

- legal certainty and clarity
- minimization of transaction costs by:
  - establishing and promoting awareness of the government's and relevant stakeholders' requirements for prior informed consent and contractual arrangements
  - ensuring awareness of existing mechanisms for applying for access, entering into arrangements, and ensuring the sharing of benefits
  - developing framework agreements, under which repeated agreement under expedited procedures can be made
  - developing standardized MTAs and benefit-sharing arrangements for similar resources and similar uses (the online version of the *Handbook* includes the BIO-EARN MTA with suggested elements of such an agreement)
- inclusion of provisions on user and provider obligations
- development of different contractual arrangements, for different resources and for different uses, and development of template agreements
- different uses may include taxonomy, collection, research, and commercialization, among other things
- mutually agreed terms should be negotiated efficiently and within a reasonable period of time
- mutually agreed terms should be set out in a written agreement

The following elements could be considered as guiding parameters in contractual agreements and as basic requirements for mutually agreed terms:

- regulating the use of resources in order to take into account ethical concerns of the particular parties and stakeholders, in particular of the indigenous and local communities concerned
- making provision to ensure the continued customary use of genetic resources and related knowledge
- provision for the use of IP rights, including joint research and the obligation to obtain rights on inventions and to provide licenses by common consent
- the possibility of joint ownership of IP rights according to the degree of contribution

3.4.2 *Typical terms*

A list of typical mutually agreed terms would include the following:

- type and quantity of genetic resources and the geographical/ecological area of activity
- any limitations on the possible use of the material
- recognition of the sovereign rights of the country of origin
- capacity building in various areas to be identified in the agreement
- a clause addressing whether the terms of the agreement, in certain circumstances, could be renegotiated
- whether the genetic resources can be transferred to third parties and conditions to be imposed in such cases.
- whether the knowledge, innovations, and practices of indigenous and local communities have been respected, preserved, and maintained, and whether the customary use of biological resources in accordance with traditional practices has been protected and encouraged
- treatment of confidential information
- provisions regarding the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products

Mutually agreed terms for access to and specific uses of genetic resources (or derivatives), in accordance with Article 15, Paragraph 4 of the Convention on Biological Diversity, may also include conditions for transfer of such genetic resources to third parties, subject to national legislation of countries of origin.

3.4.3 *The Bonn guidelines on MAT*

The development of mutually agreed terms should be based on the principles of legal certainty and minimization of cost. These principles were included in the Bonn Guidelines to respond to the concerns of scientific researchers and users of genetic resources that national procedures for obtaining access could be too complex and burdensome. The guidelines enumerate a detailed description of the type of provisions that could form part of a contractual arrangement. Some of the proposed provisions are quite innovative and include the specification of uses, the regulation of those uses in light of ethical concerns, the continuation of customary uses over genetic resources, the possibility of joint ownership of IP rights according to contributions, and the existence of confidentiality clauses and sharing of benefits from commercial and other utilization of genetic resources, including derivatives thereof. The principle subjects to be agreed upon as listed in the Bonn Guidelines are:

- type and quantity of resources
- limitations on possible use
- recognition of sovereign rights of country of origin
- capacity building
- whether terms of agreement can be renegotiated
- whether genetic resources or derivatives can be transferred to third parties
- whether traditional knowledge is respected
- treatment of confidential information
- types of benefits
- timing of benefits
- distribution of benefits
- mechanisms for benefit sharing

3.4.4 *Convention on Biological Diversity: MAT guidelines*

Box 5 provides the relevant sections on mutually agreed terms from Decision VIII/4 of the CBD.

3.5 *Material transfer agreements*

If you need to transfer biological material from a foreign country, you must sign an MTA with the authorities of the foreign country. This could cover extracts for isolation of chemical compounds, as well as dried or otherwise preserved biological material. The material could be used in the national herbarium or for breeding purposes. The MTA should include:

- a definition of the material to be transferred
- reasons for the transfer
- restrictions or stipulations on how it can be used
- an explanation of the costs of the transfer and who will pay the costs
- start and termination dates
- settlements of disputes provisions

See Box 6 (at the end of chapter) for a sample MTA that puts into place the above considerations.

3.6 *Confidentiality agreements*

Before information of possible commercial value is given to another party, normally a confidentiality agreement is signed. The confidentiality agreement states what must be kept secret and stipulates a time frame for confidentiality. The agreement also includes paragraphs on how to proceed if confidentiality is broken. The Bonn Guidelines suggest that a confidentiality agreement be included in the PIC. Before signing any confidentiality agreement, a researcher should contact the legal affairs office at his or her university.[2] See Box 7 for a sample confidentiality agreement.

5. FINDING ABS INFORMATION

Now that you have an understanding of the basic steps to take to ensure ABS-compliance, how do you find out about the ABS rules of a given country? Which kind of legislation exists in the country you want to work in? Which conventions on biological material have they signed? In order to find answers to these questions, many countries have specific Web sites.[3]

5.1 *Europe*

The E.U. and member states have signed CBD. The E.U. is now implementing ABS, but there is no common law. The E.U. Parliament and the Council directive have suggested introducing the country of origin in patent law (Directive 98/44/EG). The EC ABS portal covers: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. Some specific country information follows:

- Austria: With regard to benefit-sharing arrangements, access to natural genetic resources is free in Austria, as long as the animal and plant species are not protected by nature-protection laws, such as endangered species, national parks, hunting, and, of course, private-property laws. If somebody gets financial support from the State for scientific research and profits from the results, she or he has to pay back only the subsidy.
- Greenland: In late 2006, Greenland Home Rule Parliament adopted an Act on Commercial and Research-Related Use of Biological Resources.
- Iceland: Iceland has introduced access legislation related to microbe prospecting in volcanic areas.
- Norway: Norway recently adopted access legislation, regarding boreal coral reefs, among other things.
- Sweden: There is no specific legislation on ABS. Sweden follows E.U. legislation with few of its own initiatives. There is no authority that can certify country of origin. Material deposited in the Nordic gene bank or in Swedish botanical gardens after 1992 is available under international law.[4]

5.2 *Asia*

The ASEAN framework agreement on access to biological and genetic resources has been signed

by Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam. However, there is still great uncertainty in several countries about how to formulate contracts. Thailand, Malaysia, and Philippines are uncomplicated, while the situation in Laos and other countries is relatively complex.[5]

The Philippines was the first country to implement legislation to regulate access to biological resources. Executive Order No. 247, signed by the president of the Philippines in May 1995, was the product of discussions between government agencies, nongovernmental organizations, indigenous peoples, and academic consultants. The legislation established a framework to regulate biodiversity prospecting having four basic elements:

1. An interagency committee to consider and enforce research agreements and coordinate further policy development
2. A procedure to get prior informed consent for access to traditional knowledge
3. A two-tiered system of mandatory research agreements, incorporating benefit-sharing terms, between collectors and the government: an academic research agreement, valid for five years, and a commercial research agreement, valid for three years
4. Minimum requirements to conform to environmental protection laws and regulations.

A material supply (or transfer) agreement is required for material leaving an institution. It should set out any relevant original terms of acquisition and state any additional terms of use, transfer, and benefit sharing. The Indigenous People's Rights Act, 1997, includes a Code of Conduct for Academic Collector of Biological and Genetic Resources for collectors working in the Philippines.[6]

Other countries that passed such legislation include Bangladesh,[7] Pakistan,[8] and India.[9] Some countries in Asia plan to regulate access to genetic resources to ensure PIC and benefit-sharing mechanisms. These include Fiji, Nepal, Pakistan, Papua New Guinea, Samoa, the Seychelles, the Solomon Islands, South Sri Lanka, and Vanuatu.

5.3 *Africa*

In Africa, the OAU model law on the protection of the rights of local communities, farmers, and breeders and the regulation of access to biological resources (OAU, Addis Ababa, December 2001) has been used by some nations as a model for regulating access to biological material.[10] So far, mainly Cameroon's legislation follows the African Union principles. Case studies from Cameroon include contrasting benefit sharing in the pharmaceutical and phytomedical industries in relation to *Ancistrocladus korupensis* and sustainable harvesting of *Prunus africana* on Mount Cameroon.[11] Nigeria[12] and South Africa[13] also recently passed legislations.

5.4 *Latin America*

Costa Rica has been one of the first countries globally to take a lead in biodiversity-related legislation. Information about regional groups, national governments, or state governments already regulating access to genetic resources to ensure prior informed consent and benefit-sharing can be found in the Ley de Biodiversidad No 7788, which has been in force since 1998.[14] The rules on access to biodiversity (Presidential Decree No. 31-514) have been in force since 2003.[15] The decree covers the following topics: access to genetic resources, equitable sharing of benefits arising out of the utilization of genetic resources, equitable sharing of benefits from the utilization of traditional knowledge, innovations and practices, intellectual property rights related to genetic resources and/or protection of traditional knowledge, innovations, and practices related to genetic resources.

More broadly in Latin America, the Andean Pact decision 391/96 on the Common Regime on Genetic Resources is leading the tone of the discussions. Peru, under its National Strategy on Biological Diversity (Decreto Supremo No. 102-2001-PCM), recently added a regime on traditional knowledge (Law 27.811, August 2002). In Peru, a special national authority (INRENA) has been established to deal with access and benefit-sharing issues.

The countries of the Andean region (Bolivia, Colombia, Ecuador, Peru, and Venezuela) decided

to take a regional approach to regulating access to their genetic resources. The Andean Pact Decision 391 Agreement (1996) established a common rule on access to genetic resources for member countries, leaving implementation up to national regulation. The thinking behind this approach was that it made little sense for one country to regulate access strictly, when a neighboring country, with similar flora and fauna, had little or no regulation in place.[16]

Other countries where laws have been passed include Argentina,[17] Bolivia,[18] Brazil,[19] Mexico,[20] Panama,[21] and Peru.[22]

5.5 *Australia and the United States*

Despite the fact that the United States has never signed the Convention, most organizations and universities follow the CBD and the Bonn Guidelines.[23] Several U.S. projects are financed with universities, together with NCI or NIH, and coordinated by the Fogarty International Center.[24] Australia already regulates access to genetic resources to ensure prior informed consent and benefit sharing (the states of Western Australia and Queensland).[25]

6. CONCLUSIONS

Depending on the ABS situation (that is, no ABS situation, simple ABS situation, ABS situation, or complex ABS situation), a series of procedural steps will need to be taken pursuant to relevant national legislation. Accordingly, researchers must have a clear understanding of what documents need to be executed. These documents might include:

- Letter of intent
- Research permit
- Prior informed consent/PIC
- Mutually agreed terms/MAT
- Material transfer agreement (MTA)
- Confidentiality agreement

For each of these, it will be important to know who the authorized counterparts are in the country where collection activities are anticipated. In addition, it will be necessary to know where to find accurate and current information about the precise ABS legislation that prevails.

Although this might initially seem daunting, full compliance is necessary. Careful planning and proactive management will pay off in the long term, by minimizing the possibility of misunderstandings and possible legal problems, including detainment or expulsion.

Perhaps most importantly, these ABS regimes are in place to facilitate the building of equitable, sustainable, and solid networks for sharing biological resources for R&D programs. We all hope that the regimes ensure that any benefits that accrue will extend to all involved. ■

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1 Biber-Klemm S and S Martinez. 2006. *Access and Benefit Sharing—Good Practice for Academic Research on Genetic Resources*. 1st edition. Swiss Academy of Sciences: Bern. www.scnat.ch.

2 The Bonn Guidelines use the term *secrecy agreement*. Although there are different terms, including nondisclosure agreement, the editors of the *Handbook* prefer the term *confidentiality agreement,* which is more neutral and is used more widely.

3 For example, for Europe: www/abs.eea.eu.int. Worldwide: www.biodiv.org/programmes/socio-eco/benefit/. National focal points can be found at www.biodiv.org/doc/lists/nfp-abs.pdf. Case studies can be found at www.biodiv.org/doc/case-studies/abs/. If you are unable to open a link here, use www.biodiv.org/doc/info-centre.shtml and click on case studies.

4 See www.ngb.se/Material/seedrequest.php and www.ngb.se/Material/MTA.

5 The ASEAN Framework Agreement on Access to Biological and Genetic Resources (2000). www.grain.org/brl/?docid=785&lawid=1261. See also www.wipo.int/globalissues/databases/contracts/index.html and www.biodiv.org/programmes/socio-eco/benefit.

6 Further information: The Philippines Executive Order No 247 (May 1995) can be found at www.grain.org/brl/?docid=915&lawid=1482; www.chmbio.org.ph/e0247.html; www.chmbio.org.ph/da020-96.html.

7 www.grain.org/brl/?docid=538&lawid=1274.

8 www.grain.org/brl/?docid=683&lawid=1456.

9 During 2001 India adopted a bill for the protection of plant varieties and the farmer's rights (Bill. No.123 of 1999). A Biodiversity Bill (Bill. No.93 of 2000) has also been passed by the Parliament. www.grain.org/brl/?docid=322&lawid=1378 (in force beginning in 2002).

10 See www.grain.org/brl/?docid=798&lawid=2132. An explanatory booklet of the African Union Model Law, written by Professor J. A. Ekpere, can be found at www.grain.org/brl/?docid=798&lawid=2132.

11 www.biodiv.org/doc/case-studies/abs/cs-abs-aristo.pdf.

12 www.biodiv.org/doc/case-studies/abs/cs-abs-ng-a.pdf.

13 www.grain.org/brl/?docid=621&lawid=1222.

14 Both Spanish and English versions are at www.grain.org/brl/?docid=879&lawid=1859.

15 www.grain.org/brl/?docid=209&lawid=1872.

16 The Common Access Regime for Genetic Resources, Andean Pact Decision 391 (July 1996), can be found in Spanish at www.sice.oas.org/trade/JUNAC/decisiones/DEC391S.asp and in English at www.sice.oas.org/trade/JUNAC/decisiones/DEC391e.asp. These laws and others can also be found on the Web site of GRAIN (Genetic Resources Action International): www.grain.org/brl/index-en.cfm .

17 www.grain.org/brl/?docid=327&lawid=1677.

18 The *Reglamento de la Decision 391 Regimen Comum de Acceso a los Recursos Genticos* (in force beginning in 1997). www.lclark.edu/org/ielp/boliviaspanish.html; in English at www.lclark.edu/org/ielp/boliviaeng.html.

19 The *Acre State Law (Accesso a recursos genéticos lei estadual*) has been in force since 1997 and can be found at www.lclark.edu/org/ielp/acre.html. The *Amapá State Law on Access to Genetic Resources*, in force since 1997, can be found in Portuguese at www.lclark.edu/org/ielp/amapaportuguese.html and in English at www.lclark.edu/org/ielp/amapaenglish.html. This legislation can also be found on WIPO's site: www.wipo.int/tk/en/laws/. The *Medida Provisória No. 2.186-16* of 23 August 2001 regulates Access to Genetic Heritage, Protection of and Access to Associated Traditional Knowledge, Sharing of Benefits, and Access to and Transfer of Technology for their Conservation and Use and can be found at www.wipo.int/tk/en/documents/word/brazil-provisional-measure-por.doc in English. For Portuguese, visit www.planalto.gov.br/ccivil_03/MPV/2186-16.htm.

20 See Torres Nachon C and G Cantoe. Towards a Law on the Access and Use of Genetic Resources in Mexico. Center for Environmental Law and Economic Integration of the South. http://www.biodiv.org/doc/case-studies/abs/cs-abs-biodassur.pdf.

21 *Law No. 20* (26 June 2000) on a Special Regime of Collective Rights of Intellectual Property of Indigenous People for Protection of their Cultural Identity and their Traditional Knowledge. www.grain.org/brl/?docid=461&lawid=2002. See also www.wipo.int/tk/en/documents/word/panama-executive-decree-12.doc.

22 The *Propuesta de Regimen de Proteccion de los Conocimientos Colectivos de los Pueblos y Comunidades Indigenas Vinculados a los Recursos Biologicos* (in force beginning in 2002), can be found in Spanish and English at www.grain.org/brl/?docid=175&lawid=2041.

23 www.state.gov/g/oes/rls/or/25962.htm. For Americans working in other nations, contact: Access and Benefit-Sharing Officer, U.S. Department of State's Office of Ecology and Terrestrial Conservation, (202) 647-1804 or FAX (202) 736-7351. For research-permit applications, visit science.nature.nps.gov/research/.

24 More information about these can be found in *Chemical Prospecting: An Overview of the International Cooperative Biodiversity Groups Program, Francesca T. Grifo Fogarty International Center*. National Institutes of Health: Bethesda, MD www.fic.nih.gov/programs/research-grants/icbg/index.htm.

25 For information about performing research in national parks, see www.deh.gov.au/epbc/permits/parks/research.

26 Thornström CG and L Björk. 2006. Accessing Others' Proprietary Biological Matter and Related Information–Towards a Handbook in Access and Benefit Sharing and Related Intellectual Property. Part three: Entering Into Agreements. Unpublished.

Sennerby Forsse L. 2003. *Inventory Regarding ABS Legislation in Selected Countries*. Swedish Research Council/FORMAS: Stockholm.

Thornström CG and Björk L. 2006. Accessing Others' Proprietary Biological Matter and Related Information–Towards a Handbook in Access and Benefit Sharing and Related Intellectual Property. Part One: Chapeau. Unpublished.

Also the publication in *supra* note 1.

27 *Editors' Note:* This and other forms in this chapter have been lightly edited for English, consistency and clarity.

28 www.epaguyana.org/downloads/BiodiversityGuideLinesForResearch.pdf.

29 www.biodiv.org/decisions/default.aspx?m=COP-08&id=11016&lg=0.

Box 1A: Simple Letter Agreement for the Transfer of Materials

Ministry of Environment, People's Democratic Republic, represented by Mr./Mrs. _____; and the Department of Systematic Botany, Uppsala University, represented by Dr. Barbro Sundberg, hereby declare their intentions to develop a cooperative project in systematic botany and ethnobotany within the Nam-Nam National Biodiversity Conservation Area.

Dr. Barbro Sundberg and her Ph.D. student, Hugo Brun, Uppsala University, and Ph.D. Mak Naeng, of the National University of the PDR, are given permission to collect plant material, in the form of herbarium vouchers, within the Nam-Nam NBCA in order to study the floristic biodiversity of the area and the documentation of the PDR genetic resources. All specimens are collected in triplicate and processed, and will be detained in the NU herbarium, in the Uppsala University (UPS), with one specimen going to the Stockholm Natural History Museum (S).

All samples are marked with catalog number and the text: "*The rights to this material belong to the PDR. Any distribution or DNA sampling of this material necessitates a specific permit from the Ministry of Environment of the PDR.*" All publications deriving from the study of this material should acknowledge the Ministry of Environment of the PDR, and botanical publications should be published with consent of the curator of the NU Herbarium.

All expenses for the above-mentioned project are planned to be financed by the Swedish International Development Cooperation Agency. The project is planned to take place from July 1, 2007, to June 30, 2010. This letter of intent covers that time period only.

The Capital, February 10, 2007
The Ministries of PDR Barbro Sundberg Mak Naeng
NU Herbarium officer Hugo Brun

Box 1B: Letters of Intent—Derivatives

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. 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.

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).

All samples are marked with catalogue number and the text: "This material belongs to the PDR. Any 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."

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.

The Capital, March 3, 2007
The Ministry Åke Mattsson Thomas Lundberg
Mai Moeng Nils Svensson

Box 1C: Letters of Intent—Bioprospecting and Traditional Knowledge

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.
All field equipment used for this control will be donated to the villages after the project time expires.
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 their families
- 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
- 25% is to be used by the Ministry of Health for active disease control in the PDR
- 25% to be used by the Ministry of Environment for preservation of biological biodiversity
- 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.

The project is planned to be financed by the Swedish International Development Cooperation Agency. Project time July 1, 2007, to June 30, 2011.

Nam-Nam NBCA, February 28, 2007

Chief .....
Representative of the Council of
Village Heads of Nam Rew and
Nam Chaa Valley

Martin Stigberg
Department of Systematic Botany,
Uppsala University, Sweden

Box 1D: Letters of Intent—Education/Training Situation

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.

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.

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 Sida/SAREC to Dr. Lisa Svensson.

Vientiane, February 25, 2007

Dr. Sue-Trong
Dean of the Faculty of Sciences,
National University of PDR

Dr Lisa Svensson
Department of Systematic Botany
Uppsala University, Sweden

Box 2: Research Permit Examples

FORM B-001[27]

ENVIRONMENTAL PROTECTION AGENCY/EPA APPLICATION FOR SCIENTIFIC AND/OR COMMERCIAL RESEARCH ON BIODIVERSITY IN THE COOPERATIVE REPUBLIC OF GUYANA

The EPA welcomes applications from persons interested in conducting biodiversity research in Guyana.

NOTES TO THE APPLICANT

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.
b. All questions must be answered. Separate sheet(s) may be used for answers to any or all questions.
c. All applications must be typewritten. Failure to do so will result in a delay in processing the application.
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.
e. All current sponsors, employers, collaborating institutions, and affiliations with commercial entities, relating to any or all of the researchers, and for the proposed research, must be specified (see 11 below).
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.
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).
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.
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.
j. The Researcher must ensure that all necessary precautions be taken with regard to the health (vaccinations) of the research team.
k. The researcher/research team must work in accordance with the approved Guidelines for Biodiversity Research.

Please provide the information specified in the items below:

1. Name of authorized signatory to this application
2. Agency/institution on whose behalf the application is being made, if any
3. Postal address, telephone, fax and e-mail
4. Descriptive title of the proposed project
5. Summary of the proposed project (please attach a copy of the project proposal)
6. Objectives; proposed site(s) of the research (give as precise geographical delineation as possible); description of the proposed research, including methodology(ies):
7. What kinds of material/information are to be collected/produced/imported? (Please check appropriate boxes)
   - [ ] Specimen/sample collection (specify nature and numbers)
   - [ ] Recordings (audio and video)
   - [ ] Photographs
   - [ ] Written notes

(Continued on Next Page)

Box 2 (continued)

[ ] Computer entries
[ ] Reports
[ ] Articles and scientific papers
[ ] Other outputs (specify) _____

8. Anticipated intermediate and final destinations of all information/reports and specimens and materials:
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:
   (i) The use of samples or specimens, photographic and audiovisual materials and illustrations, for commercial purposes
   (ii) Chemical, pharmacological, and biotechnological study
   (iii) The use of materials or specimens for propagation or breeding purposes

Academic purposes here refer to only taxonomic, conservation, ecological, and biogeographical investigations

10. Time schedule (arrival in/and departure from Guyana, including dates in hinterland)
11. Composition of research team (attach very brief CVs). Also attach a statement on current sponsors.
12. Expected environmental impact of the research (brief statement)
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.
14. Proposed linkage(s) with local institution(s), if any. (State whether each institution has been formally approached and indicate (very briefly) its response.)
15. Training component for local counterparts
16. Do you intend to conduct research on lands legally owned or occupied by indigenous or local communities? If so, where?
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).

Signature of applicant
Signature of supervisor, if applicable
Office held in the Agency/Institution
Date
Environmental Protection Agency
IAST Building, U.G. Campus, Turkeyen
Greater Georgetown, GUYANA

Source: EPA, Republic of Guyana.[28]

Box 4A: 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.

(Continued on Next Page)

Box 4A (continued)

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 IEGSU, in the way of scientific publications or otherwise, as agreed by the parts.

SEVENTH: The transportation from JBN to IEGSU 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
Head Director

_____
Fdo. Dr. Britta Ekholm
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

Box 4B: Prior Informed Consent—Description and Inventory of the Flora of Malgonia

PROJECT 1: DESCRIPTION AND INVENTORY OF THE FLORA OF MALGONIA

Parties: Institute of Systematic Botany, Uppsala University, Sweden, The prefect, Dr. Sven Berg, and the performing scientist, MSc Anna Skool, Institute of Applied Botany, University of Malgon, Malgonia, The director Dr. Marin Marais, the government of Malgonia represented by the director of the Malgonian Environment Protection Agency (MEPA).

PROJECT 2. Inventory and use of the flora in Nam Noi valley, Lao People's Democratic Republic (hereafter Laos or Lao PDR).

Parties:
- Institute of Systematic Botany, Uppsala University, Sweden, The prefect, Dr. Sven Berg and the performing scientists, Eva Lund, Dr. Mikael Engström, and MSc Birgitta Karlsson
- National University of Laos, faculty of Science, the dean, Dr. Boukaone Nourinam, National University of Laos, faculty of Medicine, Dr. Bourisak Nam, NUOL represents the Government.

Box 4C: Time-Frame Examples

Project 1. Description and inventory of the Flora of Malgonia
The project is planned and financed for a three-year period with an additional six months for publishing and reporting.
Time schedule: January 1, 2007 until June 30, 2010

Project 2. Inventory and use of the flora in Nam Noi Valley, Laos
The project is financed over a three year period, but two Ph.D.s in a sandwich program are expected. The time schedule of the PIC could only be signed for three years but a renewal is prepared.
Time schedule: January 1, 2007 until December 31, 2009, with possible renewal from January 1, 2009 until December 31, 2012.

Box 4D: Examples of Geographical Definitions

Project 1. Description and inventory of the Flora of Malgonia.
The project area is defined as "mountain areas throughout the country." With respect to the Northeastern part of the country, a special permit is necessary and hereby given.

Project 2. Inventory and use of the flora in Nam Noi Valley, Laos
The project area is defined as the Nam Noi Valley and the nearby Nam Pheo Valley between Nam Theun, Laos and the Vietnamese border. The project is permitted to expand to the Nam Theun basin, which is planned to be flooded.

Box 4E: Description of Material

Example 1: Description and inventory of the Flora of Malgonia
The PIC concerns flowering plants without specific limitations. Species within the family Acrididiae will be collected for Dr. Grazia Hopper at the Museum of Natural History in Amsterdam. Reference specimens will also be given to the Museum of Natural History in Malgon. Collected specimens will be marked: *Property of Malgonia*.

Example 2. Inventory and use of the flora in Nam Noi Valley, Laos
The relevant genetic resources are species and their derivatives used for malaria and vector control. A specific permit is given to Professor Gunnar Sellström for collection of insects within the genus *Anopheles*. Collected specimens are treated the same as collected plant species. Collected specimens should be marked: *Property of Lao PDR*.

Example 3. Description and inventory of the flora of Malgonia
The project is noncommercial and intended to improve knowledge of the Malgonian flora. The project will result in the description of species and the collection of herbarium specimens. Triplicates of the specimens will be deposited at the herbaria in Malgon, Uppsala, and Stockholm. A separate MTA is signed for material deposited in Stockholm and Uppsala. The results should be published in well-known, scientific journals and will also be at the disposal of the committee of the Malgonian flora. Collected specimens will be marked: *Property of Malgonia*. Transfer of material to a third party requires a permit, granted by the Malgonian Environment Ministry. Material transferred to Dr. Grazia Hopper, Amsterdam University, is described in a separate MTA. The project is used to introduce PCR techniques and training of Staff at NUM.

Example 4: Inventory and use of the flora in Nam Noi Valley, Laos
While collecting an inventory of the flora is noncommercial, the ethnobotanical study of the use of plant may contain commercial aspects. The long-term objective of the project is improved knowledge of the genetic resources in Laos, with the hope of establishing local production. The project will have two basic dimensions:

1. Inventory of species within the Zingiberaceae family, botanical and chemical. The chemical evaluation will concentrate on the essential oils from seeds and roots. Steam distillation techniques will be introduced on sight. Identification and structure determination of chemical compounds in the essential oils will be done through GC-MS in Lund, Sweden.

2. Ethnobotanical study of plant material used to cure and control malaria and mosquitoes. Open-ended or semistructured interviews of members of different ethnic groups in the area will be followed by statistical analyses, identification of species, evaluation of processing influence on chemical composition, literature studies on species and isolated compounds, and screening for biological activity.

Active compounds are identified using GC-MS and HPLC-MS. The project will serve technology transfer and technique training for Ph.D. students at NUOL. Blood sampling and analysis is performed by scientists of the medical faculty at NUOL. Ethical permits for blood sampling are obtained by the faculty. Expected outcome: improved malaria control among the population in the studied valleys and identification of possible products for malaria control. At least two PhD students will use the project to complete their exams.

Box 5: CDB on MAT

1. [Minimum conditions for the fair and equitable sharing of the benefits arising out of the use of genetic resources, derivatives or products shall be stipulated in relevant national [access] legislations [or] [and] under the international regime] and [shall] [may] be taken into consideration in mutually agreed terms [shall] [may] be based on prior informed consent between the provider and user of given resources.]

2. [Mutually agreed terms conditions may stipulate benefit-sharing arrangements regarding derivatives and products of genetic resources.]

3. The conditions for the sharing of the benefits arising out of the use of traditional knowledge, innovations or practices and associated [with] genetic resources [derivatives and products] [will] [may] be stipulated in mutually agreed terms [between users and the competent national authority of the provider country with active involvement of concerned indigenous and local communities] [between the indigenous or local communities and the users, and where appropriate with the involvement of the provider country].

4. [Mutually agreed terms may contain provisions on whether intellectual property rights may be sought and if so under what conditions.]

5. Mutually agreed terms may stipulate monetary and/or non-monetary conditions for the use of genetic resources, [their derivatives and/or products] and associated traditional knowledge, innovations and practices.

6. [The international regime should establish basic benefit-sharing [obligations] [conditions], including the distribution of benefits through the financial mechanism, to be applicable in the absence of specific provisions in access arrangements.]

7. [Where the country of origin of the genetic resources or derivatives accessed cannot be identified, the monetary benefits there from shall accrue to the financial mechanism and the non-monetary benefits shall be made available to those Parties that need them.]

Source: CBD.[29]

Box 6: Sample MTA

This overall Material Transfer Agreement (MTA) will govern the exchange of selected biological material between the University of Nangijala and the University of Uppsala, jointly referred to below as the Parties. This MTA is based on a collaborative research contract between the parties and may be amended where any national laws or regulations require it, or upon the mutual agreement of the contracting Parties. It is understood that all exchange of biological material will be done strictly in accordance with the principles set out in the Convention on Biological Diversity.

The Parties therefore agree to the following terms and conditions:

1: Definitions

Biological material means any material of a plant or animal, or microorganisms or other genetic resources or derivatives thereof.

Provider means provider of biological material and may be the country providing a genetic resource collected from *in situ* or *ex situ* sources, including populations of both wild and domesticated species, according to the principles of the Convention of Biological Diversity. Provider may also be an institution providing part of a plant or animal, or microorganisms or other genetic resources or derivatives thereof.

2: Designation of Implementing Agency

Depending on the situation in the countries of the respective Parties, several options for the designation of implementing agency are possible:

2.1 University X hereby designates an authorized representative from Faculty Y as the competent University X representative for the purposes of this MTA. Such a representative should be at the level of Director/Dean/Chairperson, or be an appropriate representative. For clarification, it is agreed that the Faculty Y shall be responsible for ensuring that all national laws and procedures in force in Country U, relating to the exchange of biological material, are respected. Faculty Y shall make reasonable efforts to inform individual researchers/investigators of the national laws and procedures relevant to this Agreement.

2.2 If the University has not designated an authorized representative, the University is represented by the Head of the Administration, and the Administration shall be responsible for ensuring that all national laws and procedures in force in Country U relating to the exchange of biological material are respected. The Administration shall make reasonable efforts to inform individual researchers/investigators of the national laws and procedures relevant to this Agreement.

3: Purpose

The primary purpose of this Agreement is to provide a framework for the exchange of selected biological material for the purposes of research and education.

4: Ownership

4.1 Biological material exchanged in accordance with this Agreement, including any material contained or incorporated in modifications, wherever located, shall at all times be the property of the provider and shall not be used by, or transferred to, third parties without the knowledge, consent, and written authorization of the provider in accordance with the principles in the Convention on Biological Diversity. The ownership of any new intellectual property derived from material transferred under this Agreement shall be governed by the terms described in Article 7 of this Agreement. For the purpose of this MTA, the provider is defined as the Department or the University that has provided the biological material as defined in each Implementing Letter of Agreement and also defined in Article 5 of this Agreement.

(Continued on Next Page)

Box 6 (continued)

[Note: In the absence of specific legislation vesting ownership of biological material held by research institutions, it is prudent to have it vested in the Faculty or University. The Faculty in both Parties' countries need to rigorously follow the developments in the emerging access legislation and respond to any legal developments accordingly.]

4.2 The Parties agree to refer to each other any requests for the use of material from third parties not defined under this MTA.

5: Implementing Letter of Agreement
For all material to be exchanged or transferred under this Agreement, the Parties shall execute an Implementing Letter of Agreement (ILA), describing the nature of the material to be collected or transferred under this Agreement. Each ILA shall be concluded before any authorization for the transfer of material is granted. ILAs must contain the signatures of the relevant principal researchers that are providing and receiving the defined material in each ILA. The ILA must explicitly reference the rights and responsibilities of the Parties as defined by this MTA.

[The purpose of this section is to avoid a situation in which an MTA would need to be concluded for every single exchange of material. The section will accurately define the nature of the material that is transferred under each MTA.]

6: Conditions relating to the use of biological material

6.1 The Parties agree that the material collected and transferred under this agreement is to be used for teaching and academic research purposes.

6.2 It is agreed that any other application or use of the material provided, including any modification thereof, for commercial purposes shall be allowed at the sole discretion of the provider. If either of the Parties wishes to use the material, or derivatives thereof, for purposes other than that described in Article 6.1 of this MTA, the authorization for such use shall be at the sole discretion of the providing institution as described in this MTA, and such authorization shall not be reasonably withheld.

6.3 Each of the Parties agrees to comply with the terms of this Agreement. This includes any scientists or any person(s) of either Party who may come to possess the material in the ordinary course of his/her business as an employee of the Parties. Such person(s) shall not make available the material or any part thereof, or related information to any person(s) or third parties other than those personnel under the Parties' immediate and direct control.

7: Intellectual Property Rights
Any inventions that are derived in whole or in part from the biological material transferred under this MTA shall be assigned in accordance with the relevant laws governing intellectual property. Each assignment shall (1) identify the provider of the material and (2) identify the country of origin of the material used in any commercialized product(s). The assignees of inventions of any commercialized product(s) shall negotiate a good faith, mutually acceptable agreement with the provider of the material, according to the principles set out in the Convention on Biological Diversity.

8: Publication
Copyrighted publication generated from research exchanged under this agreement or extracted from biological material collected in the pursuance of this agreement shall not include any restrictions whatsoever regarding use of such publication by the Parties.

(Continued on Next Page)

Box 6 (continued)

9: Duration of the Agreement
This MTA shall be valid until the end of 2001, according to the BIO-EARN project contract. The agreement may be renewed for a new BIO-EARN Programme period (2002–2005) upon mutual agreement of the contracting Parties.

10: Termination

10.1 Unless otherwise agreed, this MTA will terminate at the expiration of the present cooperation program.

- The Parties shall remain bound to each other by the least restrictive terms applicable to the material obtained in the pursuance of the purposes of this Agreement, and any modifications thereof, in accordance with Article 7 of this Agreement.
- The Parties will discontinue their use of the material and may destroy or return any remaining material to the country of origin.
- If for any reason, either of the Parties wishes to terminate this Agreement before the completion of the research, each of the Parties agrees that it will to the other Party give written notice six months prior so as to enable the completion of ongoing research. Such written notice shall be provided to each representative of the Parties' signatory to this Agreement.

10.2 Nothing in this Agreement shall be interpreted as having the effect of preventing or delaying the publication of research findings resulting from the use of the material or modification thereof.

11: Settlement of disputes

11.1 In the event that a dispute arises regarding the interpretation or application of the provisions of the Agreement, the Parties shall initially resolve their disputes in an amicable manner through consultations.

11.2 If the Parties fail to resolve their disputes amicably within a period of six months, they shall resort to arbitration.

11.3 Each Party shall nominate two arbitrators, and a fifth arbitrator shall be nominated by the United Nations Legal Affairs Office. The latter shall be the Chair of the Arbitral Tribunal. The decision of the arbitrators shall be final. Decision shall be passed by consensus. If consensus cannot be achieved, the decision shall be made by vote.

12: Miscellaneous
The Parties acknowledge that the biological material provided in pursuance of this Agreement may have characteristics that are unknown or difficult to determine and which may be potentially hazardous. Neither Party makes any warranties, express or implied, as to the safety, quality, viability, or purity of the material, or its merchantability or fitness for any particular purpose.

University/ Research Institute in the Nation concerned

Name of University_____
Full Address_____
Authorized Officer_____
Title_____
Signature_____
Date_____

(Continued on Next Page)

Box 6 (continued)

University in Sweden_____
Name of University_____
Full Address_____

Authorized Officer_____
Title_____
Signature_____
Date_____

Box 7: Sample Confidential Disclosure Agreement

This Confidential Disclosure Agreement ("Agreement") is made and entered into as of the _____ day of _____, 20__ (the "Effective Date") by and between _____ _____ (hereinafter referred to as "LENDER") having its principle address at _____ _____, and _____ (hereinafter referred to as "BORROWER") having its principle office at _____ _____.

The LENDER and the BORROWER are each hereinafter sometimes referred to individually as a "Party" and collectively as the "Parties," for the purpose of protecting the patent, trade secret, and other proprietary rights of the LENDER and the BORROWER in the following subject matter, which may be mutually beneficial to the Parties to disclose for evaluation:
Subject Matter Description:

The Parties agree as follows:

Neither Party will directly or indirectly divulge to unauthorized persons any information received from the other Party that relates to the subject matter of this Agreement, except as otherwise required by law. As a condition to receiving such information, each Party to the Agreement hereby acknowledges that all information provided by either Party to the other in connection with the subject matter of this Agreement is confidential and proprietary with regard to the Party providing such information. Information to be subject to this Agreement shall be disclosed in writing or, if it is verbally or electronically disclosed as confidential at the time of disclosure, its confidentiality shall be confirmed in writing within twenty (20) days of disclosure by the Party making the disclosure.

Each Party, as recipient of such proprietary information from the other Party, will disclose such information only to its employees, directors, agents, consultants, bankers, and advisors ("Representatives") for the purpose of evaluation, and any Representatives to whom such information is disclosed shall be informed of the proprietary nature of the disclosure and of this Agreement and shall agree to hold such information in confidence and be bound by this Agreement in the same manner that each Party is bound. Each party shall be responsible for any breach of this Agreement by its Party Representatives.

Neither Party will use such information received from the other Party for any purpose except evaluation, testing, research, and related activities and will not disclose such information to anyone except its Representatives, unless prior written consent is obtained from the Party providing such information or as required by law.

This Agreement shall be binding on both Parties for a term of _____ ( ) years from the effective Date of this Agreement, except under the following conditions:

1. If a Party can show that such information was in its possession at the time of the disclosure; or
2. If the information disclosed by one Party to this Agreement is or becomes publicly known during the term of this Agreement other than through a breach of that Party's obligations under this Agreement; or
3. If the Party later receives such information from a third Party as a matter of right; or if such information is developed by one Party independently or any disclosures made under this Agreement, as evidenced by that Party's written records.

This Agreement shall be governed by the laws of _____.

(Continued on Next Page)

Box 7 (continued)

To evidence their Agreement to the foregoing, the Parties have, through duly authorized representatives, executed this Agreement.

LENDER _____
By: _____
Name: _____
Title: _____

BORROWER _____
By: _____
Name: _____
Title: _____