The International Cooperative Biodiversity Groups (ICBG) Program

A U.S. Government funded effort to promote equitable sharing of biodiversity benefits in the context of integrated research and development toward drug discovery, biodiversity conservation and economic development.

A Benefit-sharing case study for the Conference of Parties to Convention on Biological Diversity

by

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I. Overview

The ICBG program is an effort established in 1992 by three agencies of the U.S. Government (National Institutes of Health, National Science Foundation, United States Agency for International Development) to integrate improvement of human health through drug discovery, incentives for conservation of biodiversity, and new models of sustainable economic activity that focus on the environment, health, population and democracy. This program is based on the belief that the discovery and development of pharmaceutical and other useful agents from natural products can, under appropriate circumstances, promote sustained economic growth in developing countries while conserving the biological resources from which these products are derived. The program currently funds 5 groups working in eight countries in Latin America and Africa. The five ICBGs, consisting of diverse public and private institutions including universities, environmental organizations and pharmaceutical companies in eight countries, are collaborating on multi-disciplinary five year projects to advance the goals outlined above. Groups are linked by a series of research and benefit-sharing agreements that were formed by the investigators to address a set of operational and intellectual property and benefit-sharing principles outlined in the 1992 ICBG Request for Applications.

II. Description of the Context

Biodiversity prospecting begins with the search for potential pharmaceutical, agricultural and industrial uses of the genetic resources in the diversity of non-human life on the planet. What differentiates this search today from the way it has been done in past decades is the recognition that the process and its potential rewards should provide benefits to the source country and local communities that are the stewards of those resources.

Numerous authors in the last several years (Downes et al. 1993, Laird 1993, Grifo in press, Cragg et al. 1994, Baker et al. 1995, Grifo and Downes 1996) have discussed the important ethical and legal considerations of sharing benefits. Bioprospecting is also widely viewed as a potentially powerful tool to promote conservation of biodiversity (Reid et al. 1993, Rubin and Fish 1994, ten Kate 1995, Balick et al. 1996), although it is not yet clear how powerful it will be. In this paper I will describe how sharing benefits from bioprospecting is carried out in the International Cooperative Biodiversity Groups (ICBG) program.

Patent law is the legal instrument most commonly used to protect the right to benefit financially from scientific innovations. However, as practised in most countries, it is an inadequate tool to provide for sharing of the benefits from bioprospecting (Sedjo 1992, Axt et al. 1993, Downes et al. 1993, Greaves 1994). Patent law originated as a means of stimulating innovation. Patentable inventions and discoveries must be novel, non-obvious and useful. As a result of these requirements and others patent law is generally unable to recognise stewardship of biodiversity or maintenance of traditional knowledge of the uses of biodiversity.

Contractual agreements among bioprospecting partnerships are widely considered better means of securing benefits for the source country. In contrast to patent law, agreements can be designed to fit any conceivable relationship between collaborators. They can be used to define the types and amounts of benefits and can target recipient populations and conservation objectives. This paper will focus on a few practical issues and policy considerations that are central to making contractual bioprospecting agreements that will generate incentives for conservation.

This paper deals almost exclusively with prospecting for potential pharmaceutical products. While some of the issues raised here may also apply to agricultural germplasm, the scientific, historical and political environments are quite different.

III. Purpose/Objectives of the Benefit Sharing Arrangements

The International Co-operative Biodiversity Groups (ICBG) Programme is a four year old experimental effort established, funded and guided co-operatively by three agencies of the United States Government -- the National Institutes of Health, the National Science Foundation, and the US Agency for International Development. It was designed to stimulate the field of bioprospecting, to provide models for the development of sustainable use of biodiversity, and to gather evidence on the feasibility of bioprospecting as a means to:

1. improve human health through discovery of natural products with medicinal properties;

2. conserve biodiversity through valuation of natural resources, training and infrastructure building to aid in management;

3. promote sustainable economic activity of communities, primarily in less developed countries in which much of the world's biodiversity is found.

Each of the International Co-operative Biodiversity Groups is run by an academic principal investigator, who directs his or her own research programme in natural products chemistry, drug development or ethnobotany, and co-ordinates the activities of several associate programmes. The associate programmes generally include other academic research institutions, local and international NGOs that are working in the host countries, and in most cases, a commercial pharmaceutical partner. While each of the groups is unique, generally each associate programme is charged with one or more of the basic missions of the ICBG -- biodiversity inventory, collection and conservation, screening and chemistry, drug development, or economic development. The awards are in the form of co-operative agreements, rather than grants. This means that the US Government has continued involvement in the projects through scientific advisory committees that comprise representatives from each agency, as well as general facilitation and policy advice from the Fogarty International Centre of the NIH, which handles programme management for the ICBG awards.

The basic philosophy of this integrated conservation and development programme (ICDP) is that appropriately designed natural products research and development can bring both short and long-term benefits to the countries and communities that are the stewards of the genetic resources (Schweitzer et al. 1991, Grifo in press). Sharing benefits from both the research process and from any drug discoveries that are made down the road creates incentives for conservation and provides alternatives to destructive use.

In the context of the ICBG programme, appropriate design includes: 1) active participation of host country individuals and organisations from the planning stage onward, 2) multi-disciplinary research on diseases of both local and international significance, 3) local training and infrastructure development in both drug discovery and biodiversity management, 4) biodiversity inventory and monitoring, and 5) equitable intellectual property and benefit-sharing arrangements.

Applicants for the ICBG awards were given a description of programme goals and intellectual property principles to use in the design of their research proposals and contractual agreements. Formal written agreements that govern treatment of intellectual property and benefit-sharing were required of all applicants prior to making an award. Because the funding agencies are not parties to the research and benefit-sharing agreements, they are prohibited by US Federal law from stipulating specific contractual terms, but rather encourage the parties to develop innovative agreements that fit the nature of the organisations, countries, communities and resources involved, within the general framework of the programme's principles.

The 1992 Request for Applications (NIH, NSF, USAID TW-92-01) and some background papers describing the original principles of the program are available elsewhere (Schweitzer et al. 1991, Grifo and Downes 1996, Grifo in press). These program principles were modified for the most recent Request for Applications (NIH, NSF, FAS TW-98-01) and can be found in Appendix 1 of this paper. In general, the principles require that full disclosure and informed consent are carried out, that both near and long-term benefits are shared with appropriate source country communities and organisations, that local laws and customs are followed, and that credit be given to local indigenous or other intellectual contributors where possible.

ICBG Awards

In 1993 and 1994, following a multi-disciplinary peer review of 34 competitive proposals, five awards were made. Each is planned for a five year duration.

Dr. David Kingston of Virginia Polytechnic Institute and State University (VPISU), is studying rainforest plants in Suriname, in collaboration with the Forest People of **Suriname**, Conservation International - Suriname, the National Herbarium of Suriname, the Missouri Botanical Garden, Bedrijf Geneesmiddelen Voorziening Suriname, and Bristol-Myers Squibb Pharmaceutical Research Institute.

Dr. Jerrold Meinwald of Cornell University is the group leader for the study of insects and related organisms from the dry tropical forests of the Guanacaste Conservation Area in **Costa Rica**, in conjunction with the National Biodiversity Institute (INBio) of Costa Rica, the University of Costa Rica, and Bristol-Myers Squibb Pharmaceutical Research Institute.

Dr. Barbara Timmermann and colleagues of the University of Arizona are studying arid land plants in **Argentina, Chile, and Mexico,** in collaboration with the Instituto de Recursos Biologicos de Argentina, the Universidad Nacional de la Patagonia, Pontifica Universidad Catolica de Chile, the Universidad Nacional Autonoma de Mexico, Purdue University, G. W. L. Hansen's Disease Centre, and the Medical and Agricultural Divisions of Wyeth-Ayerst/American Cyanamid Co.

Dr. Walter Lewis of Washington University is group leader for ICBG research on plants that have been used medicinally for generations in Andean tropical rainforests of **Peru**. He is collaborating with several organisations of Aguaruna Peoples, the Universidad San Marcos and the Universidad Peruana Cayetano-Heredia in Peru, and Monsanto-Searle Co..

Dr. Brian G. Schuster leads a group from Walter Reed Army Institute of Research that is focusing on cures for parasitic diseases from rainforest plants of **Cameroon and Nigeria**. Their collaborators are

the Smithsonian Institution, the Bioresources Development and Conservation Programme, the University of Yaounde in Cameroon, the Biodiversity Support Programme, and Shaman Pharmaceuticals.

The programme is about four years old, and while it is still early to understand fully the potential of this approach, some lessons may be learned from the process of establishing agreements.

A. Types of Benefits

Benefits from bioprospecting agreements may include monetary compensation in the form of royalties and advance payments. They may also include source country capacity building efforts such as training, equipment and infrastructure development. Other benefits, less tangible but no less important, may be research on diseases or regions that are important to the host country, and the building of collaborative relationships that will endure beyond the scope or duration of a particular project.

Royalties

Royalty earnings, usually a percentage of income from a commercialised product, are the first issue that most people concentrate on in the discussion of benefits. Royalty terms in contracts are generally negotiated as a range, depending upon the relative contribution of the partners to the invention and other aspects of the drug discovery process. For example, a commercialised product that is a direct isolate or very similar to the original extract provided by source country partners may pay a higher royalty than one that is synthesised by the pharmaceutical company but based upon a lead encountered in the original extract. There may also be intermediates between these extremes.

Some pharmaceutical companies may prefer a royalty schedule that specifically rewards their own research investment in the development of proprietary mechanism-based assays. For instance, a product resulting from a positive identification in a mechanistic assay developed by the company would pay a smaller royalty to the source country than one found in a classical functional assay. An example of a mechanistic screen might be one that measures the activity of a specific enzyme thought to be important in the development of breast cancer, while a functional assay would be one that measures a simple growth response in a breast cancer cell line, without trying to identify the mechanism of action. The logic that is offered for this approach to royalty structuring is similar to that described above for direct isolates versus synthesised derivatives of the natural product. If activity is discovered in a mechanistic assay that was developed using a great deal of intellectual property from the industrial partner then the relative contribution of the provider of the crude extract to the invention may be less than otherwise.

From the standpoint of the source country provider, the functional/mechanistic approach has both advantages and disadvantages. It could conceivably make post-discovery negotiations easier by simply identifying the lead assay involved. Furthermore, pharmaceutical companies will generally attempt to modify and synthesise an active compound both to optimise its activity and to maximise their ability to defend the patent against infringement by competitors. Therefore, a royalty structure that depends upon direct isolates to provide the best terms for the source country may not often be superior. However, there are several potential pitfalls to the functional/mechanistic structure. First, many active extracts affect more than one assay in a battery, potentially hitting both functional and mechanistic

screens simultaneously. Second, mechanistic assays represent the vast of majority assays used by most pharmaceutical companies today. It is important to know what percentages of the assays they use will belong to one category or another, and how duplicate hits would be treated.

The timing of royalty negotiations may also be important. The best time for source country partners to work out royalty arrangements may be after preliminary data on an extract shows therapeutic efficacy and the compound has been chemically analysed. As in the above examples, when more information regarding a compound is added by source country partners, they are likely to command better royalty rates. Therefore, building flexibility into agreements to allow for later negotiations may be advantageous, and source countries should consider the consequences carefully before granting industrial partners exclusive licensing rights in advance of research.

Ethno-medical knowledge from source country participants can also be explicitly rewarded in the royalty structure of agreements as intellectual contributions to an invention. Such a reward may provide incentives for "in-situ" conservation of the knowledge and the plant or animal species to which it relates. From the research standpoint this makes most sense when sample collection is guided by traditional uses, or when the information is provided with the sample and helps guide the assays used. The latter is most likely to be of interest to industrial partners for a small number of assays that are expensive to run or not part of their main focus. Most screening is now so mechanised and efficient for large companies that the majority of samples they receive are generally run through the entire battery of assays that may be active at the moment, regardless of background information on the sample. For the less mechanised operations that academic and small companies rely upon, traditional uses may have a much greater role.

In some cases, disclosure of traditional knowledge during the screening process may not be acceptable to the providers of that information because it is considered sacred or because it may weaken the control they have over their intellectual property. Some companies may be willing to provide an additional return to discoveries that relate to ethno-medical knowledge even when the information is not used initially. When it is either undesirable or not possible for traditional knowledge to be compensated through the royalty schedule of a licensing agreement, it can and should be rewarded in the benefit-sharing arrangements that flow from those royalties. This occurs in several of the ICBGs.

Royalty earnings from commercialised products of biotechnology are an important benefit, and they have received much attention, however, they are only one of the benefits available (Reid et al. 1993, ten Kate 1995, Iwu 1996, Juma 1993). Furthermore, while royalty earnings from a very successful product can be significant, recent work by Simpson et al. (1996), Artuso (in press) and others suggest that they may be, on average, much smaller than the expectations of many people. This is in part because the probabilities of a commercially significant discovery are exceedingly low for any given project and the time required for development of that discovery is on the order of 10 years (Baker et al. 1995). In addition, there are many competing providers of genetic resources, resulting in downward pressure on the price (Simpson et al. 1996). Whether royalties will often be sufficient by themselves to offset income offerings from more destructive uses of natural resources, such as timber, should be assessed realistically during policy formulation.

Advance monetary payments

In agreements that involve commercial partners, advance monetary payments are frequently important to source countries for several reasons. While advance payments may involve a trade-off in lower royalty rates, they lower risk and allow early establishment of trust funds that provide small grants and other financial benefits to communities that have urgent needs. Another advantage of "up-front" monies is that they provide evidence to both local communities and governments of the sincerity and commitment of the partnerships. Such evidence can help convince local resource users and policy makers that alternatives to destructive harvesting practices may indeed be rewarded.

Advance payments in different forms have been made in three of the five ICBGs and are financing biodiversity management, health and local development projects in the source countries. The African ICBG (with no major pharmaceutical partner) has set aside a portion of its government research and development funding to act as advance payments to communities. We have found that commercial partners have very different reactions to requests for advance payments. Some may be reluctant to provide significant monetary payments until the partnership is showing productivity, but are willing to donate used equipment to host countries, especially machines that aid extraction, characterisation and data management associated with the project. Others may find a lump-sum payment to be good public relations as well as a bargaining tool, while some have preferred to make per-sample payments.

Box 1. **Types of Benefits to Source Country Partners from Bioprospecting Agreements**

Royalties - A percentage of earnings from commercial sales by the licensing partner may be agreed upon in the initial agreement, or the agreement can specify a range and require the parties to negotiate the final rate on a case by case basis. Some issues to consider in royalty structures include: a) relative contribution of partners to invention and development; b) information provided with samples; c) novelty or rarity of sample organisms.

Advance payments - Access fees may take the form of lump-sum or milestone payments, per sample fees, payment for re-supply of samples, or in-kind contributions of equipment, training, medicines, etc.. Advance payments are valuable for establishing trust funds that can provide immediate benefits to stakeholders.

Equipment, training and infrastructure - Commercial partners or non-profit funding organisations may provide resources to help build the capacity of source country partners to execute current or future needs for bioprospecting research, medical care, biodiversity management, etc..

Priority research areas - Agreements can require that locally important, but understudied, diseases and indigenous therapies will be investigated by commercial and other scientific partners. Additionally, they can focus specimen collections and identification on geographical areas or biological groups that are high priorities for conservation needs.

Capacity-building

Because of the potential limits to monetary income from bioprospecting agreements it is important to focus as much effort as possible on "capacity-building" benefits. In general, these may include training, equipment and development of source country infrastructure and institutional alliances for biodiversity management and biomedical research and service delivery. Each of the ICBGs has a variety of source country capacity-building projects including training and equipment to enhance parataxonomy, geographic information systems and other database technologies, natural products and bio-chemistry research, and sample preparation and storage. Infrastructure development efforts to date

have included provision of vehicles, renovation and improvement of laboratories, community health clinics and herbaria.

An important and sometimes overlooked type of capacity building is the development of collaborative relationships between institutions involved. Both international and within country collaborations provide the means to maximise productivity of the current project and to develop opportunities that may arise in the future (Iwu 1996). For example, the African ICBG, led by Dr. Brian Schuster of Walter Reed Army Institute of Research (WRAIR), is helping to strengthen an African non-governmental alliance, Bioresources Development and Conservation Programme (BDCP), that includes university biomedical and biodiversity researchers, government officials, traditional healers, community leaders and herbal medicine producers. In the first year of ICBG associated work this alliance has helped renovate a community health clinic, held an international congress on utilisation of medicinal plants, begun training parataxonomists from at least five African countries and purchased equipment and supplies for several university laboratories.

Research on Priority Diseases or Regions

Bioprospecting partnerships may be used to focus outside research expertise and resources on understudied diseases or biodiversity concerns of the source country. Some of the diseases that most affect developing countries do not offer sufficiently profitable markets to attract research by large US and multi-national drug companies. Locally (and globally) important health concerns such as malaria and leishmaniasis are consequently understudied and effective therapeutic treatments are few. Bioprospecting agreements can be utilised to ensure research efforts in diseases of local importance by state of the art commercial laboratories and researchers, and/or to achieve transfer of equipment and training to carry out more work in the source country.

The research of each of the ICBGs contains work on such diseases, and for several they are the thrust of the groups' work. Such efforts may promote conservation goals in at least two ways. Whether or not a financial incentive develops from the research, finding local treatments to locally important diseases may have a significant impact on the valuation of those areas and species by all concerned. Second, traditional disease eradication programmes that focus on vector control for diseases such as malaria have often directly resulted in habitat destruction (e.g., draining wetlands and broad insecticide applications) and have created an unfriendly view of tropical forests and wetlands among public health officials in many countries. Alternative treatments may reduce the need for mosquito eradication programmes and the impression that wildlands are a threat to human health.

Similarly, geographically or biologically defined regions of a country that are a priority due to high diversity or imminent threat can be investigated in conjunction with bioprospecting arrangements. Such arrangements offer the opportunity to bring experts on particular biological groups or techniques in to identify local flora and help design management strategies.

B. Who should receive benefits?

One of the most important and complex issues in bioprospecting lies in identifying the appropriate beneficiaries. Agreements can be designed to produce near and long term benefits to individuals, communities, non-governmental organisations including universities and conservation/development groups, and/or government institutions. There are many considerations in

addition to conservation objectives, including existing laws, equity, land tenure, political struggles, cultural stewardship and geographical distribution of the organisms being studied.

Legal guidelines on beneficiaries are still minimal in most countries. The U.N. Convention on Biodiversity recognises the sovereignty of nations over their genetic resources (Article 15). In addition, it requires parties to protect the interests of local and indigenous communities in their traditional knowledge and innovation (Article 8(j)), to ensure that use of their knowledge meets their approval, and to encourage fair sharing of benefits with communities providing knowledge. Conservation objectives offer a simple place to start identifying appropriate beneficiaries - - who are the stewards of the biological resources?

Individuals and Communities

In many tropical countries rural and indigenous communities have the greatest impact on the forests. Local people are in many senses stewards of those resources, even when land tenure is undefined. It is unlikely that resource use patterns can be affected unless individuals and communities see financial or other benefits emerging from alternatives to clearing a given patch of forest for timber or crop production.

The ICBG programme requires that both near and long term benefits flow back to the collaborating communities whether or not ethno-medicinal knowledge is utilised in the research process. Local individuals who collaborate with the project, frequently traditional healers or parataxonomists, generally receive payment for their services and training in collection and identification techniques. Each of the ICBGs is establishing or is associated with a trust fund for conservation and development benefits. In all cases where collections involve areas that are inhabited the funds are or will be focused on community projects focused on improving health services and sustainable use of local resources.

The Suriname ICBG established a benefit-sharing plan for monetary benefits from advance payments and royalties that provides returns to 'The Forest Peoples Fund' and five local governmental and non-governmental organisations (See Box 2). Reflecting the importance of community stewardship of those resources, the Forest Peoples Fund is the largest single recipient of any financial return, and its share is even greater in cases for which there is a documented relevant traditional use for the species that produces a commercial discovery.

However, a seemingly simple idea like returning benefits to communities can be extraordinarily complicated in practice. Are the communities defined geographically, ethnically, politically? Should the principal beneficiaries be those individuals or groups who actively participate, those who may be related, or everyone in a country?

The Peru ICBG is collaborating with the Aguaruna People of lowland Andean rainforest of northern Peru. The Aguaruna primarily reside in over 140 communities along a series of river basins. These communities share a common language and cultural heritage, including medicinal plant knowledge, and have somewhat fluid alliances with various Aguaruna political organisations.

In detailing their collection and benefit-sharing agreements the ICBG has struggled to balance competing claims of representation, the need to compensate those most actively involved and the ideal

of providing benefits to all of the relevant communities and individuals. The plan that is currently being drafted is designed to dedicate near and medium-term benefits from research activities and advance payments to the organisations and communities actively involved. Long-term contingent benefits would be available to all Aguaruna communities.

Box 2. Monetary benefit-sharing - Suriname ICBG.
Suriname portion of advance payments and royalty earnings

Advance Payments		Royalties	
		Ethno-medicinal collection	Random collection
100%	Forest Peoples Fund	50%	30%
	Bedrijf Geneesmiddelen Voorziening Suriname	10%	10%
	University of Suriname Herbarium	10%	10%
	Stichting Natuurbehoud Suriname	5%	10%
	Conservation International-Suriname	10%	10%
	Suriname Forest Service	5%	10%
	Future collaborating institutions	10%	20%
100%	Total	100%	100%

A different approach to benefit-sharing can be found in the arrangements of Shaman Pharmaceuticals. In co-ordination with their non-profit trust, the Healing Forest Conservancy, Shaman facilitates small-scale development projects and funds small grants in the communities in which they collect plants and information. For royalties that emerge from any product the company commercialises, Shaman has promised to share the proceeds with every community in which they have ever worked (King 1994). This 'global royalties' approach is motivated in part by a commitment to fairness and the need to minimise the delay and uncertainty before royalties would emerge from given project. It is less clear how such a global fund could provide sufficient returns to affect local decisions regarding resource use, and the more focused small-scale development projects may be of more utility to this end.

Benefits that accrue to individuals or local communities will most effectively translate into conservation incentives when those people believe that they have some long-term control over the resources. A community organisation or a local government may be able to factor in the long term advantages of preserving their options, but individuals have difficulty seeing the value of reining in their personal consumption patterns on land they do not own or control themselves. This problem is particularly acute at the level of the individual and the marginal hectare under consideration (Simpson et al. 1996). Unfortunately, "open access" resource regimes characterise much of the regions with the world's greatest biodiversity. Bioprospecting agreements generally involve a commitment to re-supply the same species sample if it proves to be of interest (an implicit promise to conserve the species). However, it will likely require efforts from governments and organised communities to help turn long-term, relatively diffuse incentives into decision making tools by guaranteeing some measure of long-term control over the resources and clear benefits to sustainable management practices.

Government institutions

Government organisations that manage natural resources typically have responsibility for monitoring biodiversity, and designing conservation and development strategies. These organisations are almost without exception underfunded. Whether or not it is required by national law, providing direct benefits to government institutions may be a valuable conservation strategy. Financial returns can be used to build evaluation and monitoring capacity, and even the potential of royalty-related benefits may produce positive incentives for conservation policies and legislation. Even where governments will not be direct beneficiaries of agreements it is may be advisable to address their priorities in diseases targeted for bioprospecting research, technologies for transfer, or communities that will receive training.

The benefit-sharing plan of the Suriname ICBG includes contingent benefits to several Surinamese government agencies and the National Herbarium (see Box 2). The government of Suriname is currently weighing the relative merits of several large logging concessions to foreign timber companies to gain some relief to a fiscal crisis (Sizer and Rice 1995). The resources of the Forest Service are inadequate to ensure proper monitoring of the concessions if they are granted. The legislature recently postponed a decision on the proposed concessions to better examine the probable gains of the timber concessions and alternatives. Among the many variables the legislature is considering are the potential benefits that alternative land use schemes such as that represented by the Suriname ICBG. While government officials have been apprised of the low probabilities of major financial incentives emerging from the ICBG, the possibility that their Forest Service and the Parks Management Service could receive some funding from options other than foreign timber concessions may be influential in their land use decisions.

Non-governmental organisations

In some countries there are strong reasons to recognise non-governmental organisations as stakeholders, including universities, conservation and development service organisations and private companies. In building the capacity of source countries to carry out both drug discovery and biodiversity management university herbaria and biotechnology companies are key players. Similarly, conservation organisations often provide important links to local communities, including training and other services. The African ICBG has found that making local healers associations beneficiaries is important for several reasons. Healers represent the most comprehensive repository of information on

traditional plant uses, and rewarding that knowledge increases the chances of preserving it (Iwu 1996). Healers are also frequently influential members of a community and may be able to help effect changes in local exploitation patterns.

IV. Process for Establishing the Arrangements

The ICBG Program Principles for the Treatment of Intellectual Property (Appendix 1) outline the general set of concerns that each group must address in their contractual arrangements in order to receive funding from the U.S. Government. Each group developed their own contracts and submitted them for review to the funding agencies. The funding agencies may require changes to ensure that the agreements to address those concerns. However, the funding agencies are prohibited by federal law from specifying individual terms of the contracts. The structure of the arrangements was also left up to the group members to determine. The program's philosophy has been that contacts that best fit the diverse needs of the wide variety of organisations and peoples involved will be developed by the groups themselves, when basic conditions of fairness and access to information are established.

Contractual agreements on genetic resources can take many forms. The basic issues that are generally covered include research topics, organisms to be studied, ownership and conditions of material transfer, research investment, patent rights and responsibilities, duration of agreement, and the type, amount and recipients of benefits (Downes et al. 1993, Laird 1993, Grifo and Downes 1996).

One early lesson from the ICBG partnerships is that neither funders, researchers, community organisations, conservation NGOs, governments or private companies can anticipate all the needs and strengths of a given agreement. Agreements take time and diverse expertise to develop, and flexibility and strong communication skills to maintain. Each of the ICBGs established agreements prior to beginning research and each has modified those agreements with experience as well as technical and political developments. I will describe here just a couple of key aspects of this dynamic process.

Informed consent and consensus building

The principle of full disclosure and informed consent is widely cited as a requirement for collection of genetic resources and the agreements that govern them. However, the concept of informed consent was originally conceived with regard to protection of the personal safety of human subjects participating in medical research (Belmont Report 1979). Application to intellectual property and genetic resources is a relatively recent development and a consensus on its meaning is yet to emerge.

How much should be disclosed and to whom? Informed consent has been interpreted, minimally, to mean verbal disclosure to the co-operating individual of the potential uses of his or her knowledge. At the other extreme it has been suggested that legal support should be provided to source country contacts, as well as copies of all related contracts, project descriptions, lists of collections and research results in progress for approval by the individuals, participating organisations and national government representatives. Potential conflicts exist with information that indigenous partners, researchers and industrial partners consider proprietary. This information may comprise specific bioassay techniques, financial terms in contracts, as well as plant species names, exact locations, and traditional uses of a given sample.

It has been our experience that extensive communication in the host country language to satisfy informed consent requirements during the agreement negotiations and collections process is an important tool for local capacity-building, for adequate project design, and for developing broad public support. By bringing all stakeholders into the discussion they are more likely to feel a part of the project and are more likely to support its conservation goals. An ideal partnership would involve community representatives from the design stages of a project through contract negotiations and the research process.

In practice this has in some cases proved difficult to carry out in the ICBG programme. Geographical and cultural distances between partners make it an extremely time consuming and expensive process. The Peruvian ICBG began the disclosure process primarily with cooperating individuals, a couple of organisation leaders and permit granting authorities in the government. Eventually they found it necessary and important to build a much more redundant and protracted disclosure and consensus building process, including many community individuals, village leaders, organisation leaders, NGOs and various government ministries.

In both the Peruvian and African ICBGs workshops featuring presentations by the various international partners and source country representatives with ample opportunity for open discussion among community, government and non-governmental representatives have proved to be very effective means of educating all potential collaborators. The Latin American ICBG has held a similar workshop in Buenos Aires. These are probably most important in the early development of a partnership and make an excellent prelude to contract negotiations.

Independent legal and commercial advice during negotiation

Modern bioprospecting agreements to date have largely been initiated by conservation and development practitioners, scientists and government natural resource representatives. Generally speaking, neither these people or the local community representatives involved have sufficient commercial and legal experience to negotiate agreements without competent legal counsel. Industrial partners will frequently have an advantage in this regard.

As such, it is crucial that each party to an agreement have independent legal advice during the negotiation process. For the ICBGs this has generally meant that the programme leaders lay out the basic principles of their agreements, and, with the aid of an attorney, develop rough out a first draft. Subsequently, each party sends the draft to their legal advisors for careful analysis to ensure that their needs are being met and potential confusion and shortcomings are avoided.

V. Context and Implementation of the Arrangements

Contracts can be structured in various ways. The ICBG projects begin with a type of contract, a co-operative agreement, between the US Government and a principal investigator at a US university. The government agrees to fund the work of the group to carry out the project as it was described in the

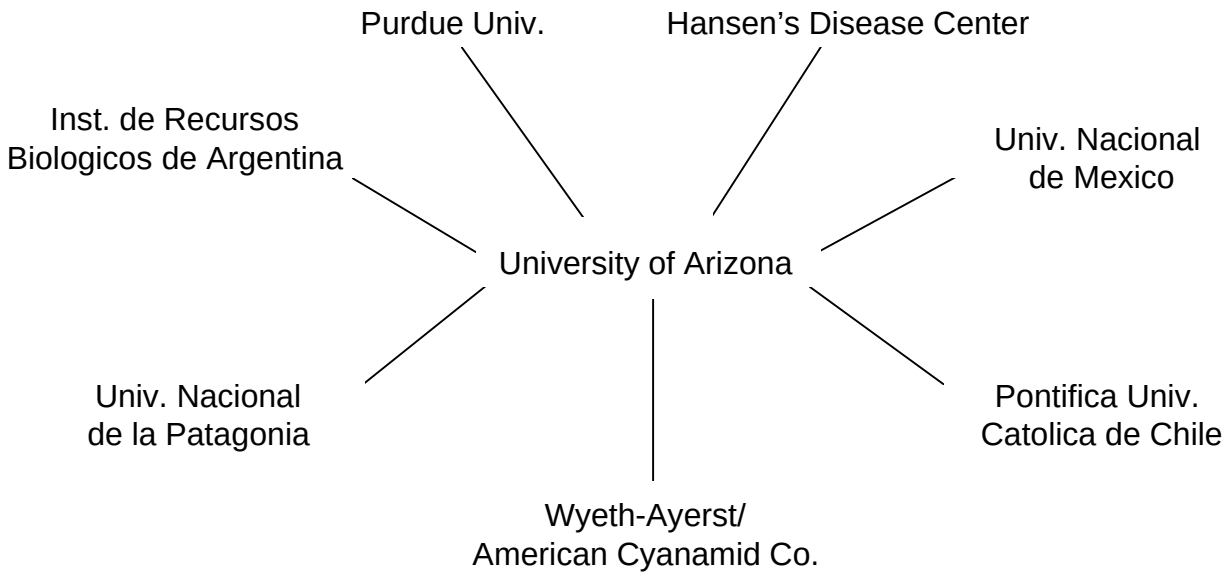
application, contingent upon the fulfilment of the set of principles described above, and given satisfactory progress and the availability of funds.

Next, each group forms one or more contracts among its members. The contracts that structure the groups are diverse, but primarily take the form of research and benefit-sharing agreements. The conceptual centre of most of the agreements is the research process. Linked to it are the commercial terms and the benefit-sharing arrangements.

The structure of the associated contracts between groups ranges from one contract that includes US university, host-country universities and conservation/development organisations and industrial partners, to a wheel of contracts between the various partners. The "one contract" model (in addition to the US Government-University co-operative agreement) is exemplified by the Costa Rican ICBG led by Dr. Jerrold Meinwald. That agreement includes Cornell University, the Cornell Research Foundation, INBio, and the Bristol-Myers Squibb Pharmaceutical Research Institute. (In fact, other agreements between INBio and the Government of Costa Rica, and INBio and the University of Costa Rica, are relevant but also relate to other projects besides the ICBG.) The ability to build one agreement among the basic partners was possible in part because of the technical sophistication, multi-disciplinary role and broad mandate to INBio from the Costa Rican Government.

At the other extreme of structural complexity, the Latin American ICBG led by Dr. Barbara Timmermann comprises a wheel of contracts. Because of the complexity of working in four different countries (Chile, Argentina, Mexico and US research laboratories) with eight different institutions, the group chose to make separate bi-lateral agreements between each of the other organisations and the institution of the principal investigator, The University of Arizona. Separate arrangements within each country are being made to distribute benefits from any discoveries. The result resembles a wheel with the U. of A. at the hub (Figure 1).

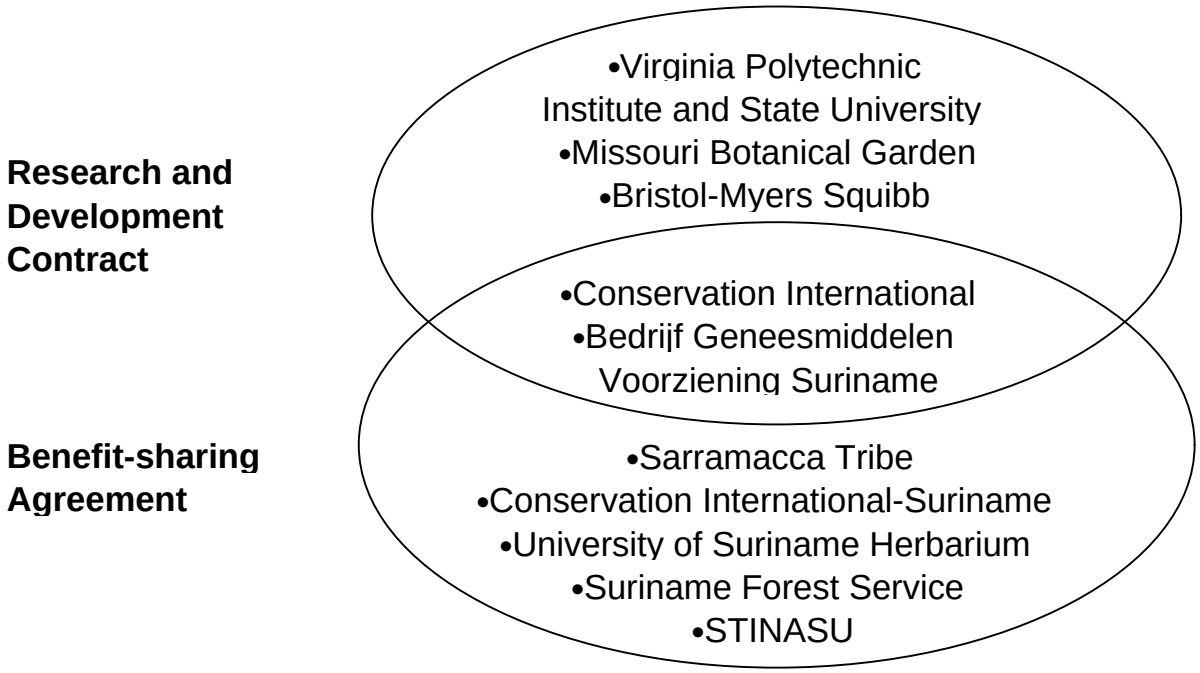
Figure 1. Agreement Structure - Latin American ICBG



Each source country of the Latin American ICBG -- Chile, Argentina and Mexico -- is developing its own terms of benefits sharing, beginning with workshops and broad discussions among local stakeholders, researchers, government representatives, and NGOs.

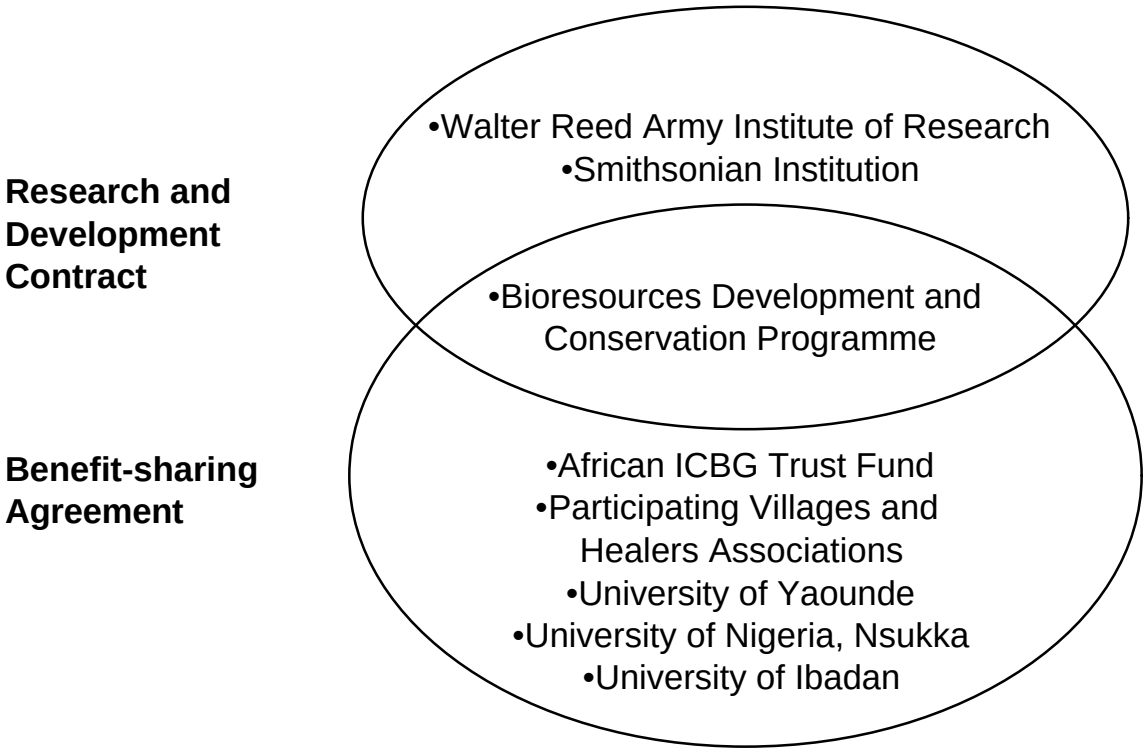
The Suriname ICBG led by Dr. David Kingston and the African ICBG led by Dr. Brian have converged on versions of a dual contract model. While they differ in several respects (the Africa ICBG has no major commercial partner), the approach they have taken basically separates the collections/benefit sharing agreement and the commercial research and development agreement. One or more host-country institutions is involved in both agreements (Figures 2 and 3).

Figure 2. Agreement Structure - Suriname ICBG



This approach partially separates the culturally and politically sensitive arrangements with local traditional or indigenous providers of tangible and intangible resources from the commercial research agreements that may include industrial partners. The structure reflects, in part, the reluctance that some industrial partners have shown to negotiating directly with local community groups that are often remote, and may have both unstable organisational structures and little understanding of the commercial and legal environment of industrial research.

Figure 3. Agreement Structure - African ICBG



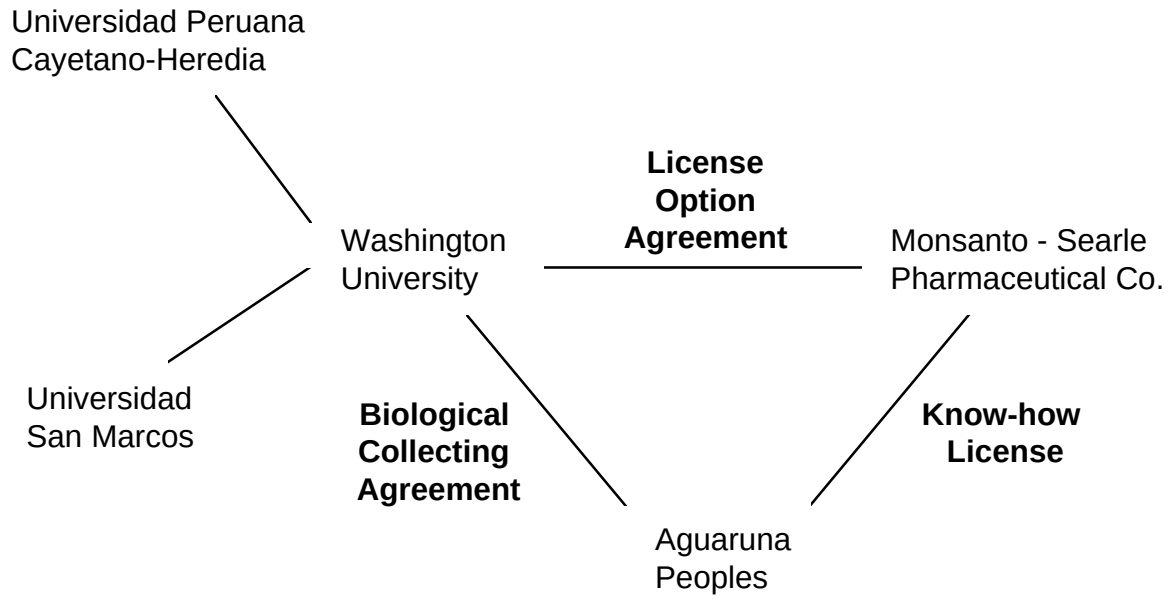
An advantage of the wheel-like structure of the Latin America ICBG and to a lesser extent the overlapping structure of the Suriname and Africa projects is that bi-lateral agreements are much easier to negotiate than multi-lateral ones are. In addition, stability for the group is greater even if one of the partners or the terms of a specific agreement change. A disadvantage is that the arrangement places an enormous burden of negotiation and management on the "hub" institution.

From the standpoint of the local communities there may be advantages to direct participation in the licensing agreements with commercial collaborators. The greatest value of such an arrangement may lie in the education that local community partners gain during negotiation. Ideally the process enables community organisations to make subsequent arrangements on their own. Another potential advantage lies in the empowerment that disenfranchised indigenous and other community groups could gain in direct dealings with international collaborators and a potential increase in local valuation of natural and intellectual resources. In addition, there is a widely held notion that a single contract may increase the bargaining power of local groups over specific commercial terms in licensing and research agreements. This may be true under certain conditions. However, it is important that local collaborators understand that they can always require the opportunity to examine related contracts and negotiate for any terms they deem important as a condition of their participation.

The Peru ICBG renegotiated its contracts in a unique manner that reflects the history of the group, the desires among various partners for bilateral arrangements and the different issues raised by

material samples and ethno-medical knowledge. The current arrangements set up a modified triangle of relationships (Figure 4).

Figure 4. Agreement Structure - Peru ICBG



The Biological Collecting Agreement between the Aguaruna Peoples (as represented by three organisations - OCCAAM, FECONARIN and FAD - under an umbrella organisation - CONAP) and Washington University outlines the basic terms of collaboration and sample collection, as well as benefit sharing among those two parties. The financial benefits involved, including royalties, would derive from the License Option Agreement between Washington University and Searle Co. In addition, a know-how license is being negotiated between the Aguaruna and Searle Co. that outlines Searle's use of the traditional knowledge and specific benefits associated with that use.

Know-How Licenses

A know-how license is a type of industrial agreement that provides the licensee with exclusive or non-exclusive rights to use informal knowledge that is not generally patentable, but is important in the execution or utilisation of an associated technology. The use of a know-how license for ethno-medicinal knowledge in the context of bioprospecting is an innovation that was suggested by the legal counsel for the Aguaruna, Brendan Tobin of the Sociedad Peruana de Derecho Ambiental (SPDA), and one that offered an interesting experiment for the representatives of Monsanto-Searle in the Peru ICBG. While the application to indigenous knowledge is not without legal complications, it offers a potentially powerful tool to provide indigenous and other local peoples recognition and protection in a type of contract that is familiar to the commercial sector.

Material Transfer Agreements

Material Transfer Agreements are already a standard tool in commercial and academic research partnerships. A material transfer agreement (MTA) is frequently narrower in scope than the co-operative research and development agreements of the ICBGs, but defines the basic rights and responsibilities related to the specific materials transferred. An alternative approach to bioprospecting partnerships places the transfer of materials, rather than the research process, at the centre of the agreements. Associated contracts are bound by the basic stipulations of the material transfer agreement. Because this approach begins with the source country property rather than the research process, it may be argued that it lends itself to greater control of the genetic materials by the source country (Putterman 1996).

Phyllis Coley and Tom Kursar, researchers directing a small project also funded by the Fogarty International Centre under the Bioprospecting Opportunity Awards (BOA) programme, are exploring this material transfer agreement approach in Panama. In collaboration with the Panamanian Natural Resources agency, a Panamanian conservation organisation, and local researchers, they are developing the MTA to define the uses to which a sample may be put and minimum benefit-sharing terms associated with the transfer of samples from collection to chemical researchers. Subsequently, commercial agreements and other research collaborations on the one end, and the terms of associated benefit-sharing on the other, will involve separate but linked agreements.

The Trust Fund Mechanism

Trust funds for local conservation/development projects appear to be one of the most equitable and flexible ways of managing monetary rewards in both the near and long-term, and are part of most benefit-sharing schemes today. As with contracts, they may be designed to suit local needs and reach the appropriate parties. Trust funds also offer the opportunity to structure local award schemes to maximise conservation incentives. The Trusts associated with the ICBGs are most often disbursed by committees that represent communities and national interests (Rubin and Fish 1994, Iwu and Laird 1995). To date, several have been able to make small grants to advance sustainable development projects. In the African ICBG, these have been used for rebuilding a local clinic, purchasing tools for preparation and storage of herbal medicines in a community pharmacy, and cultivation of medicinal hedges. In the Suriname ICBG, grants have been made for tools, training and marketing for traditional non-timber forest craft products, a meeting among indigenous leaders to promote common interests, and financing shaman apprenticeships.

VI. Policy, Legislative and Administrative Context

Planning for the ICBG program began in 1991, before the Convention on Biological Diversity was signed. The policy framework from which it arose was a strong interest on the part of the funding agencies to search for new methods of promoting conservation of biodiversity, sustainable development and improved human health. There were few precedents for benefit-sharing arrangements and no known international legislation on the issue. The program goals, as well as knowledge of the discussions around the CBD helped shape the program and its approach to benefit-sharing. The Bayh-Dole Act of 1980 (through U.S. Public Law 96-517 and regulation) established that recipients of grants or contracts from the U.S. Government retain the rights to any patents that result from their work.

Each of the ICBGs has worked with the national governments of their partner countries to clarify the policy, regulatory or legislative environment in which they operate, and in several cases have functioned as important examples for what can or cannot be done.

VII. Impact on Conservation

It is still too early to know how much bioprospecting will contribute to biodiversity conservation. Clear opportunities and examples exist for providing benefits to source countries as well as indigenous and local communities in terms of health improvement, resource management capacity, and sustainable use of natural resources. The key to its success will lie in the ability to provide near and long term benefits that effect changes in the behaviour of individuals, communities and private companies, as well as natural resource policies of both developed and developing country governments. Toward this end contractual agreements for benefit sharing offer flexible, powerful instruments. They will be most successful when they can simultaneously suit local needs, maximise local strengths, and address international political and economic conditions.

Governmental and other non-profit sources of funding may continue to be important to exploit the full range of conservation and development benefit opportunities that bioprospecting offers. Non-profit funding increases stability of partnerships and stimulates a broader set of near term benefits than purely commercial relationships would likely return. Corporate research and development budgets for natural products research in the US are not likely to grow significantly in the next few years, and demands on those budgets are multiplying as conservation and development goals are linked to the research process. Private, national and multi-lateral funding agencies are currently encountering great demand for resources to finance bioprospecting projects. Given the complexities and inevitable delays in establishing equitable partnerships in this young field, one productive option for funders may be to begin with small planning grants for source country organisations. Established source country partnerships with well defined objectives and strengths may be poised to take advantage of international funding opportunities and be more attractive to private companies.

Governments of many source countries are currently defining their laws regarding international trade in genetic resources and standards for equitable benefit-sharing agreements. Some of these laws and policies may develop as multi-lateral agreements to assure consistency and minimise conflict between neighbouring states with overlapping genetic resources. Regardless of the form these take, governments that wish to develop international bioprospecting partnerships will probably be most successful when they define clear policies, relatively simple bureaucratic procedures and allow for

innovative and flexible collaborations. Legislation on equitable benefit sharing agreements that is consistent with long-range national biodiversity strategies, development needs and other biodiversity incentive measures may yield some of the most powerful conservation tools at our disposal.

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APPENDIX 1

PRINCIPLES FOR THE TREATMENT OF INTELLECTUAL PROPERTY AND THE SHARING OF BENEFITS ASSOCIATED WITH ICBG SPONSORED RESEARCH (Modified for second Request for Applications - August 15, 1997)

In developing both research plans and intellectual property agreements it is important that all involved understand the differences between patent coverage and benefit-sharing agreements. While legal protection of the right to commercialize an invention is generally accomplished through the patent system, agreements among collaborators are generally required to designate the terms of partnerships including, among other things, the licensing of an invention and the sharing of any financial benefits that accrue from it.

The conduct of ICBG sponsored research and the agreements among the collaborators must address the following principles to be eligible for funding.

a) Protection of inventions using patents or other legal mechanisms.

Non-profit organizations (including universities) and small business firms retain the rights to any patents resulting from U.S. Government contracts, grants, or Cooperative Agreements. P.L. 96-517, through regulation, extends to businesses of any size the first option to the ownership of rights to inventions made in the performance of a federally-funded contract, grant, or Cooperative Agreement. All group members, therefore, including businesses of any size, might be full partners in the research of the Group and in rights to file patents for any inventions resulting therefrom as specified in the Group's research agreement. This includes communities organized into or represented by an appropriate legal entity.

The specific intellectual property arrangements among the institutions may vary and could include joint patent ownership, exclusive licensing arrangements, etc. Valuable intellectual resources that cannot or will not be patented, such as novel assays or traditional medicinal techniques, may require alternative protection methods such as trade secrets. Applicants are encouraged to develop an arrangement that best suits the particular circumstances of their Group.

b) Clear designation of the rights and responsibilities of all partners.

i. This is principally done through the design of adequate contractual agreements. Agreements should be among all collaborating organizations, whether or not they are recipients of government funds. These may include commercial drug developers, source country and US research institutions, and indigenous and local peoples whose resources, biological or intellectual, are utilized in the research process.
ii. It is strongly recommended that all parties to agreements have separate, competent legal counsel to represent their interests.
iii. Useful contractual tools for the designation of rights and responsibilities include material transfer agreements, research and development agreements, license options agreements, know-how licenses, benefit-sharing agreements, and structured trust funds.
iv. Unless stipulated otherwise in agreements among source country institutions and their collaborators, biological samples and associated information collected under ICBG sponsored research is the property of the source country institutions. The Government retains "march-in" rights to require licensing if the inventing organization(s) fail to pursue development of the process or invention, as described in the “Terms and Conditions of Award”.

v. The ownership and compensation terms of first generation and subsequent inventions based upon a lead discovered in ICBG work should be clearly stipulated in agreements.
vi. Agreements should specify that the basic goals of the collaboration include the drug discovery, economic development, and the conservation and sustainable use of biological diversity.
vii. Agreements should also indicate how a sustainable source of materials for follow-up analysis of a lead compound will be developed, and should preferentially use the participating country and/or communities as the first source of raw or processed materials.

c) Sharing of benefits with the appropriate source country parties.

i. Equitable distribution of benefits should accrue to all those who contribute to a commercialized product, whether they are members of the consortium or not, including research institutions and local or indigenous people who provide useful traditional knowledge.
ii. Benefits should flow back to the area in which the source plant, animal or microorganism was found, in such a way that they at least indirectly promote conservation of biological diversity.
iii. The selection of beneficiaries must be justified in terms of program goals, as well as local and international laws and customs.
iv. Benefits should be structured such that they are appropriate to the needs of the communities and the resources of the other collaborators. For example, trust funds managed by a community or community-project board may be more effective in support of conservation and health or education services than cash payments to a single individual or authority. Note that direct cash compensation may even have injurious effects on non-money economies.
v. Ideally, compensation begins flowing early in the collaboration through initial payments, training, equipment or services, to provide near term conservation incentives.

d) Disclosure and consent of indigenous or other local stewards.

i. Arrangements for the use of traditional knowledge or the collection of samples from the lands of local peoples should be based upon full disclosure and informed consent of those peoples.
ii. Indigenous concepts of intellectual property should be respected. If for instance, cooperating indigenous groups, on the basis of religious or other concerns, object to specific uses, widespread dissemination or other treatments of the knowledge they provide, these concerns should be respected in the conduct of ICBG projects.
iii. The process of disclosure and informed consent should be as inclusive and formal as is possible and culturally appropriate. The best practice is the development of written agreements with a community following complete and formal presentation of the Group's goals and methods. Presentations should provide realistic descriptions of the type, amounts and probabilities of benefits as well as any costs or risks that may accrue to cooperating communities.
iv. Arrangements with individuals who cooperate or provide information should be based upon prior community - level agreements whenever possible or appropriate.

e) Information flow that balances proprietary, collaborative and public needs.

i. Agreements and research plans should anticipate the tension between the traditional scientific ethic of public access to information, including publication of results, and the understandable desire of indigenous or commercial partners for confidentiality of information with potential commercial value, pending protection through patenting or other means.

ii. Sharing of information among collaborating institutions should be as complete as possible to maximize efficiency of research and equity in partnerships while recognizing the proprietary concerns of those partners.

f) Respect for and compliance with relevant national and international laws, conventions and other standards.

i. Relevant international conventions such as the U.N. Convention on Biological Diversity and national laws regarding study, use and commercialization of chemical, biological and cultural resources should be observed rigorously in the development of agreements and the conduct of research.
ii. An essential goal of this program is to develop models for sustainable and equitable commercial use of biodiversity-rich ecosystems. As such ICBG research agreements and activities should, wherever possible, go beyond the minimum legal standards regarding international research collaborations, looking to codes of conduct and other standards for guidance.