

**FACILITATING PRIOR INFORMED
CONSENT
In the Context of Genetic Resources
and Traditional Knowledge¹**

1. Introduction

This paper traces the evolution of prior informed consent (PIC) and describes the importance of PIC to achieving the objectives of the Convention on Biological Diversity (CBD). It briefly highlights elements of current approaches to obtaining PIC from national governments and local communities, identifies limitations to obtaining PIC, and provides examples of how the Bonn Guidelines do and do not respond to these limitations. The paper does not provide a detailed analysis of all issues related to implementation of PIC, but rather highlights issues that will, hopefully, promote constructive discussions to advance progress on implementation of PIC.

2. Evolution of the Concept of Prior Informed Consent

The concept of prior informed consent originated in the medical field as a dialogue between individuals (doctor and patient) to ensure that doctors provided patients with sufficient information to allow each patient to make an informed decision regarding an important health matter.

Subsequently, PIC came to be viewed as central to securing State sovereignty rights in relations between States. Beginning in 1987, with the Cairo Guidelines and Principles for the Environmentally Sound Management of Hazardous Wastes (which later served to inform development of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal), States began to employ PIC as a tool to control the movement of potentially harmful materials into their territories from

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exporting States.² Currently, in the contexts of hazardous and toxic materials, genetically-engineered organisms, and persistent organic pollutants, States generally have a right to some form of prior informed consent before these materials are transported into the State. In the context of access to genetic resources, States have a right to prior informed consent for transport of genetic resources out of the country.

Most recently, discussions relating to prior informed consent have centered largely on the rights of indigenous peoples and other local communities to PIC in various contexts, including logging, mining, resettlement, dam building, and access to genetic resources. These communities view PIC as central to securing their rights and protecting their vital interests when these activities may affect their interests. Official interpretations of several international instruments, including the Convention on the Elimination of Racial Discrimination; the American Convention on Human Rights; the International Covenant on Economic, Social, and Cultural Rights; and the International Labor Organization Convention 169 Concerning Indigenous and Tribal Peoples in Independent Countries, indicate that prior informed consent of indigenous peoples is central to effectuating rights within these conventions, including the right to culture, the right to self-determination, and the right to property.³ Additionally, in the last few decades, PIC has been promoted by voluntary guidelines, social and environmental codes, contractual agreements, and political referendums.⁴

² The Cairo Guidelines and Principles for the Environmentally Sound Management of Hazardous Wastes, adopted by the United Nations Environment Program in 1987 first embraced PIC in the hazardous waste context.

³ For example, within the last two years, the Committee interpreting the Convention on the Elimination of Racial Discrimination issued Recommendation XXIII, which calls for all Parties to the Convention to obtain informed consent of indigenous peoples in all decisions that may concern their rights or interests. In March 2003, the Committee censured Ecuador for “falling short” of meeting PIC requirements for indigenous communities, finding that in the context of resource exploitation on traditional lands, mere consultation was insufficient. Botswana was censured the previous year for failing to ensure that prior informed consent was secured prior to resettlement of indigenous communities. Additionally, in several recent cases interpreting the American Convention on Human Rights, the Inter-American Court of Human Rights determined that an indigenous community’s right to property was violated by the failure of the State to ensure that prior informed consent had been obtained from the community prior to logging.

⁴ For example, in 2000, the World Commission on Dams issued a set of voluntary PIC guidelines recognizing the need for “all people whose rights are involved and who bear the risks” to have a role in negotiations. In 2004, the Extractive Industries Review, commissioned by the World Bank, recommended implementation of the rights of local communities to PIC as a precondition to World Bank funding of extractive industry projects.

3. Prior Informed Consent in the Context of Access to Genetic Resources

A. Rights of National Governments and Local Communities to Prior Informed Consent

Concerns exist about companies, research institutions, other entities, and individuals acquiring and using genetic resources and traditional knowledge from biodiversity-rich countries without obtaining prior informed consent and making arrangements for benefit sharing. Several cases of “biopiracy,” including cases for which patents have been obtained in “user” countries, have been documented.⁵

Discussions concerning the rights of national governments and local communities to manage access to genetic resources and associated traditional knowledge are active within the CBD, the World Intellectual Property Organization (WIPO), and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). In these fora, however, existing measures relating to these rights may conflict with one another.

The CBD embraces three main objectives: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits resulting from use of genetic resources. The ability to manage access to genetic resources is central to achieving each of these objectives.

The CBD requires that prior informed consent be obtained from contracting Parties providing access to genetic resources and that these Parties, in turn, “respect, preserve and maintain knowledge, innovations and practices of, ...communities, ...and promote their wider application with the approval and involvement of the holders of such knowledge,”⁶ The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (the Bonn Guidelines), voluntary guidelines recently adopted by the Parties to elaborate on obligations and rights of Parties with respect to genetic resources and traditional knowledge, encourage Parties

⁵ Some well-known cases of patent applications over naturally occurring genetic resources, biological discoveries or biological inventions using genetic resources being filed and, in some cases, granted include: Neem tree, turmeric, sweet berries, enola bean and the ayahuasca plant.

⁶ Article 15.5 of the CBD states, “access to genetic resources shall be subject to prior informed consent of the contracting party providing such resources, unless otherwise determined by that Party.” Article 8(j) directs States to “respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of

to ensure that prior informed consent is obtained from communities for access to genetic resources and associated traditional knowledge.⁷

Neither WIPO nor TRIPS recognize the rights of either national governments or local communities to prior informed consent. Current interpretations of the TRIPS Agreement suggest the Agreement may be violated by requirements imposed by governments on those seeking a patent to disclose the origin of the genetic resource and provide evidence of PIC before a patent is issued.⁸ Yet some experts have proposed interpretations of TRIPS provisions that would provide the space for national governments to require evidence of PIC in a manner that is consistent with TRIPS.⁹ Some countries advocate recognition of these requirements.¹⁰ The failure of WIPO and TRIPS to require evidence of PIC and disclosure of origin could undermine the PIC requirements in other instruments.

B. Elements of Prior Informed Consent Related to Access to Genetic Resources

The application of PIC to access to genetic resources is distinct from its application in the hazardous/toxic wastes or genetically-engineered organism contexts. Rather than trying to prevent adverse impacts of movement of materials into a country, PIC for access to genetic resources focuses on preventing exploitation and movement out

biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge...”

⁷ COP Decision VI/24. See UNEP/CBD/COP/6/6. For example, Paragraph 26 of the Guidelines notes that the “consent of stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law, should also be obtained.”

⁸ These interpretations suggest that the requirements would violate TRIPS Article 27.1, which establishes the substantive conditions of patentability, Article 29, which establishes the formal conditions for granting a patent, and Article 62, which establishes the proceedings for patent acquisition.

⁹ See, for example, Pires de Carvalho, Nuno (2000), *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution*, www.law.wustl.edu/Journal/2/p371carvalho.pdf, and Vivas, David, (2001), *Strategies and Experiences to Implement Legal Origin Provisions on Genetic Resources and Traditional Knowledge*, on file at the Center for International Environmental Law, Washington, DC.

¹⁰ A recent proposal by Brazil, on behalf of a number of other countries, may ensure that this process is recognized as an important aspect of patent applications. The relevant portion of the June 2003 submission reads: “An applicant for a patent relating to biological materials or to traditional knowledge should provide, as a condition to acquiring patent rights: (i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention; (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes; and (iii) evidence of fair and equitable benefit sharing under the national regime of the country of origin.”

of the country of potentially beneficial materials, as well as ensuring that benefits derived from use of the materials accrue to the provider country. The country facing potential harm and having the right to prior informed consent is the country out of which substances may be transported.

Such distinctions necessitate different approaches to implementing prior informed consent for States. Nevertheless, activities to elaborate PIC requirements in the hazardous wastes or genetically-engineered organism contexts can inform development of the rights of national governments to PIC in the genetic resources context. Information concerning what PIC means, when information should be provided, how responsibilities for developing and providing information are allocated, and how due process concerns are addressed may be used to shape approaches to implementing the rights of national governments to PIC in the genetic resources context.

Additionally, the Bonn Guidelines provide some guidance on possible elements of PIC procedures, including: consent of the national authority and indigenous and local communities; mechanisms for the involvement of stakeholders; reasonable timing and deadlines; specification of the type of uses; direct linkage with mutually agreed terms; detailed procedures for obtaining consent; and a description of the general process for access.

For local communities, PIC for genetic resources and PIC in other contexts basically involve the same rights; i.e., the rights of local communities to participate in management of resources on lands they occupy. Nevertheless, differences exist between these contexts that could influence various approaches to PIC. These include, for example, differences in the abilities of communities to be aware of and physically control the activities (i.e., use of genetic resources may be much more difficult to detect and prevent than the other activities), and differences in the complexities of legal structures that govern use of the resources (i.e., intellectual property laws that may govern use of certain genetic resources/traditional knowledge may be more complex and rely more on foreign laws than laws that govern use of other resources).

While the definition of PIC for local communities varies by context, it is generally described as a consultative process whereby the potentially affected community engages in an open dialogue with individuals interested in conducting activities in the area(s)

occupied or traditionally used by the affected community. Discussions should occur prior to, and continue throughout, the time that the activity is conducted. Although PIC procedures may have culturally specific variations, a number of commonalities or “best practices” can be identified from the genetic resources, traditional knowledge, and extractive industries fields.¹¹ Many communities have articulated these procedures.

Some ideas include:

1. The person seeking access must obtain consent from every affected community in the traditionally recognized manner (i.e., according to the customary laws and practices of the concerned community).
2. Before seeking consent, the person seeking access should distribute and hold community discussions regarding all information relevant to the community in a culturally appropriate manner (i.e., both written and oral, in a language understandable to the local community).
3. Relevant information includes:
 - a. disclosure of proposed objectives, i.e., what one hopes to obtain and the foreseeable consequences of the research, including effects (social, economic, environmental) on the local community, the potential for commercial applications, the quantity of the resource sought, the duration of the activity, and the specific geographical prospecting area;
 - b. disclosure of legal and financial information, including any affiliations, where money will be coming from, who is in charge, and what/how benefits will be shared with the local community;
 - c. disclosure of any impact statements (environmental and other) concerning the local activity;
 - d. disclosure of previous or related activities undertaken by the person seeking access (and by affiliated organizations), including a description of any previous consent plans, how the objective was met, any effects on the community, etc.

¹¹ Laird, Sarah, ed., (2001), Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice, and the World Commission on Dams Guidelines, found in *Dams and Development, a New Framework for Decision*, at <http://www.dams.org/report/> (last visited, May 19, 2004).

4. The community at large should be notified of the proposed activities, and informed decisions should be made in a traditionally recognized, culturally appropriate manner. Discussions should be inclusive so that all affected local populations have an opportunity to participate actively.
5. Consent should be part of an ongoing process conducted throughout the planning, design, implementation, and evaluation of the project. The process must include a substantive dialogue through which the community may choose to give or not to give consent.
6. Community leaders may revoke consent for legitimate, good faith reasons.
7. Consent should include agreement of how legal questions will be resolved, such as issues of jurisdiction and enforcement.

C. Limitations to Obtaining Prior Informed Consent

Interrelated legal, political, and economic barriers exist to obtaining prior informed consent. They include, for example, a lack of relevant or effective laws and regulations, burdensome procedures and transaction costs, lack of articulated community procedures, a lack of desire of many communities and some governments to facilitate access, and, perhaps, unrealistic expectations.

Despite the rights of national governments to manage access to genetic resources and to require prior informed consent, many have not acted to adopt or implement national access laws and regulations. Many of the following concerns may prompt this government inaction:

(i) Lack of certainty about approaches to institutional structures, processes, and information

Many governments lack certainty about the institutional structures, processes, and information needed to achieve the dual objectives of facilitating access while ensuring benefit sharing. Uncertainty exists, for example, about how to address the information needed to make informed decisions, and how, when, and from whom consent should be obtained. Additionally, questions remain about what mechanisms are available for enforcement of PIC requirements and how effective these mechanisms are.

(ii) *Unwillingness to address divisive issues*

Some governments are unwilling to address issues when different groups call for actions that appear antithetical to one another. In many situations, for example, one faction of the population may want to work within the existing intellectual property system, while another (frequently including local communities) may demand that genetic resources and traditional knowledge not be subject to this system.

(iii) *Lack of certainty about how to address community rights*

For some governments, uncertainties exist about how to address local community rights to prior informed consent. Issues raised include those related to what prior informed consent means in the context of access to genetic resources. Do local communities have the absolute right to say no in every situation? Can this right ever be qualified by a larger public interest, and, if so, under what circumstances and how should this larger public interest be identified?

(iv) *Lack of security in benefits*

Governments may be uncertain about costs to them and benefits to be derived from providing access to genetic resources, particularly when patents will be sought. Benefits for genetic resources may be less obvious or quantifiable than benefits in other resource use contexts, and the issues related to determining these benefits are more complex. Will technology be transferred? How will a patent obtained in another country limit the State's ability to benefit from these genetic resources? Intellectual property issues are very technical and involve legal systems in other countries – systems over which relatively little control exists.

Even when laws and regulations do exist, barriers to obtaining PIC sometimes persist. These barriers include:

(v) *Inadequacy of laws and regulations*

Some laws and regulations regulating access respond inadequately to issues related to implementation of PIC, providing insufficient detail and direction to governments and potential participants.

(vi) *Lack of articulated community procedures*

While most communities have well-established decision-making processes, some communities have not articulated in writing a process by which consent may be obtained from them by outside groups. Articulating these procedures often requires additional financial, personnel, and technical resources.

(vii) *Burdensome procedures and excessive costs*

Many entities seeking access to genetic resources and traditional knowledge believe that laws, regulations, and procedures? particularly those relating to PIC from local communities? impose unnecessary barriers to access that generate excessive costs. Many scientific institutions, in particular, believe that laws and regulations are too complicated and transaction costs too high, given that their research activities likely pose relatively modest adverse impacts to biodiversity and that their proposed uses are almost always non-commercial. These institutions believe laws and regulations should distinguish between uses and treat them differently.

(viii) *Lack of desire to facilitate access*

Many local communities simply have no interest in facilitating greater access to genetic resources and traditional knowledge, particularly when a patent might be sought for use of the resource. Because these resources may serve vital spiritual, cultural, and sustenance needs, the overriding interest of the community may be to protect the resources and ensure continued community access to them. Additionally, many communities worry that efforts to facilitate access will not adequately consider their interests nor respect their rights.

(ix) *Unrealistic expectations*

Sometimes those seeking access to genetic resources and traditional knowledge expect that processes by which consent is obtained will be modeled after “northern” consent processes. These expectations are likely to be unrealistic, particularly when dealing with indigenous communities, given the cultural and value differences between those providing and those using resources. Sometimes governments providing resources expect that fortunes will be made by those seeking to use the resources. Accordingly, they may excessively regulate access to the resources.

D. Some Examples of How the Bonn Guidelines Respond to Limitations

The Bonn Guidelines that address issues related to prior informed consent provide governments with a set of options for responding to many of the limitations to obtaining consent. These include provisions that:

(i) Address institution, process, and information issues

The guidelines address government uncertainties about how to structure institutions and processes to satisfy queries about how PIC can be obtained. The guidelines suggest that a national focal point be established to respond to queries about how PIC can be acquired, and they embrace recognition of a single national authority from which PIC can be obtained. Furthermore, they identify and describe possible elements of a prior informed consent system.

(ii) Address some benefit and enforcement issues

The guidelines respond to limitations related to trust and enforcement issues by identifying and promoting measures that “user” countries can adopt to help secure for provider States sovereignty over their resources as well as the rights of their local communities. The guidelines raise awareness about the significance of requirements for disclosure of origin and evidence of prior informed consent, which may provide some assurance to governments that their concerns are being heard. Additionally, the guidelines require users to ensure “fair and equitable” sharing of benefits, including technology transfer.

(iii) Describe and encourage approaches to reducing regulatory obstacles and costs

Several provisions, including, for example, those relating to the “basic principles” of a PIC system, attempt to promote reduction in costs and regulatory obstacles. The guidelines note, for example, that “access to genetic resources should be facilitated at minimum cost.”

(iv) Respond to some of the concerns of local communities

The guidelines respond to some concerns of indigenous and local communities by promoting respect for their customs, traditions, and values as well as encouraging support for capacity building.

E. Some Outstanding Limitations

Despite the potential of the Bonn Guidelines to respond to limitations to obtaining prior informed consent, many issues remain outstanding. Some of these include:

(i) *Addressing Indigenous Issues*

Despite provisions in the Guidelines that support local communities, many indigenous representatives have significant concerns about the phrasing of the Guidelines and how the Guidelines might adversely impact their rights. Several limitations to obtaining consent are rooted in the lack of certainty for indigenous peoples. Indigenous peoples are concerned that the phrasing, “the consent of relevant stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law, should also be obtained,” fails to recognize that their rights to prior informed consent are recognized by international law and are not derived from national recognition of these rights. Also, the term “stakeholders” fails to recognize that indigenous peoples are “rights holders.”

(ii) *Recognizing Different Uses*

Scientific institutions and other users suggest that PIC provisions of the Guidelines do not adequately reflect differences in uses of the resources. As a result, requirements imposed on institutions seeking non-commercial uses of resources may be disproportionate to potential adverse impacts.

(iii) *Understanding Implementation Difficulties and the Need for User Measures*

Many collectors/users of genetic resources believe that the guidelines do not evidence an understanding of difficulties associated with implementing user measures. Users point to the difficulties of disclosing origin or providing evidence of PIC when the user has obtained the resource from someone else or has had the resource for a long period of time in a collection. Furthermore, many users believe that the guidelines fail to capture the essence of the “biopiracy” problem, which they assert is more acute regarding seeds and animals for which patents will not be sought, than it is for genetic resources. Additionally, these users suggest that the focus on disclosure of origin is misplaced, because most patent applications already disclose origin.

(iv) *Enforcing PIC requirements*

Guidelines provide little guidance on how enforcement mechanisms and measures might be structured, and, by virtue of being voluntary, do not provide any mechanism pursuant to which PIC requirements could be enforced.

4. Questions Raised Concerning Implementation of Prior Informed Consent

The following questions are intended to facilitate discussion to (1) promote a better understanding of limitations within a specific country to implementation of prior informed consent for use of genetic resources or traditional knowledge, (2) stimulate thinking on ways to address these limitations, (3) identify various possible approaches of stakeholders within a country to facilitating prior informed consent, and (4) develop a better understanding of the role that IUCN and others can play to facilitate implementation of prior informed consent of governments and local communities.

Questions concerning implementation of prior informed consent:

- (1) How significant are opportunities for your country or indigenous and other local communities within your country to obtain benefits from sustainable use of genetic resources and traditional knowledge?
- (2) Do you perceive that the ability to capitalize on these opportunities is hindered by lack of certainty for those seeking to use the genetic resources or traditional knowledge about how to obtain authorization for use of these resources? Are opportunities limited by user perceptions that costs/time to obtain authorization are too significant?
- (3) Are inadequate or non-existent laws in your country a result of government unwillingness to address divisive issues? Are they a result of lack of information about how to address institutional structures and processes? Is there a concern that facilitating access will impair benefits to governments? Communities? Is hesitancy to enact laws a result of concern that laws and regulations would be difficult to enforce?
- (4) Do you perceive that potential users can be distinguished on the basis of how genetic resources or traditional knowledge will be used, potential financial benefits that might accrue to each user, and/or potential restrictions that each user might impose on use by provider governments/local communities? Do you believe that these distinctions are significant enough to warrant different degrees/types of regulation?
- (5) Are indigenous and other local communities working on the protection, promotion, and preservation of biological resources and traditional knowledge informed of the opportunities as well as the risks posed by intellectual property? Do they receive legal and technical support to make informed decisions and develop realistic expectations of the results of their options? Are they made aware of the bigger questions surrounding intellectual property and development?

(6) How prevalent is unauthorized use of genetic resources/traditional knowledge with respect to resources from your country? Is it more prevalent with respect to genetic resources for which patents are sought, or more prevalent with respect to biological resources for which patents are not sought?

(7) Do you believe that specific incidents of unauthorized patenting of genetic resources or traditional knowledge would be prevented by a requirement imposed by the “user” country that origin of genetic resources/traditional knowledge be disclosed in a patent application? Would such incidents be prevented by a requirement that evidence of prior informed consent be provided?

(8) Does the government take consistent positions taken in different international fora with regards to issues linked to access and benefit sharing, i.e., does the government take a consistent position on “user measures” – requirements by user countries that those seeking patents provide evidence of prior informed consent and disclosure of origin? Are there informal or formal structures for information exchange between the different government ministries in charge? Are the Bonn Guidelines being used to inform efforts to address access and benefit sharing issues? Are social, environmental, and indigenous authorities part of trade and intellectual property delegations?

(9) Do groups promoting PIC and other measures for access and benefit sharing have fluid communication with the government’s intellectual property offices and other negotiators of international intellectual property standards? Are they able to inform the government’s national and international intellectual property strategies and policies?

Questions concerning resources for moving forward:

(10) Would development of laws/regulations benefit from more information concerning, for example, the potential for benefits associated with facilitating access to prior informed consent, the potential for biopiracy, the potential costs to providing access for each use? Other information?

(11) Would case studies/examples of indigenous peoples and other local community approaches to PIC procedures or government approaches to PIC be useful?

(12) Would other technical resources, e.g. legal resources, be useful or necessary for government and/or community efforts to draft laws, regulations, procedures, or otherwise ensure implementation of prior informed consent? Are financial resources needed to accomplish these tasks?

(13) Would greater dialogue among communities and governments be useful? Among governments? Among institutions within government?