You Say Yes, I Say No; Defining Community Prior Informed Consent under the Convention on Biological Diversity

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CONTENTS

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I. INTRODUCTION

The Convention on Biological Diversity (CBD) has reinvigorated long-standing tensions between local communities and national governments. Specifically, the focus on "fair and equitable sharing"[1] of benefits has fueled a complex power struggle between traditional communities (particularly those with age-old knowledge of medicinal plants) and national governments (especially those that see biodiversity as a promising means to needed revenue). Many indigenous groups and non-governmental organizations (NGOs) argue that in order for the CBD's objective of fair and equitable sharing of benefits to have any meaning, the duty set out in Article 8 of the Convention to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities"[2] should qualify state sovereignty, particularly over genetic resources and traditional knowledge.[3]

Given that indigenous peoples represent ninety-five percent of the world's cultural diversity and generally inhabit areas of the planet that possess the greatest biological diversity,[4] the Convention recognizes the vital need to involve indigenous and traditional communities in any attempt to conserve and sustainably use the world's biodiversity.[5] In fact, many scholars have argued that

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1. United Nations Conference on Environment and Development: Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818, 823 (entered into force Dec. 29, 1993) [hereinafter Convention on Biological Diversity].

2. *Id.* at art. 8(j).

3. *See* Rosemary J. Coombe, *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conversation of Biodiversity*, 6 IND. J. GLOBAL LEGAL STUD. 59, 102 (1998); R. V. Anuradha, *In Search of Knowledge and Resources: Who Sows, Who Reaps?*, 6 REV. OF EUR. COMM. & INT'L ENVTL. L. 263, 263 (1997).

4. *Participation and Prior Informed Consent of Indigenous Peoples in the Implementation of the Convention on Biological Diversity*, Report on the III International Indigenous Forum on Biodiversity (Bratislava, Slovakia, 4-6 May, 1998) and the Fourth Conference of the Parties of the Convention on Biological Diversity (4-15 May, 1998) (Onel Masardule Arias, et al. eds., AECI and WATTU Accion Indigena), *available at* http://trade-info.cec.eu.int/civil_soc/documents/meeting/me-4-trips_c01.pdf (last visited Sept. 10, 2003).

5. "*Recognizing* the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge innovations and practices relevant to the conservation of biological diversity and the sustainable us of its components." Convention on Biological Diversity, *supra* note 1, at pmbl.; *see id.* art. 8(j).

indigenous and traditional communities are responsible for much of the cultivation and preservation of biological diversity that the Convention seeks to protect. As one scholar noted, "[t]he juxtaposition of biological diversity and cultural diversity among local communities is not a coincidence: the latter has arisen as a human adaptation to the former and has in turn nurtured it."[6]

The point of greatest controversy within the CBD context has surrounded traditional communities' knowledge of medicinal plants and cultivation of specialized plant varieties. These resources and knowledge are highly valuable to pharmaceutical developers, cosmetic companies, and other corporate and academic interests.[7] Additionally, medicinal plants constitute the primary form of health care for approximately eighty percent of the world.[8] Thus, local and indigenous communities provide valuable knowledge and resources for a diverse group of needs, from today's local community members to future consumers of synthetic drugs. However, companies are granted valuable patents developed from such knowledge or plant varieties, while traditional communities rarely reap any tangible benefits and have no control over the use of such products. While the CBD consistently emphasizes the need to involve traditional communities, its language strongly asserts national sovereignty over genetic resources, while providing only vague recognition of local entitlements.

A. LOCAL AND INDIGENOUS COMMUNITY CONSENT REQUIREMENTS IN THE CBD

Despite its lofty goals, the Convention's language provides little to indigenous and traditional communities when trying to assert their rights over genetic resources and traditional knowledge within the national context. Virtually all of the language referring to the rights of indigenous people to control their genetic resources and traditional knowledge is qualified by phrases such as "subject to national legislation" or weak verbs such as "endeavor to" or "encourage."[9]

The specific articles of the CBD give some rights to local communities, but only explicitly recognize power to control access to traditional knowledge, rather than genetic resources. Article 15(5) of the Convention on Biological Diversity states that "access to genetic resources shall be subject to prior informed consent of the contracting party providing such resources, unless otherwise determined by that Party."[10] This statement does not specifically refer to local and indigenous communities. However, Article 8(j) requires each party to:

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6. Anuradha, *supra* note 3.

7. The U.S. dietary supplement market for herbals or botanicals was nearly U.S. $4 billion in 1997, with a U.S. $5 billion 1998 projection and compounded yearly growth rate of fifteen to twenty-five percent. Katy Moran, *Bioprospecting: Lessons from Benefit-Sharing Experiences*, 2 INT. J. BIOTECHNOLOGY 132, 141 (2000).

8. *Id.* Additionally, seventy-four percent of the active compounds isolated from higher plants and used in Western medicine have the same therapeutic use as in native societies. *Id.* at 133.

9. *See* Convention on Biological Diversity, *supra* note 1, at arts. 8(i) & (j).

10. *Id.* at art. 15. The term "Contracting Party" refers to sovereign nations party to the CBD.

> [s]ubject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application *with the approval and involvement of the holders of such knowledge*, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.[11]

Furthermore, Article 10(c) requires that each party "protect and encourage customary use of biological resources in accordance with traditional cultural practices and that are compatible with conservation or sustainable use requirements."[12] Together, these clauses suggest that any interested party must obtain consent from the competent government authority to obtain access to genetic resources. They also suggest that the relevant local communities must be consulted and involved in order to gain access to associated traditional knowledge in any country party to the CBD.

The Conference of the Parties (COP) to the CBD has adopted General Principles clarifying that "[a]ccess to traditional knowledge, innovations and practices of indigenous and local communities should be subject to prior informed consent or prior informed approval from the holders of such knowledge, innovations and practices."[13] Therefore, States party to the CBD should recognize community rights over traditional knowledge and develop policies elaborating the prior informed consent process.[14]

Community rights over genetic resources themselves have been more controversial. The balance between community and State control of genetic resources seems to rest in the State's hands because of the consistent emphasis within the CBD on national sovereignty. Indigenous and local communities have argued that human rights, cultural rights, and indigenous rights should qualify national sovereignty.[15] But some national governments, such as Brazil, have been resistant to relinquish any control to local communities. Brazil has gone so far as to propose a constitutional amendment to make all genetic resources part of the national heritage.[16] Today these struggles are far from resolved.

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11. *Id.* (emphasis added).

12. *Id.*

13. Decision V/16 of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity, Article 8(j) and Related Provisions, Annex: Programme of Work, I. General Principles, at 139-42, UNEP, U.N. Doc. UNEP/CBD/COP/5/23 (2000), *available at* http://www.biodiv.org/decisions/default.asp?lg=0&dec=V/16.

14. Preston Hardison, *Prior Informed Consent (PIC) Prior Informed Approval (PIA) Part I.*, IBIN.NET No. 15 (Canadian Indigenous Caucus on the Convention On Biological Diversity Quebec, Canada), Oct. 2000.

15. *See id.* For a detailed discussion of Prior Informed Consent as a human right, *see* James S. Anaya & Robert A. Williams, Jr., *The Protection of Indigenous Peoples' Rights Over Lands and Natural Resources Under the Inter-American Human Rights System*, 14 HARV. HUM. RTS. J. 33 (2001).

16. *See* Cristiane Derani, *Patrimônio genético e conhecimento tradicional associado: considerações jurídicas sobre seu acesso*, *in* O DIREITO PARA O BRASIL SOCIOAMBIENTAL 145 (Sergio Antonio Fabris ed., 2002).

Many scholars and NGOs have argued that the distinction between rights to control genetic resources and traditional knowledge is insignificant in most cases because "the knowledge of these local communities is intrinsically linked to the resources itself."[17] Professor Coombe has argued that "[r]esources . . . cannot be appropriated without the concomitant appropriation of knowledge. Thus, access to resources should not be addressed except with regard to the indigenous knowledge concerns addressed in Article 8(j)."[18] Although the COP has acknowledged that access to genetic resources is closely tied to the concerns of Article 8(j), it is unclear what such ties mean in practice.[19]

B. NATIONAL ACCESS LAWS IMPLEMENTING THE CBD

Now that the CBD has been almost universally ratified,[20] the power struggle between traditional communities and national governments will be fought and determined through the elaboration and implementation of national access legislation. Legislative bodies and administrative agencies throughout the world are striving to design laws or rules that will: (1) encourage valuation of traditional knowledge and genetic resources; (2) recognize the contribution of local communities in preserving genetic resources and developing traditional knowledge associated with it; and (3) affirm local and national participation in decision-making regarding the access and use of both genetic resources and traditional knowledge. However, extreme tensions between protection, participation, and access make this balance precarious. Many nations have already passed broadly worded laws governing access to genetic resources and traditional knowledge,[21] but few have developed any regulatory procedures or enforcement mechanisms.[22]

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17. Anuradha, *supra* note 3.

18. Coombe, *supra* note 3.

19. *See id.* at 102–03.

20. One hundred eighty-seven countries are now party to the Convention. Notably, the United States has signed, but not ratified, the Convention. For a country-by-country list, *see* Parties to the Convention on Biological Diversity, *at* http://www.biodiv.org/world/parties.asp (last visited May 14, 2003).

21.

> As of the beginning of 2000, some 42 countries have introduced access and benefit sharing regulations or have laws under development. Regional frameworks, which respond to the occurrence of biodiversity regionally, are also under consideration in the five States of the Andean Commission, the Association of South East Asian Nations (ASEAN), the Organization of African Unity (OAU), and the South Pacific Regional Environment Programme (SPREP).

Moran, *supra* note 7, at 133.

22. *See* Genetic Resources Action International, *Biodiversity Rights Legislation: Asia & Pacific*, *at* http://www.grain.org/brl/region-asia-brl-en.cfm (last visited June 1, 2003); International Environmental Law Project, *Access to Genetic Resources*, *at* http://www.lclark.edu/org/ielp/genetic.html (last visited June 1, 2003). Countries with particularly elaborate laws regarding implementation and enforcement of Prior Informed Consent include the Philippines, Bangladesh, and Peru. *See id.*

II. THE BENEFITS AND CHALLENGES OF PRIOR INFORMED CONSENT

A. THE IMPORTANCE OF PRIOR INFORMED CONSENT

For traditional communities, the fundamental mechanism for participation and self-determination within access legislation is Prior Informed Consent (PIC).[23] The Working Group on Article 8(j) has emphasized the importance of formal regulation, or officially endorsed protocols specifying the procedures for acquiring PIC from traditional knowledge-holders, to accomplish the goals of Article 8(j), namely to allow for effective community involvement in decision-making regarding the use of traditional knowledge.[24] In most national legislation specifically governing access to traditional knowledge and/or genetic resources, the PIC of indigenous communities is required before access can be granted to genetic resources and traditional knowledge.[25] However, definitions of PIC remain

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23. Other relevant international agreements and declarations directly or indirectly requiring PIC include The Convention Concerning the Protection of the World Cultural and Natural Heritage, Nov. 17, 1972, 1037 U.N.T.S. 51, (the UNESCO Heritage Convention);UNESCO, The Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property, Nov. 14, 1970, art. 4, 823 U.N.T.S. 231; Convention concerning Indigenous and Tribal Peoples in Independent Countries (ILO No. 169), 72 ILO Official Bull. 59, *entered into force* Sept. 5, 1991; FAO Resolution 4/89, International Undertaking on Plant Genetic Resources, Annex I, (1989); The United Nations Convention to Combat Desertification in Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa, July 4, 1994, 33 I.L.M. 1332 (the UNCCD); Draft United Nations Declaration on the Rights of Indigenous Peoples, U.N. Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, 46th Sess., art.7, U.N. Doc. E/CN.4/Sub.2/1994/30 (1994), reprinted in 34 I.L.M. 541; and United Nations Conference on Environment and Development (UNCED), Agenda 21: Programme of Action for Sustainable Development, in Annex II to the Report of the United Nations Conference on Environmental Development, art.4 (Rio de Janeiro, June 3-14, 1992). All of these agreements infer and/or affirm the right of indigenous communities to control access to and use of the resources and associated knowledge within their territories.

Furthermore, the following Statements and Declarations of Indigenous Peoples demand PIC before accessing genetic resources or traditional knowledge within indigenous land: Declaration of Principles of the World Council of Indigenous Peoples, September 28-30, 1984; Kari-Oca Declaration and the Indigenous Peoples' Earth Charter, May 30, 1992; Charter of the Indigenous and Tribal Peoples of the Tropical Forests (IAIP Charter), Penang, Malaysia, February 15, 1992; U.N. Draft Declaration on the Rights of Indigenous Peoples, U.N. Doc. E/CN.4/Sub2/1993/29/Annex I, Aug. 23, 1993, 34 I.L.M. 541; Final Statement from the UNDP Consultation on Indigenous Peoples' Knowledge (Sabah Declaration) (1995), *available at* http://users.ox.ac.uk/~wgtrr/sabah.htm (last visited June 1, 2003); International Alliance of Indigenous Tribal peoples of the Tropical Forests: The Biodiversity Convention – the Concerns of indigenous Peoples (1995), *available at* http://iaip.gn.apc.org/IFB/cbd-ip~1.htm; Results of the International Meeting of Indigenous and Other Forest-Dependant Peoples on the Management, Conservation and Sustainable Development of All Types of Forests: a Contribution to the Intergovernmental panel on Forests ('Leticia Statement') (1996), *available at* http://iaip.gn.apc.org/let/report.htm (last visited June 1, 2003); Second International Indigenous Forum on Biodiversity: Submission to the Workshop on Traditional Knowledge and Biological Diversity (1997), *available at* http://csf.colorado.edu/mail/elan/dec97/0022.html (last visited June 1, 2003); Carta de São Luis do Maranhão: Indigenous Healer Representatives of Brazil. (December 6, 2002).

24. Convention on Biological Diversity Working Group on Article 8(j), *Meeting Docs: Participatory Mechanisms for Indigenous and Local Communities,* ¶11 UNEP/CBD WG8J/2/4 (Nov. 27, 2001) [hereinafter Meeting Docs: Participatory Mechanisms].

25. PIC of local and indigenous communities is required in Andean Pact countries, ASEAN model legislation, Bangladesh, Cameroon, Costa Rica, Fiji, India, OAU model legislation, and the Philippines. *See*

vague, and few attempts have been made by governments to elaborate PIC in the context of traditional communities.[26]

This article examines PIC as a mechanism for insuring community involvement, participation, decision-making, and self-determination. It proposes a number of potential requirements for protocols or regulations of prior informed consent and examines the policy considerations surrounding these alternatives. This article also addresses the potential role of governments and the remaining challenges to implementation of an effective PIC policy. The information provided below should inform communities, institutions, and governments in designing their own guidelines under the CBD.

B. CHALLENGES TO THE ACHIEVEMENT OF FAIR AND EQUITABLE AGREEMENTS REGARDING ACCESS TO TRADITIONAL KNOWLEDGE AND GENETIC RESOURCES

Before delving into the specific aspects of PIC, it is important to keep in mind the challenges to achieving truly fair and equitable agreements with traditional communities. The background laws, customs, and power dynamics between states and traditional communities can create conditions that inhibit effective negotiation. For example, the wide variation in values, beliefs, and ownership laws between and within communities can make a single PIC system simultaneously under- and over-protective. Additionally, organization within and between communities may be difficult for outsiders to decipher and utilize. Moreover, political and social rights of traditional communities may not be adequately protected, creating inadequate conditions for equitable negotiations. Communities may not have the capacity to analyze the proposals being offered, and cultural practices of information sharing can compromise community con-

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supra, note 22 (providing sources for all texts of relevant national PIC legislations). Brazil requires only prior authorization, although it is unclear how much this will differ in practice from the informational requirements under a PIC regime. Medida Provisória No. 2.186-16, Aug. 24, 2001 (Braz.). Within national legislation, approaches to PIC vary from vague declarations to refined prescriptive procedures. The relationship between the government and local communities also varies from extremely interventionist to allowing significant local autonomy.

In addition to national access legislations, many countries have been pressuring international organizations, such as the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO) and the Convention of Farmers and Breeders, to require proof of PIC before intellectual property protection can be granted. *See TRIPS Council Split Over Role of Intellectual Property to Prevent 'Biopiracy,'* BRIDGES TRADE BIORES (The World Conservation Union), July 11, 2002, *available at* http://www.ictsd.org/biores/02-07-11/story1.htm (last visited on Sept. 9, 2003) (explaining various efforts to utilize inter-governmental organizations to strengthen CBD PIC requirements, and including links to texts of specific proposals that have been submitted).

26. For example, Costa Rica's Biodiversity Law No.7788 (1998) defines PIC as "[p]rocedure through which the State, private owners or the local or indigenous communities, as the case may be, properly supplied with all the required information, allow access to their biological resources or to intangible components associated to them, under mutually agreed conditions." The law does not specify specific requirements for indigenous communities, but does foresee determination of a *sui generis* system to be determined in the future.

trol. Finally, lack of national recognition of community status or land ownership can undermine the purpose or effectiveness of community rights to begin with. In the following section each of these challenges are explored in more detail.

1. Community Diversity

There is tremendous diversity both within and between traditional communities. People that share the same knowledge or resources may have varying values and belief structures. Thus, it is difficult to design a rule that will be workable for every community and every issue. For example, some communities may be extremely comfortable with western business traditions and transactions and would like to be able to freely contract with institutions for use of their knowledge or resources. Any government restriction on their ability to contract may be seen as paternalistic or as inhibiting economic development. On the other hand, many communities may not be familiar with non-indigenous languages, much less complex legal and business concepts such as intellectual property rights and royalty agreements. These latter types of communities may need more protection from exploitation and might require outside advisors and capacity-building programs.

Additionally, some knowledge or resources may be individually or family "owned" within a community, and therefore it may be improper to require the consent of the entire community. Indeed, in many cases, only a segment of society may hold certain kinds of knowledge. For example, women may hold certain kinds of knowledge regarding childbirth. Should only the women in a community be given power over decision-making regarding access to and use of such knowledge? Should the entire community be involved? Determining the point at which knowledge or resources are traditionally communally "owned" is difficult and can lead to corruption and internal power struggles.

2. Community Organization

Unlike countries, most communities do not have a secretariat set up to receive and disseminate information. In many communities, no single body clearly represents the community for issues regarding use of traditional knowledge and genetic resources. There may be more than one body that must give consent, or there may be conflicting bodies vying for community legitimacy. This is a particular problem for issues surrounding outside access to traditional knowledge and genetic resources since often there are different bodies for spiritual and political issues, both of which may claim power over such decisions. Additionally, bodies set up through government agencies for this purpose may not be perceived as legitimate representatives of the community. Thus, it is important to recognize and involve customary decision-making bodies, and to be as inclusive as possible to avoid possible conflicts.

Furthermore, communities that may not formally communicate or make decisions together often share knowledge and resources.[27] An appropriate representative organization may be lacking, or communities who share local medicinal knowledge may each have individual, and at times rivalrous, representatives.[28] Thus, a lack of formal inter-community organization may complicate meaningful and effective negotiations.

3. Power Relationships

In nations with long histories of oppression and distrust between indigenous people and outside institutions, inherent power dynamics make freely given consent impossible in practice. Such power dynamics are worsened by the intimidation felt by those with little education in western business transactions and legal regimes, as well as the disadvantage that may be felt when negotiating in a non-native language. Worldwide, there are more than 300 million indigenous peoples, most of whom are marginalized from state governments.[29] Thus, it may be impossible to design effective PIC without confronting the social and political rights of traditional communities more generally.[30]

4. Expertise, Information, Education

Power dynamics aside, communities must receive and analyze a wealth of complex information in order to make an "informed" decision. Few communities have the necessary legal and business expertise readily available within the

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27. For example, in the case of the agreement between the Craô and the Federal University of São Paulo, only three (out of a total of seventeen) individual tribes were consulted and included in the contract. The remaining fourteen tribes later sued the institution for twenty-five million Reais (approximately nine million U.S. dollars at the time the suit was filed) for using the tribes' traditional knowledge without their consent. According to a story in the newspaper Folha de São Paulo, the university was involved in a project to study certain medicinal plants used by the tribe and develop medicines that would result in royalties for the tribes. However, an internal dispute and the lack of clear authority for the project by the government's Federal Indian Agency led to complaints by a number of the tribes alleging biopiracy. Reinaldo José Lopes, *Associação da etnia craô quer taxa pelo uso de conhecimento tradicional feito por cientistas de São Paulo; Tribo Quer R$25 mi por ervas medicinais* FOLHA DE SAO PAULO, June 19, 2002, at A14.

28. *See* Rachel Wynberg, *Traditional Healers and Biodiversity Prospecting in South Africa: Overcoming Constraints to Meaningful Benefit Sharing*, *in* BIODIVERSITY AND TRADITIONAL KNOWLEDGE; EQUITABLE PARTNERSHIPS IN PRACTICE 217-18 (Sarah A. Laird. ed., 2002).

29. *See* U.N. Office of the High Commissioner for Human Rights, *Fact Sheet No. 9 (Rev. 1) The Rights of Indigenous Peoples*, Introduction: The permanent forum on indigenous peoples, *available at* http://www.unhchr.ch/html/menu6/2/fs9.htm.

30. *See* David Mosse, *The Social Constructions of 'People's Knowledge' in Participatory Rural Development*, *in* ASSESSING PARTICIPATION; A DEBATE FROM SOUTH ASIA 135-180 (Sunil Bastian et al. eds., Konark Publishers, PVT Ltd. 1996) (deconstructing the complex power relationships in local community participation in development projects, particularly in India); *see also* Ralf Starkloff, *Participatory Discourse and Practice in a Water Resource Crisis in Sri Lanka*, *in* ASSESSING PARTICIPATION; A DEBATE FROM SOUTH ASIA 110-116 (Sunil Bastian et al. eds., Konark Publishers, PVT Ltd. 1996) (describing the challenge of truly achieving an empowering participatory process due to entrenched "top-down power relations").

community. However, outside experts may be seen as suspect, prohibitively expensive, or otherwise inaccessible. Without some sort of capacity-building program, communities may be unable to process the information provided or evaluate proposals.[31]

5. Cultural Barriers

Some communities may not feel that it is appropriate to restrict access to certain kinds of information. It has been common for individuals within a community to voluntarily divulge information, unaware of the implications that may have for future use. The average member of a community may not be familiar with the use of patents or, more specifically, the concept that someone can appropriate what is common knowledge within a community and restrict its future use by others. Cultural values in sharing knowledge and general hospitality may inhibit more protective practices by individuals in a community. However, under the current intellectual property rights regimes in most countries, voluntary sharing of information without an agreement regarding intellectual property rights or dissemination can compromise community control and enable appropriation and misuse of such information.

6. National Laws

In many nations, the rights of indigenous people to inhabit and control use of their ancestral lands is not recognized or otherwise enforced. Without such rights, communities cannot assert control over access to genetic resources within their territory and effective enforcement of PIC in any arena seems unlikely. Additionally, many traditional groups may not be officially recognized by national governments. Without official recognition, it is doubtful that the rights of local communities over traditional knowledge or resources will be enforced or otherwise available.

Given these challenges to fair and equitable negotiations with traditional communities, it is clear that PIC in this area should not be approached in isolation. PIC represents one mechanism for communities to participate in, and ideally control, projects involving their traditional knowledge and genetic resources. However, such efforts may be effective only in conjunction with capacity-building programs and recognition of community rights. Even as traditional communities obtain more recognition and political power, it is important to continue to examine the specific challenges in the context of

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31. *See* Starkloff, *supra* note 30, at 108-10 (describing the dynamics of knowledge and information communication in a participatory water development project in Sri Lanka and emphasizing the importance of translating expert knowledge to community members as a vital purpose of a project and not just a means to an end).

negotiations with traditional communities in order to design an effective PIC system. The next section examines the history of PIC as a mechanism of empowerment and the theory behind the use of the term.

III. PRIOR INFORMED CONSENT AS A MECHANISM TO ENSURE COMMUNITY INVOLVEMENT, PARTICIPATION, DECISION-MAKING, AND SELF-DETERMINATION

PIC has arisen as a means to ensure empowerment over decision-making in various contexts. This section describes the legal requirement of PIC in contexts other than traditional knowledge and genetic resources, and examines the theory behind the use of PIC in the CBD.

A. PREVIOUS USE OF PRIOR INFORMED CONSENT

The concept of PIC has arisen primarily from two distinct areas: international agreements regarding hazardous waste and hazardous substances and requirements concerning medical procedures. These two previous uses of PIC address situations that are arguably very different from the situations of access agreements involving indigenous groups or local communities and private institutions. PIC "was initially constructed as a relationship between individuals (a doctor and a patient) or between Nation-States (which are treated as corporate individuals) in a dialogue over matters restricted in scope (e.g., chemicals) and time (e.g., an immediate decision over a treatment or shipment)."[32] In order to determine the meaning of PIC for communities under the CBD, it is informative to examine the nature of previous experiences with this concept.

1. International Conventions Regulating Hazardous Chemicals and Waste

The PIC procedures within international conventions regulating hazardous waste and chemicals have been characterized as an "information and decision support system."[33] The Rotterdam Convention on Prior Informed Consent (1998), which regulates hazardous chemicals, has the most developed international system of PIC. As described by Jonathan Krueger, the Convention's prior informed consent system, "generates and distributes information about chemical properties, their environmental and health effects, and national regulations that have been taken; after this information is distributed internationally, importing countries must inform exporters of their decision to consent or refuse imports of a given chemical or pesticide."[34]

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32. Hardison, *supra* note 14.

33. Jonathan Krueger, Belfer Center for Science and International Affairs 2000, Information in International Environmental Governance: The Prior Informed Consent Procedure for Trade in Hazardous Chemicals and Pesticides, *available at* http://environment.harvard.edu/gea (last visited June 1, 2003).

34. *Id.* at Introduction.

The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1989) has also instituted a system of prior notification and consent, however that system has developed more slowly and has focused in many cases on bans on dumping and prohibitions on trade.[35]

Particularly as applied in the Rotterdam Convention, PIC provides essentially "a system for managing assessments of chemicals."[36] That system principally consists of standardized information exchange and a transparent framework for decision-making. "[I]nformation exchange 'provides participating countries with a one-way flow of information on how certain chemicals are regulated in other countries [and] each participating country makes use of the information as decided nationally.' "[37] The benefits of this method are that information on chemical properties, potential effects on the environment and human health, and treatment under national regulations are disclosed. However, this may only begin a process of awareness of potential problems and does not alleviate problems in chemical management practices.[38]

Additionally, decision-making is facilitated through a Decision Guidance Document (DGD), sent together with an Importing Country Response (ICR) form and instructions for completion. "The DGDs are intended to help governments analyze, taking into account their public health, economic, environmental and administrative conditions, the potential hazards connected with the handling and use of the chemical, and to assist countries in [m]aking a decision whether to allow or prohibit future import of the chemical."[39] This procedure sets a framework through which decisions can be made, while allowing countries to give their own free consent based on their individual concerns.[40]

2. Medical Consent

National laws often regulate medical procedures through an informed consent process. Such laws generally define "informed" to mean "sufficient information on the alternatives and potential benefits and harmful consequences," and "consent" to mean "having the competency, freedom from coercion and authority to make a decision."[41]

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35. *Id.* at 12. "The more recent 2000 Cartagena Protocol on Biosafety will also rely heavily on information provision and exchange – its 'advance informed agreement' (AIA) mechanism – modeled on PIC." *Id.*

36. *Id.* at Introduction.

37. *Id.* § 4.1, *quoting* UNEP/FAO, 1991c:3.

38. *Id.* §5.0.

39. *Id.* § 4.2.

40. There had been complaints, however, that this procedure was given too short a time frame, and now the Convention allows for more flexibility in this regard. "The Convention now specifies that import responses are to be made 'as soon as possible, and in any event no later than nine months after the date of dispatch of the DGD' (Article 10.2)." *Id.* § 4.3.

41. Hardison, *supra* note 14.

While this process is arguably simpler than the situation in access agreements because it generally calls for consent from an individual, and in some cases from that individual's family, the medical consent process faces many similar challenges. The complexity of medical procedures and the uncertainty of the consequences are similar to the situation faced by researchers or access-seekers. Additionally, language barriers are potential problems in both. Also of note is the fact that social or spiritual consequences are rarely addressed within the legal requirements of medical consent.[42]

B. CONCEPTUAL MEANINGS OF PIC UNDER THE CBD

The formulation of Prior Informed Consent guidelines under the CBD should be informed by the type of community participation policy-makers foresee. Laird and Noejovich have identified and defined five different types of community participation in a project:

- *Information distribution:* a one-way flow of information from one party another;
- *Consultation:* a two-way flow of information between parties in a manner that assists in subsequent decision-making;
- *Negotiation:* a meeting of 'equals' in which the intended products are legally binding agreements that respect and define rights and obligations between parties for the future;
- *Collaboration:* a joint venture, or joint decision-making process in which all parties have an equal say in the development of a project;
- *Community controlled research or 'empowerment':* when decision-making and design are in the hands of communities.[43]

Unfortunately, exactly where PIC under the CBD should fit within this framework is unclear. Examples of all these types of participation are within case studies purporting to employ PIC policies under the CBD.[44] Furthermore,

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42. *Id.*

43. *See* Sara A. Laird & Flavia Noejovich, *Building Equitable Research Relationships with Indigenous Peoples and Local Communities: Prior Informed Consent and Research Agreements*, *in* BIODIVERSITY AND TRADITIONAL KNOWLEDGE; EQUITABLE PARTNERSHIPS IN PRACTICE 187-88 (Sarah A. Laird. ed., 2002); *see also*, Mallika Samaranayake, *Significance of Participatory Approaches in Empowering People for Sustainable Development*, *in* ASSESSING PARTICIPATION; A DEBATE FROM SOUTH ASIA 48 (Sunil Bastian, et al. eds. 1996) (describing forms of participation within development contexts as varying from "ratification meetings," "labour contribution," and "consultation," to "self-organisation, self-responsibility and self-actualisation" with "collective decision-making as its final goal").

44. For examples of case studies, *see Synthesis of Case-Studies on Benefit Sharing*, U.N. Doc. UNEP/CBD/COP/4/Inf. 7 (1998), *available at* http://www.biodiv.org/doc/meetings/cop/cop-04/information/cop-04-inf-07-en.pdf; *Access to Genetic Resources and Benefit Sharing Case Studies*, UNEP/CBD, *available at* http://www.biodiv.org/programmes/socio-eco/benefit/case-studies.asp; ENVIRONMENTAL POLICY STUDIES WORKSHOP, ACCESS TO GENETIC RESOURCES: AN EVALUATION OF THE DEVELOPMENT AND IMPLEMENTATION OF RECENT REGULATION AND ACCESS AGREEMENTS 53 (School of International and Public Affairs, Columbia University,

guidelines created by Working Groups within the Convention itself suggest conflicting models.

Working Groups within the Convention have identified certain guiding principles for elaboration of PIC procedures. First, holders of traditional knowledge should be "accorded equal status to the other members of the partnerships."[45] Such equal treatment suggests PIC should be envisioned as a "negotiation" or "collaboration." However, other guidelines suggest a more powerful role for communities. For example, "holders of traditional knowledge [should]. . . feel secure in tenure arrangements regarding their traditional land, forest and marine/inland water estates. . . [and] be convinced of a common purpose compatible with their cultural and ecological values."[46] These guidelines seem to envision a PIC system more compatible with a "community controlled research or empowerment"[47] model of participation.

Regardless of which model is followed, the Convention has made clear that PIC applies only to the specific purpose and activity for which it was granted. Thus, further permission must be granted prior to using the genetic resources in a way that is not stipulated in the initial agreement.[48] However, means of separating differences in the purpose and use of materials or knowledge should be elaborated by specific policy requirements in order to avoid misunderstandings in negotiations. India's Model Biodiversity Related Community Intellectual Rights Act, for example, specifies seven uses of biological resources or innovations that must receive PIC.[49] Most countries specify that additional PIC must be obtained (1) in order to transfer material or information to third parties, and (2) if academic research develops an unforeseen commercial interest. Therefore, it is more appropriate to envision PIC as a process, rather than a one-time contractual event, given that the use of genetic resources and traditional knowledge will constantly grow and evolve. Moreover, community consent to, and involvement in, each step of the project serves to strengthen the sustainability of the projects itself.[50]

Working Paper No. 4, 1999) *available at* http://www.biodiv.org/doc/case-studies/cs-abs-agr-rpt.pdf (last visited June 1, 2003) [hereinafter ENVIRONMENTAL POLICY STUDIES WORKSHOP]. *See generally*, BIODIVERSITY AND TRADITIONAL KNOWLEDGE; EQUITABLE PARTNERSHIPS IN PRACTICE 187-88 (Sarah A. Laird. ed., 2002).

45. UNEP/CBD, Elaboration of Key Terms of Article 8(j) and Related Provisions in Articles 10(c), and 17.2 and 18.4, *available at* http://www.biodiv.org/indig/tkbd-4e.htm.

46. *Id. See generally*, Note, *Market Realities v. Indigenous Equities*, 26 BROOK. J. INT'L L. 1147 (2001) [hereinafter *Market Realities*].

47. See *supra* note 43.

48. UNEP/CBD, *supra* note 45; UNEP/CBD, *Report of the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing*, Part IV (C), COP/6/6 (31 Oct. 2001).

49. The seven uses include: (1) the production and/or duplication of the resource through any manner, (2) the development of traditional products based on the resource, (3) the development of new products utilizing local knowledge and based on local innovation, (4) the offering for sale, (5) the marketing, (6) export, and (7) import. Model Biodiversity Related Community Intellectual Rights Act, §3, cl.12(a) (1994) (India), *available at* http://www.grain.org/brl/region-asia-brl-en.cfm (last visited June 1, 2003).

50. Experience in the context of development projects in Asia has shown "the importance of the participation of the people concerned in the decision making process throughout the steps of the development cycle. A sense

The next section lists and analyzes specific requirements within current PIC systems under the CBD.

IV. DESIGNING SPECIFIC REQUIREMENTS FOR PIC

All PIC guidelines must encompass certain basic elements. These issues can be broken down into three parts:

(1) Prior: What activities require consent?[51] What should be the time frame given for deliberation and negotiations (i.e., how far in advance must PIC be sought)?
(2) Informed: What information must be provided? In what form should information disclosure take place?
(3) Consent: Who can give consent? How can negotiations maintain trust and legitimacy? In what form should consent be issued, and how detailed should any statement or agreement be?

In general, substantive requirements will define what information must be provided, while procedural requirements will address the other issues mentioned above.

Under the CBD, policies regarding PIC differ in the detail of substantive information required as well as the rigor of the procedural requirements. Some countries have not defined any specific requirements for PIC, while others, such as the Philippines, have such strict requirements that currently only two of thirty-seven applications for access to genetic resources by commercial and academic interests have been approved by the government.[52]

The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore and the UNEP CBD WG-ABS[53] have recommended that different requirements be used for different types of access-seekers. Countries such as Peru, India, and the Philippines have separate procedures for research with purely academic ends from commercial prospecting. Others require the same procedures for PIC regardless of the project purpose.

The subsections below outline the specific substantive and procedural requirements that countries, institutions, and communities have used in PIC policies under the CBD. After each general requirement, a brief analysis of the major

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of ownership of assets arises when there is participation in planning, design, implementation, monitoring and evaluation." Samaranayake, *supra* note 43, at 52.

51. A major challenge within this question is how resources/information already in the public domain should be treated. Should IP law structure PIC requirements under the CBD?

52. Environmental Policy Studies Workshop, *supra* note 44, at 55.

53. United Nations Environment Program/Convention on Biological Diversity/Working Group on Access and Benefit Sharing.

policy concerns accompanying that issue is included. No current legislation includes all these requirements. They are listed to present the breadth of possibilities for formulation of PIC in the context of traditional knowledge and genetic resources.

A. SUBSTANTIVE PROPOSALS

The following proposals are a synthesis of requirements in tribal codes, institutional guidelines, and national and international laws and proposals, which address the issue of information disclosure:

(1) *An access-seeker must disclose its proposed project methodology*, specifically including the type and quantity of genetic resources sought, starting date and duration of the activity, geographic prospecting area, identification of where the research and development will take place, and how the research and development is to be carried out.[54]

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54. The following are examples of proposed methodology requirements in tribal codes, institutional guidelines, and national and international laws and proposals:

The access-seeker must disclose:

(a) the research methodology (Inuit Tapirisat of Canada, *reprinted in* Laird & Noejovich, *supra* note 43, at 194);
(b) the duration, geographic area, and collecting methods of the proposed research (Pew Scholars Initiative, *reprinted in* Laird & Noejovich, *supra* note 43, at 190-91);
(c) information on the kind of material being taken, the quantity of the sampling, and the conservation status of the material being sampled (University of the South Pacific (USP)-Verata contract in Fiji as described in ENVIRONMENTAL POLICY STUDIES WORKSHOP, *supra* note 44, at 52);
(d) a description of the research program, the types of organisms desired, and the purpose and means of collecting samples (US Yellowstone-Diversa Agreement, U.S. permit application as described in ENVIRONMENTAL POLICY STUDIES WORKSHOP, *supra* note 44, at 62);
(e) a brief description of the objectives and reason for the research, as well as the activities that will be conducted; indication of the location(s) where activities will take place and the time period necessary to finish research activities; information regarding the destination of material and derived products and data or traditional knowledge collected (Instituto SocioAmbiental Recommendations for Scientific Research in Indigenous Land, *reprinted in* Ana Valéria Araújo, *Acesso A Recursos Genéticos e Proteção aos Conhecimentos Tradicionais Associados, in* O DIREITO PARA O BRASIL SOCIOAMBIENTAL, 85, 97-98 (Sergio Antonio Fabris ed., 2002);
(f) "detailed and specific information about nature of access sought and specimen to be collected; precise sites where the specimen is/are located as well as the places where the proposed research and development activities will be carried out; clear indication of the primary destination of the resource and its subsequent destinations" (Biodiversity and Community Knowledge Protection Act of Bangladesh, art. 13(9)(a) (Sept. 29, 1998) (Bangl.), *available at* http://www.grain.org/brl/region-asia-brl-en.cfm [hereinafter Biodiversity and Community Knowledge Protection Act of Bangladesh]);
(g) the "purpose/s, methodology/ies, duration, species/ specimen and number/quantity to be used and/or taken" (Executive Order No. 247, Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By-Products and Derivative, for Scientific and Commercial Purposes, and for Other Purposes, § 4. (1995) (Phil.), *available at* http://www.grain.org/brl/region-asia-brl-en.cfm [hereinafter Executive Order No. 247]);

Policy Considerations: Communities should understand what activities would occur on their land and what processes will occur once traditional knowledge or physical samples have been acquired. Such information can help protect against destruction of habitat, as well as aide in explaining the purpose and implications of a project.[55] This requirement seems to be a basic requirement in most policies and should not be too burdensome to provide.

(2) *An access-seeker must disclose any foreseeable consequences of the project*, specifically including but not limited to the possible destination of knowledge or material acquired, its ownership status, and any impact on the local environment, community or culture.[56]

(h) the "specific area and location of the bioprospecting activity; the defined period when the collection activities will take place; the specific purposes, objectives, resources to be used, activities and methodologies, expected outputs and other related information" (The ASEAN Framework Agreement on Access to Biological and Genetic Resources Draft Text, art. 10 (Feb. 24, 2000), *available at* http://www.grain.org/brl/region-asia-brl-en.cfm);

(i) "the resources to which access is sought, including the sites from which it will be collected; the identity of the location where the research and development will be carried out; the primary destination of the resource and its probable subsequent destination(s)" (African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, III (4) (2000) (OAU), *available at* http://www.grain.org/brl/region-asia-brl-en.cfm [hereinafter African Model Legislation]);

(j) the type and quantity of genetic resources to which access is sought, starting date and duration of the activity, geographic prospecting area, identification of where the research and development will take place, information on how the research and development is to be carried out (Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, Decision VI/24 (Apr. 18-19, 2002), *available at* http://www.biodiv.org/decisions/default.asp?m=cop-06&d=24 (last modified May 6, 2003) [hereinafter Bonn Guidelines]).

55. Most government agencies regulating access to genetic resources require this information in a permit application. Therefore, such information should not be difficult to generate from the access-seeker's perspective. While not all research and development may be foreseeable from the beginning, it should not be difficult to provide an initial research plan and update the community on changes to such methodologies. It may be challenging to explain high-tech research and development methodologies carried out on samples in laboratories, but efforts can be made to provide at least an overview of the type of activities to be carried out.

56. The following are examples of requirements to disclose foreseeable consequences:

The access-seeker must disclose:

(a) the "full implications that can realistically be foreseen." BIODIVERSITY AND TRADITIONAL KNOWLEDGE; EQUITABLE PARTNERSHIPS IN PRACTICE xxiv (Sarah A. Laird ed., 2002);

(b) "the foreseeable consequences of the research for resources, people and accessors, including the potential commercial value" and the non-commercial values, such as academic recognition and advancement for the researcher and any social and/or cultural risks (Pew Scholars Initiative, *supra* note 54, at 190-91);

(c) "the potential benefits and possible problems associated with the research for people and the environment" (Inuit Tapirisat of Canada, *supra* note 54, at 191, 194);

(d) "the destination of knowledge or material that is to be acquired, its ownership status and the rights of local people to it once it has left the community" (Posey & Dutfield, *reprinted in* Laird & Noejovich, *supra* note 43, at 190);

(e) the "present and potential uses including its sustainability and the risks, which may arise from access and collection; whether any collection of the biological and genetic resource endangers

Policy Considerations: Consequences of the activity for the community should be disclosed as soon as the researcher can reasonably foresee them. Special attention should be paid to the impact the project could have on the local health, environment, and well being of the community. Consequences of the benefit sharing arrangements should also be estimated, including both positive and negative impacts. This category is broad and may be difficult for the researcher to predict in all circumstances, but it is vital for truly informed, autonomous consent.[57]

(3) *An access-seeker must provide information regarding the legal entity and affiliation of the applicant and its sponsors*, including identification of participating individuals, financing and collaborating organizations, local bodies involved, and possible third party involvement.[58]

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any component of biological diversity, and/or ecosystem, and/or livelihood of any Community holding Residual Title" (Biodiversity and Community Knowledge Protection Act of Bangladesh, *supra* note 54, at art. 13);

(f) the proposed activity, risks, and implications (Ley No. 27811, Ley Que Establece el Regimen de Proteccion de los Conocimientos Colectivos de los Pueblos Indigenas Vinculados a los Recursos Biologicos, title II art. 2 (2002) (Peru));

(g) the "evaluation of how the access activity may impact on conservation and sustainable use of biodiversity, to determine the relative costs and benefits of granting access" (Bonn Guidelines, *supra* note 54).

57. The lack of communication of the foreseeable consequences became an issue in an agreement between the Kani tribe and the Tropical Botanical Garden and Research Institute (TBGRI) in India regarding Tricopus zeylanicus, also referred to as "Arogyapacha." In that case, the Kani guides were not informed of the "implications of bioprospecting – such as the strain on the surrounding natural resources which could drastically alter the Kanis' traditional lifestyle and environment." *Market Realities, supra* note 46. While the researchers intended for the project to benefit the Kani people, they did not allow the people themselves decide whether the project was truly in their best interests. For a full explanation and analysis of this case study, *see id.*, *citing* Benefit Sharing Model Experimented by Tropical Botanic Garden and Research Institute (TBGRI), A National Center of Excellence on Tropical Plant Diversity, Ministry of Environment & Forests, Government of India, *at* http://www.biodiv.org/chm/techno/Casestudies_pdf/India.PDF (last visited June 30, 2000).

58. The following are examples of applicant information requirements in tribal codes, institutional guidelines, and national and international laws and proposals:

The access-seeker must disclose:

(a) the legal entity and affiliation of the applicant and/or collector and contact person when the applicant is an institution (Bonn Guidelines, *supra* note 54, at 36(e));

(b) information on who is funding the research and all parties that will participate in the research (Fiji national legislation as described in ENVIRONMENTAL POLICY STUDIES WORKSHOP, *supra* note 44, at 52-53);

(c) "the identity of those carrying out the activity and its sponsors, if different" (Posey & Dutfield, *supra* note 56, at 190);

(d) the sponsors of the research and the person in charge (Inuit Tapirisat of Canada, *supra* note 54, at 194);

(e) the identification of the researcher(s) and recommendation(s) from the institution(s) responsible for the research (Araújo, *supra* note 54, at 85, 97-98);

(f) "the identification of the applicant and the documents which testify to his/her legal capacity to contract" (Biodiversity and Community Knowledge Protection Act of Bangladesh, *supra* note 54, at art. 13);

Policy Considerations: Any information on new participants or third party involvement should be fully disclosed prior to finalizing agreements. Such information could be particularly effective if a registry of researchers and institutions were established, providing information on prior activities and conduct. Additionally, this information could facilitate the enforcement of individual and institutional liability for misuses of any privileges granted.

(4) *An access-seeker must indicate some form of benefit-sharing arrangements.*[59]

Policy Considerations: This information empowers communities to demand a fair and equitable share of benefits and opens further dialogue on benefit sharing and mutually agreed upon terms. It also forces access-seekers to consider local

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(g) the source of funds of the proposed project (Executive Order No. 247, *supra* note 54, at §4);
(h) the "name of the researcher, collector or collaborator, information on the local collaborator" (ASEAN Framework Agreement, *supra* note 54, at art. 10);
(i) "the identity of the applicant and the documents that testify to her/his legal capacity to contract, including, where appropriate, the identity of all partners with the contracting party; the identification of the national institution or institutions which will participate in the research and be in charge of the monitoring process" (African Model Legislation, *supra* note 54, at III(4));
(j) the identification of local bodies for collaboration in research and development; possible third party involvement (Bonn Guidelines, *supra* note 54, at 36(i)).

59. The following are examples of requirements for disclosure of benefit-sharing arrangements in tribal codes, institutional guidelines and national and international laws and proposals:

The access-seeker must provide:

(a) an "indication of benefit-sharing arrangements; kinds/types of benefits that could come from obtaining access to the resource" (Bonn Guidelines, *supra* note 54, at 36(m));
(b) information on "the benefits for the people or person whose consent is being requested" (Posey & Dutfield, *supra* note 56, at 190);
(c) identification of the forms of profits for the community, assurance that the project will result in social benefits for the community, and guarantee that benefits of the research will be shared in accordance with the CBD and other relevant laws, whether it be through payment of a defined value defined together with the community/indigenous people/association, participation in the financial results resulting from commercialization of derived products, or some other form of payment (Araújo, *supra* note 54, at 85, 97-98);
(d) proposed mechanisms and arrangements for benefit sharing including knowledge, technology and/or financial transfer to Bangladesh to the concerned Communities, and the manner and extent of intended involvement of Bangladesh in the necessary research and development; indication of the benefits, whether economic, technical, bio-technological, scientific, cultural social or otherwise, that may derive to Bangladesh and the concerned Communities (Biodiversity and Community Knowledge Protection Act of Bangladesh, *supra* note 54, at art. 13);
(e) an indication of the "potential benefits to the country" (ASEAN Framework Agreement, *supra* note 54, at art. 10);
(f) a description of the manner and extent of local and national collaboration in the research and development of the biological resource concerned; the economic, social, technical, biotechnological, scientific, environmental or any other benefits that are intended, or may be likely to, accrue to the country and local communities providing the biological resource as well as the collector and the country or countries where he/she operates; the proposed mechanisms and arrangements for benefit sharing (African Model Legislation, *supra* note 54, at III(4)).

benefits that can result from their project from the beginning of the negotiations. Because finalizing a benefit-sharing agreement takes time, this requirement may not be a binding commitment, but rather a statement of intent that should be more general in nature.

(5) *An access-seeker must indicate possible alternative activities and procedures.*[60]

Policy Considerations: This information allows communities to understand alternative options available and forces access-seekers to consider alternative methodologies that may have fewer environmental or cultural impacts. However, this requirement is not common in current PIC protocols.

(6) *An access-seeker must disclose all discoveries made in the course of the activity that might affect the interests of the community.*[61]

Policy Considerations: This requirement envisions a continuous process of disclosure to ensure that the community is able to evaluate its interests in the project throughout all stages. If communities are not informed of the discoveries or developments of their resources and traditional knowledge they cannot control their use. It is important, however, to clarify the kinds of developments that demand disclosure and differentiate between discoveries and new uses that would require additional PIC (i.e., commercialization, IP application, transfer to third parties, etc.). In addition, sharing discoveries with communities ensures that research is *given back* to communities, rather than only *taken from* communities.

(7) *An access-seeker must evaluate the environmental impact of the proposed activity.*[62]

Policy Considerations: A full environmental impact assessment can be extremely expensive and create long delays. Therefore, it is important to specify when an assessment should be conducted, who should conduct the study, and

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60. Posey & Dutfield, *supra* note 56, at 190.

61. Access seekers should disclose "[d]iscoveries made in the course of the activity that might affect the willingness of the people to continue to cooperate." Posey & Dutfield, *supra* note 56, at 190.

62. The following are examples of environmental impact requirements in tribal codes, institutional guidelines and national and international laws and proposals:

The access-seeker shall provide:

(a) a "presentation of anticipated environmental and ecological impact and impact on the livelihood of the Communities holding Residual Titles" (Biodiversity and Community Knowledge Protection Act of Bangladesh, *supra* note 54, at art. 13);

(b) "information on the potential environmental and ecological impact of the bioprospecting activity" (ASEAN Framework Agreement, *supra* note 54, at art. 10);

(c) an assessment of "whether any collection of the resource endangers any component of biological diversity and the risks which may arise from the access; an environmental and socio-economic impact assessment covering at least the coming three generations, in cases where the collection is in large quantities" (African Model Legislation, *supra* note 54, at III(4)).

what the study should encompass. Whether an environmental impact assessment is required could depend on the nature of the activity, such as whether significant biological sampling will take place. This element is not commonly included as a separate element in PIC procedures. It is more common that the environmental risks be included in the information provided on the foreseeable consequences of the project.

(8) *An access-seeker must identify any and all intended uses and commercial interests.*[63]

Policy Considerations: Because the intended use may change and evolve as research develops, the original intended uses should be clear so that additional PIC can be required for uses not originally disclosed. This information also allows for a clearer understanding of the nature of the proposed activity.

(9) *The community must be made aware of all legal options available to them if they refuse to allow the activity.*[64]

Policy Considerations: Communities should be advised of their rights to forbid access to or the use of genetic resources or traditional knowledge. Such information is essential for truly free consent and more equitable relationships. This requirement is rarely included in formal PIC procedures, however. This absence may be reflective of the uncertainty over who should provide this information, i.e., the access-seeker or the government. Some countries may have government-funded community legal education programs. However, even where those programs exist, they are likely not to address the specific rights concerning traditional knowledge and genetic resources and may not always reach the specific community concerned.[65] Therefore, the access-seeker could be required

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63. The following are examples of requirements to disclose intended uses or commercial interests:

The access-seeker shall provide:

(a) "accurate information regarding intended use (e.g., taxonomy, collection, research, commercialisation)" (Bonn Guidelines, *supra* note 54, at 36(f));
(b) "any commercial interest that the performers and sponsors have in the activity and in the knowledge or material acquired" (Posey & Dutfield, *supra* note 56, at 190);
(c) "the purpose for which access and collection is requested including, where it is appropriate, the type and extent of commercial use expected to be derived from the undertaking" (Biodiversity and Community Knowledge Protection Act of Bangladesh, *supra* note 54, at art. 13);
(d) the eventual use of the knowledge and the value of such knowledge (Ley No. 27811, *supra* note 56, at II(2));
(e) the present and potential uses of the resource; "the purpose for which access to the resource is requested including the type and extent of research, teaching or commercial use expected to be derived from it" (African Model Legislation, *supra* note 54).

64. Posey & Dutfield, *supra* note 56, at 190.

65. For an example of the material used in one of the most long-standing community legal education programs, see COMMUNITY LEGAL EDUCATION MATERIAL, National Clearinghouse for Legal Services (3d ed. 1973).

to clearly inform the community of its rights in any particular project, and government services or capacity-building programs could supplement such efforts. In the end, it is unlikely that a simple requirement to inform communities of their right to refuse access would be effective without supplemental legal counsel.

(10) *An access-seeker should provide a copy of the guidelines the researcher is following and previous practices used in similar projects.*[66]

Policy Considerations: This information allows for a clear understanding of the intentions of the project and develops trust between the community and the researcher. It also allows communities to demand that researchers follow codes and monitor infractions of such procedures. A registry of access-seekers, which would allow communities to exchange information and conduct background checks, could be used to supplement this information when available.

B. PROCEDURAL PROPOSALS

Procedural rules govern when and in what form PIC will occur. The following proposals are a synthesis of requirements in tribal codes, institutional guidelines and national and international laws and proposals that address these issues.

(1) *All information provided must be in a language understandable to the local community.*[67]

Policy Considerations: In order to minimize miscommunication and allow for all members of a community to understand the proposed activities, as much

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66. The following are examples of requirements for the disclosure of prior practices and ethical guidelines from tribal codes, institutional guidelines, and national and international laws and proposals:

The access-seeker shall indicate:

(a) "the guidelines the researcher is following, as well as his/her practice in previous similar projects" (Pew Scholars Initiative, *supra* note 54, at 190-91);
(b) the policy regarding "treatment of confidential information" (Bonn Guidelines, *supra* note 54, at 36(o));
(c) the information submitted to the relevant board of ethics responsible for the project (Araújo, *supra* note 54, at 85, 97-98).

67. The following are examples of local language requirements in tribal codes, institutional guidelines, and national and international laws and proposals:

(a) All communications should be in the local language (Pew Scholars Initiative, *supra* note 54, at 190-91);
(b) Collector(s) must provide written commitment that all research reports and results associated with the Specimen collected from Bangladesh is provided to the National Biodiversity Authority and the concerned Communities in Bangla language, failing which, access will be denied; the request to have access to biological and genetic resources and intellectual and cultural knowledge of the Communities of Bangladesh shall require written application. The application shall be in Bangla language in a simple and easy style. (Biodiversity and Community Knowledge Protection Act of Bangladesh, *supra* note 54, at art. 13);

information as possible should be translated into the local language. This requirement could include all documentation, or be limited to draft proposals.[68]

(2) *An access-seeker must obtain consent from the community and from any individuals involved.*[69]

Policy Considerations: Whether representatives can give full consent for a project or whether all individuals involved must be separately consulted could be determined by national legislation or by the communities themselves. In the interest of avoiding conflicts later in the project, however, access-seekers should seek to include all individuals that will be involved, as well as the official representatives, in all decision-making.

(3) *The community at large should be notified of the proposed activities.*[70]

(c) "the disclosure of any information pertaining to the access shall be in a language understandable to the local communities" (ASEAN Framework Agreement, *supra* note 54, at art. 10).

68. In the USP-Verata negotiations in Fiji, for example, all draft agreements were translated into the local language for distribution to the community at large. For a full discussion of this case study, *see* ENVIRONMENTAL POLICY STUDIES WORKSHOP, *supra* note 44, at 53.

69. The following are examples of requirements for consent from both individuals involved and the community as a group:

(a) Consent should be obtained "from the community and from any individuals involved in research" (Inuit Tapirisat of Canada, *supra* note 54, at 191-94);

(b) All affected people should have the opportunity to fully and actively participate in negotiations prior to significant decision-making so that all decisions reflect the desires of the indigenous people as a whole (Tobin et al., *Consultation Best Practice Guidelines* (1998), *reprinted in* Laird & Noejovich, *supra* note 43, at 201);

(c) The National Biodiversity Authority shall make sure that political representatives... of the Community or the representative citizens belonging to the Community, who are permanently living in the area from where the Specimen are collected, be informed adequately about any proposal for research or bioprospecting activities for commercial purposes; The National Biodiversity Authority shall make sure that the Collector has deposited the application to the relevant Local Government (Union Parishad) in order to make it available to Communities in the offices of the relevant Union Parishad. (Biodiversity and Community Knowledge Protection Act of Bangladesh, *supra* note 54, at art. 13).

70. The following are examples of requirements to notify the community of the access-seeker's intent:

(a) The community at large should be notified by some means (e.g. public meeting) (Pew Scholars Initiative, *supra* note 54, at 190-91);

(b) No agreement will be valid unless National Biodiversity Authority has adequately publicized the collection to the Community or Communities from where the biological materials, resources, information, etc are going to be collected. The application will not be considered unless it is deposited in the Local Government office and remained available to the local communities to see, read and study for at least thirty days from the day the document(s) are available. (Biodiversity and Community Knowledge Protection Act of Bangladesh, *supra* note 54, at art. 13);

(c) The Principal/Collector shall inform the [Indigenous Peoples, Local Communities, Protected Area Management Boards,] or Private Land Owners concerned through various media such as, but not limited to, newspaper, radio or television advertisements that the Principal/Collector intends to conduct bioprospecting within their particular areas, fully disclosing the activity to be undertaken; the Principal/Collector shall call for a community assembly, notice of which shall be

Policy Considerations: Public meetings could help promote the involvement of the community in the research, minimize divisions within the community, and lessen the likelihood of misunderstandings.[71] The purpose of PIC is to achieve consent, and therefore access-seekers should seek to include various internal divisions within communities rather than exploiting conflicts of interests within communities.[72] However, in some cases, this process might be seen as undermining traditional power structures. In order to avoid imposing non-traditional decision-making processes, community meetings should be informational in nature and not include voting or other forms of decision-making.

(4) *PIC should be obtained according to the customary laws and practices of the concerned community, making use of existing community-based organizational structure.*[73]

Policy Considerations: Identifying who can represent a community and how permission is customarily granted can be difficult to clarify. However, early identification of the proper representatives is essential to avoid problems later in the project.[74] Community organizations are extremely diverse and can be tremendously complex. In addition to customary laws and hierarchies, there are political organizations and complex land ownership laws that must be understood.[75] In general, it is important for access-seekers to include both spiritual and political leaders of communities in order to avoid internal conflicts and divisions. Given the challenge of understanding community power structures, access-

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announced or posted in a conspicuous place in the area where bioprospecting shall be conducted, at least a week before said assembly. (Department Administrative Order No. 96-20, Subject: Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources, § 7. (June 21, 1996) (Phil.), *available at* http://www.grain.org/brl/region-asia-brl-en.cfm [hereinafter Dept. Admin. Order No. 96-20]).

71. *See* Environmental Policy Studies Workshop, *supra* note 44, at 53.

72. See Miguel N. Alexiades & Daniel M. Peluso, Prior Informed Consent: The Anthropology and Politics of Cross Cultural Exchange, reprinted in Laird & Noejovich, *supra* note 43, at annex 7.1.

73. The following are examples of rules concerning the status of customary practices in PIC provisions from tribal codes and national laws:

(a) "Consultations should make use of existing community-based formal and informal organizational structure, oral communication and time frames appropriate for consensus decision-making and local cultural norms" (Inuit Tapirisat of Canada, *supra* note 54, at 191, 194);

(b) PIC must be obtained according to the customary laws of the concerned community, "A copy of the proposal must be submitted to the recognized head of the local or Indigenous cultural community or communities that may be affected" (Executive Order No. 247, *supra* note 54, at §§ 2, 4).

74. In the case of the Kanis in India, for example, there is no indication that the two Kanis who disclosed the tribe's indigenous knowledge were representative of the entire tribe's interest. *See Market Realities, supra* note 46. In Brazil, problems have arisen when only three of seventeen tribes of one ethnic group where consulted for a research venture. *See* Lopes, *supra* note 27, at A14.

75. For example, in Fiji, the pre-colonial system of land tenure was codified. Thus, when negotiations between USP and Verata occurred, decisions were made through the unanimous consensus of the community council. ENVIRONMENTAL POLICY STUDIES WORKSHOP, *supra* note 44, at 52.

seekers might consult with researchers, individuals, or government agencies familiar with the local community. Official registers of traditional community representatives and decision-making laws or customs would also help access-seekers in identifying relevant bodies and respecting the customary laws of communities.

(5) *An access-seeker should encourage participation of the community - especially youth, women, and elders - in decision-making, as well as in the activities themselves.*[76]

Policy Considerations: How proactive a project should be in involving disempowered groups within traditional communities is a sensitive issue. Some scholars have argued that community power over decision-making can undermine the autonomy of individuals and ignore dissent and diversity within traditional communities.[77] It is unclear whether special attention to certain groups within communities should be mandated in national legislation or whether that should be left to the parties to determine.[78] In general, this might depend on the community and the nature of the research being conducted.

(6) *The access-seeker should provide copies of relevant project documents throughout the project. Relevant documents many include, but may not be limited to, the project proposal, the project budget, and approval of relevant boards of ethics or government agencies, when appropriate.*[79]

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76. The following are examples of requirements to include and encourage participation from individuals in the community:

(a) "The researcher should seek the participation of, or contact with, residents of the community. . . . Research design should endeavour to anticipate and provide meaningful training of aboriginal researchers." (Inuit Tapirisat of Canada, *supra* note 54, at 191, 194);
(b) research should attempt to secure participation of all sectors of the society effected, particularly women, youth, and elders (Tobin et al., *supra* note 69, at 201);
(c) PIC must be obtained from "the concerned local communities, ensuring that women are also involved in decision making" (African Model Legislation, *supra* note 54, at III(4)).

77. Madhavi Sunder, *Intellectual Property and Identity Politics: Playing with Fire,* 4 J. GENDER RACE & JUST. 60 (Fall 2000). Sunder writes:

> If differences within cultures are on the rise (with views about cultural identity and authenticity ranging widely from the orthodox to the progressive), will intellectual property in cultural identity be used to protect some cultural meanings over others? Who decides which meanings should be protected and on what basis will such decisions be made? Most importantly, how much autonomy—in the form of dissent and the right to make meaning—are we willing to sacrifice in the name of cultural survival?

Id.

78. For example, the USP-Verata agreement specifically provides for the inclusion of women and youth groups in the project, although no specific means are specified. *See* ENVIRONMENTAL POLICY STUDIES WORKSHOP, *supra* note 44, at 53.

79. The following are examples of requirements to provide certain project documents:

(a) The researcher/access-seeker should "provide copies of relevant project documents, or summaries thereof preferably including the project budget, in the local language. In the case of commercial prospecting, researchers must share such documents." (Pew Scholars Initiative, *supra* note 54, at 190-91);

Policy Considerations: Such procedures promote trust and equity between the researchers and the community. Additionally, this information allows communities to understand issues such as the goals of the project, the resources available, and the role of the access-seekers in relation to the larger project. In most cases, it will be necessary to translate relevant documents into local languages. It is unlikely that all project-related documents need to be translated and shared. However, if only relevant documents need be shared, it is important to design an effective process of deciding which documents are relevant. Protocols could identify certain types of documents, such as ethical guidelines, budgets, and data results or analysis.

(7) *The access-seeker should share findings and include the community in all stages.*[80]

Policy Considerations: Mechanisms could be designed to ensure community participation throughout the project, including the planning, design, implementation, and evaluation of the project.[81] At a minimum, a summary report of all work should be shared with the community at various stages of the project.

(b) The access-seeker should provide a copy of the project's budget. (Bonn Guidelines, *supra* note 54, at 36(n));

(c) "The Principal/Collector shall likewise furnish. . . a copy/ies of a brief summary or outline of the research proposal in a language or dialect understandable to them;" third parties much share the written drafts of all manuscripts before publication with acknowledged contributions of all parties (Dept. Admin. Order No. 96-20, *supra* note 70; *see* ENVIRONMENTAL POLICY STUDIES WORKSHOP, *supra* note 44, at 58).

80. The following are examples of requirements for inclusion of the community in all stages of the project:

(a) The researcher/access-seeker "must share findings at different stages with the providers." (Pew Scholars Initiative, *supra* note 54, at 190-91);

(b) "Serious efforts must be made to include local and traditional knowledge in all stages of research, including problem identification. . . . Ongoing communications of research objective, methods, findings and interpretations from inception to completion of projects should occur." (Inuit Tapirisat of Canada, *supra* note 54, at 191, 194);

(c) consultations should be continuous, "held throughout the planning, design, implementation and evaluation of the project" (Tobin, et al., *supra* note 69, at 201);

(d) A report on the work of experimentation or other studies done from the accessed genetic material must be submitted to the national authority and local communities as applicable (Supreme Decree No. 24676, Regulation of Decision 391 on the Common Regime for Access to Genetic Resources, title III, ch. I, art. 15 (June 21, 1997) (Bol.), *available at* http://www.grain.org/brl/region-asia-brl-en.cfm);

(e) "A quarterly report of the collections made, indicating the kind and quantity of the biological and/or genetic material/resources/specimens collected, and semi-annual progress reports, including the ecological condition/state of the study area/s and/or species and research results shall be submitted to the IACBGR through its Technical Secretariat." (Dept. Admin. Order No. 96-20, *supra* note 70, at §8).

81. Mechanisms to share research findings and maintain the participation of the local community throughout the project have been developed in a number of agreements throughout the world. In the INBio-Merck Collaboration Agreement, for example, the parties must report all developments involving INBio samples to the other party. Developments include the discovery of bioactive compounds and sublicensing agreements involving third parties. Parties also must consult with one another about the preparation, application, follow-up,

(8) *A complete copy of the research results, all discoveries, and all derived commercial products should be provided to the local community.*[82]

Policy Considerations: Giving results back to the community allows for communities to better understand the purpose of the research and builds trust and a sense of partnership between the community and the access-seekers. Ideally, communities should have access to the data in a language and medium that can be utilized by the community at-large, rather than a select few. Whether all derived commercial products must be provided to the local community is more controversial. This is required in places such as the Philippines[83] and seems consistent with the idea of ensuring fair and equitable benefits arising from genetic resources and traditional knowledge.

(9) *A protocol of acknowledgements, citation, authorship, and inventorship should be agreed upon, and in all cases, anonymity and confidentiality should be offered.*[84]

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and maintenance of patents. This process was facilitated by the fact that the parties in that case were two organizations and the contract itself did not explicitly require consent from communities. *See* ENVIRONMENTAL POLICY STUDIES WORKSHOP, *supra* note 44, at 21.

In Fiji, PIC is specifically required to extract samples and to export them from the country. The USP-Verata agreement further required that USP inform Verata of any meetings or subsequent negotiations or activities involving samples or associated information and third parties and keep Verata informed of all research carried out after the final agreements have been signed. Additionally, any new commercial activity involving information from an extract must be fully discussed with the community prior to development. In addition to these requirements, the UPS-Verata agreement requires that a report be written every three months regarding materials collected and transported, research progress, and money received and disbursed. Furthermore, USP must hold workshops every six months in the community so that all stake holders can be informed and discuss the progress of all research activities. ENVIRONMENTAL POLICY STUDIES WORKSHOP, *supra* note 44, at 52-53.

82. The following are examples of requirements to share project results with communities:

(a) "Aboriginal people should have access to research data, not just receive summaries and research report. The extent of data accessibility that participants/communities can expect should be clearly stated and agreed upon as part of any approval process. . . . Written information should be available in the appropriate language(s)." (Inuit Tapirisat of Canada, *supra* note 54, at 191, 194);
(b) a summary of the results of research should be given to the community, as well as a complete copy of the project results in Portuguese (Araújo, *supra* note 54, at 85, 97-98);
(c) "All discoveries of commercial product/s derived from Philippine biological and genetic resources shall be made available to the Philippine government and local communities concerned." (Dept. Admin. Order No. 96-20, *supra* note 70, at §8);
(d) an access-seeker must " guarantee to deposit duplicates of, with complete field information on, each specimen of the biological resource or the records of community innovation, practice, knowledge or technology collected with the duly designated governmental agencies and, if so required, with local community organizations" (African Model Legislation, *supra* note 54, at III(4)).

83. As stated in *supra* note 82, the relevant law in the Philippines requires that, "[a]ll discoveries of commercial product/s derived from Philippine biological and genetic resources shall be made available to the Philippine government and local communities concerned." Dept. Admin. Order No. 96-20, *supra* note 70, at §8).

84. The following are examples of rules regarding authorship, inventorship, and confidentiality:

(a) "The peer review process must be communicated to the communities, and their advice and/or participation sought in the process. . . . Anonymity and confidentiality must be offered and, if accepted, guaranteed except where this is legally precluded." (Inuit Tapirisat of Canada, *supra* note 54, at 191, 194);

Policy Considerations: In order to avoid unwanted disclosure of information and to respect the desire of communities who do not want their knowledge published, communities should give consent to the form that information will be published or otherwise disbursed.[85] Explaining the academic peer review process, for example, is important so that communities understand how the information will be dispersed and what benefits the researcher will be gaining from the project. This requirement might be included as part of the mutually agreed upon terms of access agreements.

(10) *All individuals involved in a project must respect the privacy, dignity, culture, traditions, and rights of the community.*[86]

Policy Considerations: This requirement furthers trust between the community and the access-seeker by imposing an explicit duty on access-seekers in line with the internationally-recognized human and cultural rights of traditional communities.[87] Researchers and other access-seekers may desire to respect the culture and traditions of a community they work with, however, in some cases this requires a deep understanding of a culture. Therefore researchers might seek to work with an anthropologist or other intermediary familiar with local culture and practices.

(11) *If at any point the project is unacceptable to the community, the research should be suspended.*[88]

(b) the parties "must agree on a protocol of acknowledgements, citation, authorship, inventorship as applicable, either citing local innovators or conservators or respecting requests for anonymity" (Pew Scholars Initiative, *supra* note 54, at 190-91);

(c) "the concerned parties shall take all the necessary and reasonable steps to ensure the confidentiality of information and relevant data mutually agreed to be regarded as such" (Dept. Admin. Order No. 96-20, *supra* note 70, at §8).

85. In the case of the Kanis, Anuradha, an attorney from New Delhi, India, who closely researched the Kani model for the Foundation for International Law and Development (FIELD), reported that the tribes regarded their knowledge of the Arogyapacha plant as a sacred tribal secret. Therefore, publication or other disclosure of such information should have been explained prior to initiating the project in order to avoid unwanted disclosure. *See Market Realities*, *supra* note 46.

86. The following are examples of requirements to respect community rights from tribal codes, institutional guidelines, and national and international laws and proposals:

(a) "Research must avoid social disruption. Research must respect the privacy, dignity, cultures, traditions and rights of aboriginal people." (Inuit Tapirisat of Canada, *supra* note 54, at 191, 194);

(b) all consultations must be "respectful of the culture, laws and representative organizations of indigenous people" (Tobin, et al., *supra* note 69, at 201);

(c) an access-seeker must provide a "categorical statement that said activity to be conducted in their area/s will not in any way affect their traditional use of the resources" (Dept. Admin. Order No. 96-20, *supra* note 70, at §8).

87. *See generally* International Labour Organization, Convention No. 169, Art. 6.2; U.N. Draft Declaration on the Rights of Indigenous Peoples, U.N. Subcommission on Prevention of Discrimination and Protection of Minorities, Res. 1994/5, Part 5–6, U.N. Doc. E/CN.4/Sub.2/1994/56 (1994).

88. The following are examples of provisions regarding community rights to suspend the project:

(a) "If during the research, the community decides the research is unacceptable, the research should be suspended." (Inuit Tapirisat of Canada, *supra* note 54, at 191, 194);

Policy Considerations: This is an explicit right of local communities in many countries. If the community cannot suspend research when it becomes unacceptable, it loses significant negotiating power and ultimately its ability to protect its culture and environment. On the other hand, if a community can stop the project at any time for any reason, the other party may be reluctant to invest significantly without certainty of access. Therefore, some countries have specified acceptable reasons for suspensions of projects, such as protection of culture or environment and failure to complete benefit sharing or other contractual obligations.

(12) *All parties must act in good faith.*[89]

Policy Considerations: At a minimum, this means that consent cannot be obtained through bribery, threats, or coercion.[90] Good faith could be defined by common law contractual duties of good faith or in part by the duty discussed above to respect the privacy, dignity, culture, traditions, and rights of the community.[91]

(13) *Consultations should be sufficiently funded to enable communities to disseminate information, contract necessary technical and legal support, and attend necessary decision-making events.*[92]

(b) local communities have the right to refuse access to their biological resources, innovations, practices, knowledge and technologies where such access will be detrimental to the integrity of their natural or cultural heritage; Local communities shall have the right to withdraw consent or place restrictions on the activities relating to access where such activities are likely to be detrimental to their socio-economic life, or their natural or cultural heritage (African Model Legislation, *supra* note 54, at III(4)).

89. The following are examples of good faith requirements in tribal codes, institutional guidelines, and national and international laws and proposals:

(a) All consultations must be carried out in good faith; consultations should not involve "any threat of economic force or retaliation or any other form of force as a means to influence acceptance" of any part of the agreement (Tobin, et al., *supra* note 69, at 201);
(b) All parties "must not engage in bribery or making false promises" (Pew Scholars Initiative, *supra* note 54, at 190-91).

90. At times even well-meaning researchers do not act in good faith when obtaining PIC. In an abstract submitted by the TBGRI to the Executive Secretary at the third meeting of the Conference of the Parties for the Convention on Biological Diversity (TBGRI Abstract), research scientists divulged that Kani guides had been extremely reluctant to disclose any information about Arogyapacha, a sacred plant used by the tribe. The TBGRI Abstract also acknowledged that in order to encourage the Kanis to reveal their knowledge, researchers convinced the tribes that any information they received from the Kanis would not be misused. The Kanis' eventual disclosure to researchers was a product of coercion and faith that the TBGRI was not acting in a purely self-interested manner. *See Market Realities*, *supra* note 46.

91. *See* requirement 10 of the proposed procedural requirements, *supra* Part IV.B.

92. The following are examples of funding requirements and provisions for legal counsel:

(a) Consultations should be sufficiently funded, by the access-seeker when necessary, in order to enable indigenous communities "to attend relevant decision-making fora, prepare commentaries on technical documents and diffuse information pertaining to the relevant activity amongst its people, as well as to contract necessary technical and legal support services." (Tobin, et al., *supra* note 69, at 201);

Policy Considerations: Technical support is vital for communities when negotiating mutually agreed contractual terms and understanding complex concepts such as intellectual property ownership and benefit-sharing.[93] However, traditional communities may be suspect of legal representation provided by the other negotiating party. Therefore, government-recommended attorneys or non-governmental organizations could aide in providing such counseling. The Philippines approaches this issue by requiring that a governmental or non-governmental group sign all PIC certificates as a witness.[94]

(14) *All consultations should be recorded and documented in written form*; at a minimum the draft agreements should be documented in written form.[95]

Policy Considerations: Writing provides more legal certainty for both parties, but drastically changes the nature of the negotiating relationship between the parties. In some cases it may compromise the necessary informal relationship academic researchers have with traditional communities. Furthermore, many traditional communities regard contracts as suspect given the history of exploitation of many indigenous groups. However, commercial agreements should always be recorded to provide proof of benefit-sharing arrangements.[96]

(15) *Consent must be sought adequately in advance*.[97]

(b) the access seeker should provide legal representation for the local community during consultations and negotiations (proposed in *Market Realities*, *supra* note 46);

(c) "A representative/s of the IACBGR and/or non-government organizations/people's organizations may participate in the conduct of activities . . . , and shall sign as witnesses in the PIC Certificate" (Dept. Admin. Order No. 96-20, *supra* note 70).

93. In the USP-Verata Agreement, USP was required to provide free legal help to the Verata to advise them on all aspects of the negotiation process. Additionally, a representative of the research project was required to be present at all council meetings to inform the council on the project. *See* ENVIRONMENTAL POLICY STUDIES WORKSHOP, *supra* note 44, at 53.

94. Dept. Admin. Order No. 96-20, *supra* note 70, §5.

95. The following are examples of requirements to record in written form all consultations and agreements between the access-seeker and the community:

(a) All consultations should be recorded with precision so that indigenous concerns are well documented and taken into consideration in decision-making processes. (Tobin, et al., *supra* note 69, at 201);

(b) "Applications for access to genetic resources through prior informed consent and decisions by the competent authority(ies) to grant access to genetic resources or not shall be documented in written form." (Bonn Guidelines, *supra* note 54, at 38).

96. The team of TBGRI researchers who continued the Arogyapacha project in India, for example, failed to document their intentions and their promises to pay the Kanis half of any profit received from the development of Arogyapacha until the project was well underway. *See Market Realities*, *supra* note 46.

97. The following are examples of temporal requirements for PIC within national and international laws and proposals:

(a) "Prior informed consent is to be sought adequately in advance to be meaningful both for those seeking and for those granting access. Decisions on applications for access to genetic resources should also be taken within a reasonable period of time." (Bonn Guidelines, *supra* note 54, at 38);

Policy Considerations: Enough time should be allowed for communities to study and discuss the proposed activities between themselves.[98] Ideally, a time period would accommodate the needs of researchers, while not pressuring communities to make ad hoc decisions.[99] Although flexibility may encourage research, it can also result in pressure on local communities where unequal power arrangements exist.

(16) *The sources of all genetic material and knowledge should be acknowledged*, indicating the community and geographic origin.[100]

Policy Considerations: Acknowledgment of the source of resources and knowledge allows communities to maintain some right of control over their use and aides in monitoring intellectual property claims and enforcing benefit-sharing requirements.

V. THE ROLE OF GOVERNMENTS WITHIN ACCESS LEGISLATION

Governments must decide what role they will take within access agreements between indigenous parties and private or institutional parties. A range of roles is possible under the CBD, from the government as a mandatory party to any

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(b) "Action on the proposal shall be made only after 60 days has lapsed after a copy of the proposal is received by the persons concerned." (Executive Order No. 247, *supra* note 54, at § 4).

98. In India, TBGRI, although well intentioned, disclosed the full implications of the project only after the original scientists unilaterally initiated the project. They still maintain that the tribe was involved and informed throughout the planning stages. *See Market Realities*, *supra* note 46 (*citing* Benefit Sharing Model Experimented by Tropical Botanic Garden and Research Institute (TBGRI), A National Center of Excellence on Tropical Plant Diversity, Ministry of Environment & Forests, Government of India, *at* http:// www.biodiv.org/chm/techno/Casestudies_pdf/India.PDF (last visited June 30, 2000)); R.V. Anuradha, *Sharing with the Kanis: A Case Study from Kerala, India*, *at* http://www.biodiv.org/chm/techno/casestudies_pdf/Kanis.pdf (last visited June 30, 2000).

99. Some countries, such as the Philippines and Bangladesh, set minimum time periods for local communities to give their consent (i.e., PIC cannot be granted for 30 to 60 days). In the Philippines, such procedures have been criticized as "expensive and time consuming, discouraging any scientific or commercial exploration in the country." Charles V. Barber et al., *Developing and Implementing National Measures for Genetic Resources Access Regulation and Benefit Sharing*, *in* BIODIVERSITY AND TRADITIONAL KNOWLEDGE; EQUITABLE PARTNERSHIPS IN PRACTICE 407–11 (Sarah A. Laird. ed., 2002). In particular, it was suggested that procedures require fewer trips to remote areas to get consent and that the period of 60 days be shortened. *Id.*

Other countries, such as Fiji, leave the process open for the parties to decide. The USP-Verata agreement in Fiji required that the community be informed of all pursuant negotiations regarding development of the samples and involvement of third parties and be given ample time to respond. However, no time period was set for such consultations. *See* ENVIRONMENTAL POLICY STUDIES WORKSHOP, *supra* note 44, at 53.

100. The access seeker should acknowledge the source of all products derived from genetic resources and traditional knowledge originating from the local/indigenous community; commit to indicating the community with whom research was conducted in all publications or other means of disclosure, as well as the products resulting from the research, identifying both the material collected as well as the traditional knowledge accessed, in order to ensure that such information is registered as originating from that community. (Araújo, *supra* note 54, at 85, 97-98).

agreement, to the government as a passive enforcer of contracts.[101] However, the structure of governmental involvement is particularly important in assuring that detailed PIC requirements will be effective in achieving their goals in practice.

Governments must confront a number of central policy issues when deciding what role is appropriate, including whether a central agency should be created; how such an agency would be composed, and who it would be accountable to; how indigenous and local communities will be involved in government decision making; in what form governments will actively intervene in projects; and how any PIC policy will be funded.

A. SHOULD A CENTRAL AGENCY BE CREATED?

The lack of coordination between various ministries complicates community autonomy and can discourage access-seekers from approaching communities. Governments should streamline the process between government bureaucracies, allowing more time to be spent consulting with communities and less between agencies. The CBD Working Group on Access and Benefit Sharing (Working Group) has recommended that governments designate one national focal point for access and benefit-sharing that would inform access-seekers on, among other things, procedures for acquiring PIC and the relevant stakeholders that must be consulted.[102] The Working Group has suggested that a national authority be responsible for advising the negotiations process, monitoring and evaluating access agreements, and developing mechanisms for indigenous and local communities to effectively participate.[103]

National governments should also clarify the role of state and local governments in the decision-making process. In Brazil, for example, state governments have passed their own laws regarding access to genetic resources and traditional knowledge.[104] The Working Group has emphasized that "[t]he competent national authorit[ies] that have the legal power to grant prior informed consent may delegate this power to other entities, as appropriate."[105] Therefore, state or local governments could have the power to grant PIC for access to genetic resources if that power were delegated or otherwise granted by the national government. Of course, under the CBD, the powers that national governments may delegate do not encompass the rights of communities to grant PIC over their traditional knowledge.

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101. *See generally*, Bonn Guidelines, *supra* note 54; Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. WIPO, *Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Genetic Resources and Benefit-Sharing*, 2nd Sess., Geneva, U.N. Doc. WIPO/GRTKF/IC/2/3, Sept. 10, 2001.

102. Bonn Guidelines, *supra* note 54.

103. *Id.*

104. *See* Lei Estadual N° 1235, Acesso A Recursos Genéticos. (July 9, 1997) (Acre, Braz.); Lei N. 0388/97, Dispõe sobre os instrumentos de controle do acesso á biodiversidade do estado do Amapá de dá outras providências. (1997) (Amapá, Braz.), *available at* http://www.grain.org/brl/region-asia-brl-en.cfm).

105. Bonn Guidelines, *supra* note 53, at 13.

B. HOW SHOULD INDIGENOUS AND LOCAL COMMUNITIES BE INVOLVED?

Article 8(j) of the CBD effectively creates a duty on Parties to facilitate the participation and inclusions of traditional knowledge holders in decision-making regarding such knowledge.[106] The CBD Working Group on Article 8(j) and Related Provisions (Article 8(j) Working Group) has recommended that governments ensure "indigenous and local community representation on any statutory or other bodies established to provide advice or oversee any activity related to the conservation and sustainable use of biological diversity."[107] The Article 8(j) Working Group specifies the establishment of advisory boards or committees as a favored mechanism to ensure such participation.

Whether indigenous and local communities are represented through advisor bodies, committees, or other direct representatives, the communities should determine who represents them.[108] Election by communities, rather than appointment by a government official, would create both legitimacy and accountability. Analyzing such centralized institutions in Australia and the Philippines, Goldzimer observed that "[i]n both cases, the lack of accountability of these institutions to their indigenous beneficiaries was one of the main reasons for their failure to effectively implement prior informed consent."[109]

C. WHAT ROLE SHOULD GOVERNMENT TAKE?

1. Intermediary

The role of government bodies as intermediaries might take two forms: active negotiating agents or passive supervisors. An agent would negotiate on the community's behalf and facilitate a PIC process. Such a body should have the necessary technical and legal capacity, as well as great familiarity and accountability with local communities.[110] A supervising body could observe negotiations and PIC, and provide support as necessary. Such a body might provide a safeguard for abuse and intimidation, without running the risk of imposing its own practices and views on communities. Such a supervising body might also facilitate PIC by housing information on the structure and practices of both communities and access-seekers and could be the first recourse for complaints, questions, or concerns. Non-governmental bodies might fill either of these roles when governments do not have the capacity or legitimacy to fulfill such a need.

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106. Meeting Docs: Participatory Mechanisms, *supra* note 24, at para. 7.

107. *Id.*

108. *See* Meeting Docs: Participatory Mechanisms, *supra* note 24, at para 13.

109. AARON MARC GOLDZIMER, PRIOR INFORMED CONSENT OF PROJECT-AFFECTED INDIGENOUS PEOPLES: AN ANALYSIS OF CASE STUDIES 35 (2000).

110. One example of such a body is the Northern land Council in Australia. *See id.* at 36–37.

2. Capacity Builder

Arguably, governments have a duty under Article 8(j) of the CBD to develop the capacities of indigenous and local communities to play equal roles in any decision-making process regarding traditional knowledge.[111] Capacity building programs could include the provision of "legal and scientific advice [or] the help of a linguist and/or anthropologist, in order to accurately assess: (a) How their traditional knowledge is to be used (practical use, publication); (b) The implications of such use; (c) What conditions they should attach to its use (secret/sacred knowledge); (d) The most suitable means to protect their traditional knowledge (e.g., legal contract, mou [memorandum of understanding]); and (e) How they can benefit from its application."[112] More generally, capacity programs could focus on building the skills necessary within communities to conduct inventories of genetic resources or traditional knowledge, negotiate contracts, draft legal documents, and navigate through relevant intellectual property systems.[113] Again, non-governmental organizations should be encouraged to serve this role as well.

3. Monitor

Once a PIC regime is in place, a monitoring mechanism must be instituted for any real efficacy. The Article 8(j) Working Group recommends that governments set up committees composed of primarily indigenous representative that can act as a procedural monitoring and review body.[114] Additionally, the Article 8(j) Working Group proposes that governments facilitate the exchange of information between communities, allowing them to share experiences and information regarding repeat players and intermediaries.[115]

4. Enforcer

Enforcement mechanisms have drastic effects on the effectiveness of PIC. Governments should take an active role in punishing noncompliance and avoid placing this burden entirely on communities. However, some redress for harm should be available to communities through the courts. At a minimum, projects should be subject to cancellation if access-seekers do not comply with PIC requirements or mutually agreed upon terms.[116] In addition, governments may impose administrative or criminal sanctions for noncompliance.[117] To facilitate

111. *See* Meeting Docs: Participatory Mechanisms, *supra* note 24, at para. 5.

112. *See id.* at para. 19.

113. *See* Bonn Guidelines, *supra* note 53.

114. *See* Meeting Docs: Participatory Mechanisms, *supra* note 24, at para. 12-16.

115. *See id.* at para. 22.

116. *See* Goldzimer, *supra* note 108, at 37.

117. "Parties may take appropriate effective and proportionate measure for violations of national legislative, administrative or policy measures implementing the access and benefit-sharing provisions of the Convention on

enforcement efforts, PIC requirements should be clearly defined. Flexibility in requirements may be necessary to accommodate the diverse needs of communities, but may also create ambiguity and conflicting interpretations.[118]

D. HOW SHOULD THESE GOVERNMENT PROGRAMS BE FUNDED?

Funding structures are vital to achieving effective, accountable, and legitimate government programs. If funds are insufficient, programs may not be able to implement all tasks effectively. On the other hand, if funds are derived from access fees, there may be incentives to accommodate access-seekers, thus compromising the legitimacy of the government program.[119] Therefore, any government body, whether acting as a neutral body or an agent of communities, should be financially independent.[120]

Thus, governments promulgating PIC legislation or regulation under the CBD have many choices as to the role they will take in negotiations. Ultimately States must find a compromise that can guarantee State oversight and legitimacy, avoid bureaucratic bottlenecks, and secure the rights of traditional communities. However, not all issues can be addressed through protocols and the institutional structure of government.

VI. REMAINING CHALLENGES TO ENSURING COMMUNITY PARTICIPATION AND EMPOWERMENT UNDER THE CBD

Despite the best efforts of States and other institutions, some challenges will inevitably remain to achieving fair and equitable agreements regarding traditional knowledge and genetic resources. Some of these may be addressed by governments through means other than the promulgation of access legislation or other government access programs. Other obstacles may remain despite any governmental efforts.

A. CREATING CONDITIONS FOR EFFECTIVE PIC

Governments must address a number of issues through means other than the CBD implementing legislation. First, governments should seek to clarify what constitutes traditional knowledge and what lies in the public domain under

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Biological Diversity, including requirements related to prior informed consent and mutually agreed terms." Bonn Guidelines, *supra* note 53, at 61.

118. *See* Goldzimer, *supra* note 108, at 37.

119. *See id.* at 36.

120. The Article 8(j) Working Group stated that implementation of Article 8(j) "requires both substantial and secure levels of funding." They suggested the Global Environmental Facility and the Voluntary Fund for Indigenous Populations as potential sources of funds. *See* Meeting Docs: Participatory Mechanisms, *supra* note 24, at para. 88.

national intellectual property legislation.[121] Resolution of these issues helps reduce ambiguities surrounding who may grant PIC and when it is required. These issues are complicated by the fact that similar traditional communities may reside in separate but neighboring countries with different definitions of what lies in the public domain and distinct access procedures. Thus a regional approach, as has been taken by the Association of Southeast Asian Nations (ASEAN), the Organization of African Unity (OAU), and the Andean countries, is ideal for creating consistency and predictability.

Second, the exercise of PIC by traditional communities is inherently tied to the territorial and cultural rights of such communities. Without recognition of community rights over their own land, culture, and knowledge, PIC becomes irrelevant. Therefore, governments must recognize the rights of traditional communities within their own national body of laws. A number of countries have recently passed laws specifically recognizing these community rights.[122]

B. REMAINING CHALLENGES

A number of obstacles will remain, regardless of state efforts. First, it is often difficult to recognize and predict the implications of a project. Despite the best intentions by a researcher, information can be appropriated and misused contrary to the wishes of communities. Second, it is difficult to "communicate complex abstract and culturally alien concepts across cultural differences created by difference in nationality, ethnicity, socio-economic class, level of academic instruction or personal, historical or social experience."[123] Although governments should take an active role in building capacity within communities to assess the complex legal choices in front of them, it is unclear how effective these efforts will be.[124] Third, unequal power relationships are generally unavoidable during negotiations; it may be virtually impossible to achieve truly free and informed consent in some cases.[125] Power relationships are especially questionable when basic rights of communities are not generally recognized or past human rights abuses have occurred. These issues are not listed to imply that PIC is not a worthy pursuit, but rather to ensure that these concerns are woven into legislation as much as possible.

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121. The detailed definition of what constitutes traditional knowledge and what lies in the public domain is generally left to national legal interpretations under TRIPS. *See* WIPO, *Traditional Knowledge – Operational Terms and Definitions* 3, WIPO/GRTKF/IC/3/9 (May 20, 2002).

122. For a list and copies of national legislation on community rights, see Genetic Resources Action International, *Community Rights*, *available at* http://www.grain.org/brl/comm-brl-en.cfm (last visited June 1, 2003).

123. Some researchers have "conducted workshops and showed audio-visual materials to introduce and discuss out field techniques and the characteristics of such research products as academic publications and herbarium specimens" in order to confront this challenge. *See* Alexiades & Peluso, *supra* note 72.

124. *See* Meeting Docs: Participatory Mechanisms, *supra* note 24, at 4.

125. *See* Alexiades & Peluso, *supra* note 72.

VII. CONCLUSION

Despite international and national efforts, indigenous and local communities face many challenges to achieving control over access and use of their traditional knowledge and genetic resources. Truly effective implementation of PIC could provide a mechanism for community involvement, participation, and decision-making regarding access to such knowledge and resources. But so far, few attempts have been made to elaborate what PIC will mean in practice. Such uncertainty is detrimental to both communities and potential access-seekers.

This article has sought to examine the development of PIC as a mechanism for empowerment over decision-making, identify potential substantive and procedural requirements for PIC, elaborate potential roles for government bodies, and discuss remaining challenges to community empowerment over traditional knowledge and genetic resources. Specific substantive disclosure requirements, as well as procedural rules, are vital to effective community participation and consent policies. In addition, governments should take active roles in delegating oversight authority, facilitating negotiations, building community capacity, and monitoring and enforcing PIC. Such government efforts will be more legitimate and effective if they include community representation, are sufficiently and independently funded, and are informed by the challenges traditional communities face in achieving an equal place at the negotiating table. These proposals are aimed at informing communities, institutions, and governments as they design their own systems of guidelines under the CBD.