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Politics, Culture, and Governance in the Development of Prior Informed Consent in Indigenous Communities

by Joshua P. Rosenthal¹

Why did an early effort to build an ethical bioprospecting relationship with indigenous people in Peru survive when a more sophisticated approach with arguably better opportunities for indigenous communities in Mexico later foundered in a sea of criticism? Two projects funded under the International Cooperative Biodiversity Groups (ICBG), one working with Aguaruna people in Peru and another working with Maya people in Chiapas, Mexico, have struggled with identification of appropriate representation of community interests and with concerted campaigns by nongovernmental organizations (NGOs) to halt their efforts despite broad interest among the indigenous communities they contacted. The Peru ICBG ultimately succeeded in developing credible working partnerships and carried the project through to completion, while the Maya (Mexico) ICBG became mired in defense of its approach to prior informed consent and was terminated early. In this paper I summarize relevant aspects of the history of these two landmark projects and draw some lessons about the role of culture, politics, and local governance in the differing outcomes of their efforts. In particular, I point to the role of preexisting and broadly representative indigenous governance as a key factor in determining the feasibility and integrity of prior informed consent for the use of traditional knowledge. This conclusion is important because it suggests concerted movement away from the traditional model of individually oriented ethnobotanical studies for bioprospecting that involves indigenous communities toward one that is structured around institutional relationships.

The central thesis of the ICBGs is that research and development projects designed to discover new pharmaceutical precursors in developing countries can, carefully constructed and equitably managed, produce benefits to health, conservation, and sustainable development. Since 1993 several agencies of the U.S. government—the National Institutes of Health

(NIH), the National Science Foundation (NSF), and the U.S. Department of Agriculture (USDA)—have supported eight such projects in 12 countries in Asia, Africa, and Latin America. A critical component of the program is the development of ethically sound partnerships among diverse organizations, including the indigenous communities involved in or significantly affected by a project (Rosenthal et al. 1999). In this paper I aim to analyze the context, basic approaches, and results of efforts by the Peru and Maya ICBGs to develop prior informed consent and to negotiate access and benefit-sharing agreements with the Aguaruna and Maya indigenous communities in 1995–99 and 1998–2001, respectively.

In the past two years this journal has hosted an important debate on the potential cultural costs that may accrue to indigenous groups such as the Maya and the Aguaruna that participate in modern scientific projects like the ICBGs (Nigh 2002; Anderson 2002; Greene 2004). The benefits that may accrue to indigenous groups from such projects are also a topic of debate (for reviews see Barsh 2001; Moran, King, and Carlson 2001; Laird 2002). I do not attempt to treat these important questions in any depth here. Rather, my aim is to identify major contextual factors that can facilitate or inhibit the development of cooperative research projects with indigenous peoples. I write from the perspective of a research administrator with a fundamental belief that increasing interactions of indigenous societies with the Western scientific community are not only inevitable in this shrinking world but capable of yielding substantial social gains for both. The critical question becomes how to develop research projects that minimize risks to participants and maximize the benefits to indigenous societies and the global community.

Prior informed consent by research subjects is a fundamental part of the answer to this question. However, Emanuel et al. (2004) and others have rightly pointed out that prior informed consent of research participants does not in itself make human-subjects research ethical, and they provide a range of important questions relating to the objectives and

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design of a project that need to be addressed before one considers consent issues. Ethical research (1) generates useful knowledge, (2) is scientifically rigorous, (3) chooses research subjects fairly, (4) has a favorable risk-benefit ratio, (5) is independently reviewed, (6) maintains the privacy and monitors the well-being of participating individuals, and, finally, (7) requires the prior informed voluntary consent of the participants. Each of these issues is a major topic in itself. I focus on prior informed consent here because it is the operational locus for some of the most important concerns that underlie the philosophical and political environment of bioprospecting research involving indigenous societies.

The regulatory requirement of freely given and informed consent to participate in research is based on ethical principles including respect for persons, human dignity, and autonomy (NBAC 2001). The concept of informed consent was developed mainly for clinical research. In this context the aim is to ensure that research subjects understand the risks of potential harm that they may be exposed to as well as the potential benefits that may accrue to them, to others, and to medical science (CIOMS 1993; NBAC 2001). In recent years the concept has been adopted and adapted as a regulatory element of environmental protection (e.g., the Rotterdam Convention), including environmental impact assessments relating to land use or other development projects that involve Native American communities (Hardison 2000a). In contrast to most clinical research, environmental applications generally receive consent at the community or nation-state rather than the individual level. Physical anthropologists are now grappling with informed-consent issues in relation to research in human population genetics (see, e.g., Greely 2001), and applications in cultural anthropology have been addressed briefly in the American Anthropological Association's Statement on Ethnography and Institutional Review Boards (AAA 2004). While the AAA's statement recognizes that ethnographic research can produce harm in certain situations, it asserts that because most ethnographic research is noninvasive and focuses on the normal lives of people it poses risks no greater than those ordinarily encountered in daily life.²

Research on traditional knowledge and genetic resources from plants, animals, and microorganisms has stimulated a parallel, if more political, discussion of prior informed consent. While there are several types of harm, including social conflict (see, e.g., Greene 2004), that may affect communities or individuals that collaborate with ethnobotanists and other scientists in a bioprospecting project, these are not the concerns driving the debate. The principal concerns relate to the possibility of exploitation of local people for scientific and commercial purposes. Exploitation is a danger in any scientific

2. The AAA statement does not specifically address knowledge ownership issues but rather offers a general statement regarding informed consent procedures as they relate to institutional review boards. It points out that written consent is not always appropriate and indicates that community authorities sometimes need to be consulted before individuals are approached.

research project involving human subjects because the principal interest of the investigators—scientific knowledge—is generally not as available or important to the lay participants (Benatar 2004). However, bioprospecting is particularly suspect in that significant economic benefits may accrue to that rare venture that leads to a commercially successful pharmaceutical drug. The distribution of economic benefits in today's commercial and intellectual-property frameworks generally undervalues the contributions of biodiversity and traditional knowledge and leaves indigenous societies that contribute to them particularly vulnerable to exploitation.

Driven by long-standing concerns about exploitation and coupled with interest in promoting incentives for conservation, the sharing of benefits with participating communities and nations is one of the principal objectives of the UN Convention on Biological Diversity. Space constraints do not allow for a discussion of benefits here, but the emerging consensus 12 years into the experiment in modern "ethical bioprospecting" framed by the convention is that, while commercially successful pharmaceutical products are a relatively rare outcome of such ventures, a variety of more modest but often important monetary and nonmonetary benefits can generally be developed (Rosenthal et al. 1999; Beattie et al. n.d.).

Discussions of prior informed consent related to bioprospecting under the convention have tended to be legalistic and focused on national authorities. Consent has been identified as a basic requirement for access to genetic resources and associated traditional knowledge. In the context of genetic resources it is defined by the International Union for Conservation of Nature and Natural Resources (IUCN) guide to the convention as "(1) consent of the contracting party which is the genetic resource provider (2) based on full and complete information provided by the potential genetic resource user (3) prior to consent for access being granted" (Glowka, Burhenne-Guilmin, and Synge 1994, 105). "Parties" are nation-states. The Bonn Guidelines on Access and Benefit-sharing have modestly elaborated upon these principles. A widely accepted definition of prior informed consent in relation to traditional knowledge has yet to emerge. What is clear is that, for the reasons outlined above, it is especially concerned with discussion and negotiation of benefits.

The ICBG program approaches the questions of prior informed consent on the basis of three principles. First, it acknowledges the above-described implications of communal origin and stewardship of traditional knowledge and recognizes that community interests must be respected. Second, it recognizes the possibility of harm to or exploitation of community interests. Third, prior informed consent is part of a multipurpose outreach effort that includes raising awareness of the potential global values of biodiversity and traditional knowledge as well as negotiation of benefit sharing. Standard practice is that prior informed consent be developed at the community level before seeking it from individuals (NIH, NSF, and USDA 1998). Finally, it is assumed from the beginning that *if prior informed consent is properly developed,*

indigenous peoples will be able to make intelligent decisions about the risks and benefits of participation.

In the remainder of this paper I focus on several important dimensions of the social context that make prior informed consent feasible or not in bioprospecting arrangements with indigenous peoples: culture, governance, and politics.

Culture, Governance, and Politics in Prior Informed Consent

While there is likely to be considerable variation among indigenous peoples regarding the degree of sharing/secretcy of knowledge and the role of specialist healers, it is clear that in most cases a significant portion of traditional knowledge relevant to drug discovery is communally held (Posey and Dutfield 1996; Johns, John, and Kimanani 1996; Berlin and Berlin 1996; Reyes-García, Godoy, and Vadez 2003). Thus, if we recognize communal origins and stewardship of knowledge of healing practices, then for many uses by outsiders such knowledge may be treated as a communal resource.

Nonetheless, arriving at consensus on what constitutes the relevant “community” that can legitimately make decisions regarding sharing of knowledge is a significant challenge. Hayden (2003) discusses the problem in an extreme case in which the knowledge involved (medicinal markets in Mexico) is so fluid and cosmopolitan that identification of “community” becomes arbitrary. Even in the situation more commonly of interest to ethnobiologists—in which an ethnic group, the plants they use, and the knowledge that links the two co-occur (e.g., Johns, John, and Kimanani 1990)—identifying the relevant social unit with which to collaborate is challenging. Is it the village, the municipality, the clan, the entire language group, or all those who inhabit the bioregion? Ethnographic studies that help determine the degree to which relevant knowledge is held in common across these groups (e.g., Johns, John, and Kimanani 1990; Reyes-García, Godoy, and Vadez 2003) may be a useful starting point in some cases. However, this conceptually appealing academic approach is unlikely to be practical for many potential partnerships because of the time and expense involved. Moreover, it is unlikely to be satisfying to many stakeholders and outside commentators because of governance and political issues that may impinge on the definition of the relevant unit of “community.”

The legal authority to give informed consent with regard to genetic resources is defined in the UN Convention on Biodiversity at the minimal level of the nation-state (UNEP 1992, art. 15). For some nations, such as Argentina, significant authorities for resource management are identified in the constitution at the province/department/state or lower level, but for the most part the implications for genetic resources are not yet articulated in regulations. Legal assignment of consent authority to indigenous communities has been slow in many countries because of preexisting disputes over land ownership or use rights between indigenous peoples and governments.

However, the convention (UNEP 1992, art. 8j; UNEP 2002, art. 4. C.) strongly encourages and most countries recognize at some level the principle that prior informed consent must be obtained from indigenous and local communities for the use of traditional knowledge associated with biodiversity. Frequently this principle is extended to cover rights to use the associated genetic resources with or without use of the knowledge.

Even where prior informed consent is not legally required, most scientists wishing to use traditional knowledge are willing and often eager to go through culturally appropriate channels to obtain it. However, their ability to do so is greatly influenced by the degree to which the process is clearly defined and communicated to them and possible to achieve with reasonable effort. A number of both general and ethnicity-specific models for the process of obtaining prior informed consent are emerging (see Laird 2002 for examples). The principal problem for the research community is the absence of a clearly delineated governance hierarchy in many indigenous societies that formally establishes *for the outside world* what level of an indigenous community or nation has the authority to give consent. Moreover, the self-defined authorities of some indigenous groups overlap and may change over time (Brown 1993; Posey and Dutfield 1996; Greene 2004). Frequently, overlap occurs because self-defined “communities” may share language, knowledge traditions, and land-use rights with other such communities. The temporal fluidity of some authorities may derive from strong traditions of family and village or clan autonomy (Brown 1993) or other factors such as nomadism or intermarriage. Finally, indigenous governance systems are rarely acknowledged formally in national laws. Consequently, a research scientist is rarely secure that the consent granted by an indigenous society through the locally identified mechanism is authoritative or enduring.

In addition to the broad areas of culture and governance, a third important determinant of the feasibility of obtaining prior informed consent is politics at local, national, and international levels. Tensions among indigenous communities, between those communities and national governments, and among national governments in discussions around the Convention on Biodiversity and the World Intellectual Property Organization (WIPO) make it difficult to achieve clear and reasonable dialogue on issues such as intellectual property rights and benefit sharing. Emotionally charged issues related to human rights, land tenure, the ability of poor communities to exploit the patent system, and the morality of patenting inventions derived from study of living organisms frequently inject themselves into the debate. All of these levels of political turmoil enter both public and private discussions around high-profile projects such as the ICBGs.

Below, I outline the efforts to develop prior informed consent and negotiate research and benefit-sharing agreements in the Peru ICBG and in the Maya ICBG and discuss the roles of culture, governance, and politics in determining their outcomes. Finally, I explore the implications of these expe-

riences for ethnobotany, anthropology, and other research with indigenous peoples.

Prior Informed Consent in the Peru ICBG (1994–99)

The Peru ICBG began to deal with these complex issues in 1994, when there was very little formal guidance on prior informed consent from the anthropological community, the Convention on Biodiversity, national governments, or indigenous societies. The Peru ICBG was a partnership among Washington University, the Universidad Peruana Cayetano Heredia, the Universidad San Marcos, and the Searle-Monsanto Company. It aimed to integrate biodiversity conservation and community development with development of new therapeutic agents against a wide range of infectious and chronic diseases of relevance to both Peru and the United States. It focussed primarily on tropical plants that were used by traditional healers among the Aguaruna peoples of the Alto Marañón region of northern Peru.

The initial plan was to work with a small clan-based Aguaruna organization called the Organización Comunal de Comunidades Aguarunas del Alto Marañón (OCCAAM) that Dr. Walter Lewis of Washington University had encountered in previous fieldwork. The ICBG funding agencies, NIH, NSF, and USAID, required that agreements and permits be in place before the grant could be awarded. A short time frame (four months) was imposed because the government budget calendar required that NIH make the award by the end of the fiscal year. Under this time pressure and given logistical and linguistic difficulties in communication between OCCAAM and the universities, the investigators chose to make the first formal arrangement with another NGO, the Consejo Aguaruna y Huambisa (CAH), which appeared to be larger, better-organized, and easier to communicate with than OCCAAM. A letter of intent was signed between the CAH and the three university partners. Within a few months of establishing this partnership a formal complaint was sent by representatives of the CAH to the lead funding agency, the Fogarty International Center of the NIH, asserting that prior informed consent had not been properly obtained. The principal complaint of the CAH was that it had not been informed in an appropriate and timely manner of the development of a linked license option agreement between Washington University and Searle-Monsanto to test and develop any discoveries using Peruvian samples and associated knowledge. Furthermore, it was dissatisfied with the terms of that agreement. The funding agencies responded by imposing a temporary moratorium on drug discovery activities in the project, conducting an investigation into the matter, and calling on the investigators to resolve the conflict with the involvement of the Peruvian government and outside expertise.

The funding agencies concluded that mistakes had been made on all sides, that there was insufficient communication and stakeholder involvement, and that the limited time al-

lowed for the establishment of the agreements was a significant contributor to the problems. The agencies provided the Peru ICBG limited financial support and a more flexible time frame to rebuild the project, starting with a rigorous consent process, and encouraged the investigators to be as inclusive as possible both in this process and in inviting multiple Aguaruna organizations to participate in the project. The project directors were also advised that all parties should have competent and independent legal counsel to represent their interests during the negotiation process. In the year and a half that followed, three clan-based Aguaruna federations (OCCAAM, the Federación Aguaruna del Río Domingusa [FAD], the Federación de Comunidades Nativa Aguaruna del Río Nieva [FECONARIN]), under the leadership of their national umbrella organization, the Confederación de Nacionalidades Amazónicas del Perú (CONAP), participated in a series of workshops and meetings held in Lima, provincial cities, and villages in Peru and in St. Louis. Other participants in the meetings included representatives from other indigenous organizations, Aguaruna community leaders, the Sociedad Peruana de Derecha Ambiental (SPDA), the Peruvian government, the U.S. government, the participating universities, and Searle-Monsanto, among others.

Lewis and Ramani (2003) and Greene (2004) provide more details of the informed consent and negotiation process. Of note here is that it was an iterative, redundant process representing multiple layers of Aguaruna society from national organizations and their local clan affiliates to the communities and individuals that belonged to them. This was seen as necessary in order to obtain prior informed consent from a “community” as it could best be defined in the context of Aguaruna culture and governance at that time. Notably, individuals from the Aguaruna federations, all three universities, and Searle-Monsanto were committed to making the process work. Even so, resolution of the problems would not have been possible in the absence of credible leadership by the umbrella federation and the use of a preexisting collective decision-making process of the Aguaruna called *ipaamamu* (articulated by Cesar Sarasara, leader of CONAP) for arriving at demonstrable consensus on matters of shared concern among communities. Ultimately, 55 communities represented by three local federations were represented in the process, and later a fourth federation, Organización Aguaruna del Alto Mayo (OAAM), joined the collaboration. The CAH was not invited to rejoin; I will return to this point below.

While important in setting the stage, once the process began in earnest external organizations, including international NGOs as well as the Peruvian and U.S. government agencies, became primarily observers that provided advice and reference points in existing regulations. Consent authority for the project ultimately rested in the affiliated federations under CONAP and applied to geographically restricted areas for which these organizations could demonstrate legitimacy to Aguaruna, the Peruvian government, the ICBG partners, and the global community.

The process was a landmark event for the ICBG that some consider exemplary (see, e.g., Barsh 2001; Lewis and Ramani 2003). However, it failed to achieve at least one outcome seen as desirable by the funding agencies and others. A significant group of Aguaruna clans, including the communities that continued to be members of the CAH, did not participate (Greene 2004). According to several reports, the omission of the CAH and some of the events of the first year exacerbated preexisting discord among the CAH and the federations associated with CONAP and continues to be a source of tension eight years later. Another significant unintended consequence of the project appears to have been a realignment of a number of Aguaruna communities and their federations with CONAP and away from the CAH.

The two-stage history of the Peru ICBG produced a web of agreements that evolved from a series of direct and formal negotiations among indigenous NGOs, the U.S. and Peruvian universities, and the industrial partner. These included a biological collecting agreement, a know-how license for the use of traditional knowledge, a commercial license option agreement, and subcontracts with the Peruvian universities. Lewis and Ramani (2003) and Tobin, Render, and Bannister (n.d.) discuss these agreements and the negotiations that produced them in detail. They were carefully studied in Peru and elsewhere (e.g., WIPO 2000) and used in the subsequent development of Peruvian national laws on genetic resources and traditional knowledge (Ruiz 1997).

Prior Informed Consent in the Maya ICBG (1998–2001)

The Maya ICBG proposed to build upon decades of work by the principal investigators, the anthropologists Brent and Elois Ann Berlin, with a diverse group of Mayan communities from two language groups, Tzeltal and Tzotzil, in the central highlands of Chiapas. It was a partnership of the University of Georgia, El Colegio de la Frontera Sur (ECOSUR), and Molecular Nature Ltd., a small natural-products pharmaceutical and botanical company in Britain. It proposed to develop an association called PROMAYA to incorporate Maya communities and manage a trust fund that would distribute any earnings. The aims of the project were multiple but centered on drug discovery from the plants and macrofungi most widely used by the highland Maya. Rather than work with specialist healers, the investigators chose to focus on the species most often cited by community members as useful medicinally. A substantial amount of the ethnomedical information was already in the public domain in one form or another, and a large proportion of the plants of interest were cosmopolitan weedy species.

The highland communities of Chiapas include approximately 8,000 villages representing 900,000 Maya-speaking people. They are deeply stressed by poverty, a deteriorating natural resource base, and extraordinary population growth. Communities are further riven by religious conflicts, succes-

sive attempts at agrarian reform, and divergent loyalties to the Zapatistas and the national government of Mexico (Larson-Guerra et al. 2004). The concept of a “community” in Chiapas today is the subject of intense debate (Nigh 2002; Anderson 2002; Berlin and Berlin 2005). The most generally recognized “community” is the village or *paraje*. Villages are organized into municipalities by Mexican national law, but Maya traditions of village autonomy and a lack of municipal institutional structure and truly participatory processes challenge the authority of municipalities as appropriate entities for bioprospecting-related consent. As is the case for many indigenous societies, a tradition of general communal assembly exists for decisions of generalized import, but the participants in such assemblies are self-identified and the authority of those assemblies to represent the rest of the community is a subject of debate. In contrast to the situation in Peru, there are no indigenous political organizations that exist continuously and are authorized to speak on behalf of communities in relation to local or national resource issues (Berlin and Berlin 2005).

The Maya ICBG began the development of an elaborate informed-consent protocol concurrent with the non-drug-discovery portions of its work in 1999. The early work included training Maya participants and ECOSUR students, establishing a laboratory at ECOSUR, establishing local horticultural projects (nontimber forest products and botanical gardens), translating, analyzing, and disseminating ethnobotanical knowledge to communities, collecting plant specimens for taxonomic research, and experimenting in a variety of agroecology projects focused on pest control and crop productivity. Recognizing the national stage on which they were working, the project members, led by the ECOSUR team, began the informed-consent process by organizing a national forum on Mexican experiences with bioprospecting to draw lessons from other projects. They followed with an invited general-information assembly of Maya community members, flyers in native languages, and radio spots. In addition, they put much of their proposal as well as their progress reports on the project web site at the University of Georgia and invited comments to improve their plans.

The heart of their community consent process was a one-act play performed in native languages designed by ECOSUR and Mayan project members and enacted by a group of about 20 Mayan ethnobotanical apprentices. The play depicted the aims and methods of the project, the proposed near- and long-term elements of the benefit-sharing plan, the low probability of a commercially successful drug discovery, and the more likely concrete benefits from other parts of the project (e.g., agroecology research, community gardens, etc.). The play was performed at ECOSUR for community officials and accompanying community members who responded to general and specific invitations from the group. These representatives were then given a tour of the laboratory under construction and other ICBG projects at ECOSUR and invited to ask questions. Project members subsequently offered to

visit villages to enact the play and answer questions for the entire community and, where invited, did so. After a performance of the play in a village assembly, the community was invited to participate in the project and to draft and sign a general memorandum of understanding expressing its interest. In the three-month period in which this play was enacted, 46 of the 47 *parajes* in the 15 municipalities visited signed up (Berlin and Berlin 2005).

The project's approach to the question of whom to engage was based on the generally accepted and legally defined notion of community for the highland Maya (Berlin and Berlin 2005, but see Nigh 2002 for a different view of Maya community). It focused initially on communities in which ECOSUR had had previous contacts in order to obtain a critical mass of consenting partners upon which the project would be grounded and planned to broaden participation throughout the duration of the project.

What the project did not anticipate was a concerted campaign to halt it. Several other high-profile bioprospecting projects in Mexico (Larson-Guerra et al. 2004) had begun to receive significant criticism from academics, NGOs, and the press. A confederation of local healers' organizations (Consejo de Médicos y Parteras Indígenas Tradicionales de Chiapas [COMPITCH]), in concert with international advocacy NGOs (principally the Rural Advancement Foundation International [RAFI]) launched an aggressive media, Internet, and word-of-mouth campaign that highlighted a variety of local, national, and international concerns including "patenting of traditional knowledge and biodiversity" and linked these to U.S. colonialism and the ongoing occupation of Chiapas by Mexican troops. The project's critics asserted that the prior informed consent process was invalid and therefore the expressed interest of the participating communities should be, in effect, overruled. Their basic critique was the one leveled at all bioprospecting projects—that there is insufficient legal protection of indigenous rights over genetic and intellectual resources at the national and global levels. Their more specific criticisms of the Maya ICBG consent process were (1) that the informative play omitted a description of the global policy debate about patents and traditional knowledge, (2) that the signatures on many of the community memoranda of understanding did not represent the percentage of community members required by customary law, and (3) that until all Maya-speaking communities in Mexico and Guatemala (over 2 million people) were engaged, valid consent could not be achieved (RAFI 2000).

Given the atmosphere of suspicion that surrounds bioprospecting globally, the complex history of Mexico-U.S. relations, and the long-simmering conflict in Chiapas, the objections of COMPITCH received considerable attention. The emotional appeal of its charges was greatly strengthened by the advice of media-savvy international NGOs and their ability to mount web sites, participate in listserves, and present the media with articulate "indigenous" spokespersons. The campaign reignited a national and international debate on

bioprospecting, the patent system, and the plight of the Maya of Chiapas.³ The critical questions what constitutes prior informed consent and who can legitimately provide it were lost in the media-fueled war of words that enveloped the project (Hardison 2000b). Unfortunately, the 46 relatively remote communities that signed onto the project did not play a role in this debate. Community participants were rarely presented by the press even when they had been interviewed. They did not have their own web sites or listserves to present their views. The NGO seminar that publicly evaluated the project and "rejected" it was held in Mexico City (RAFI 2000) and included no formal participation from these communities. Lacking organizational structure, these basic but distributed stakeholders did not have a visible representative body, a biopolitically savvy indigenous leader to speak on their behalf, or a medium through which to express their opinions on the regional, national, or international stage.

While there were differences of opinion within the relevant Mexican government agencies, they had been largely supportive of the project in the beginning. Not surprisingly, as the debate enflamed the national media, they became more and more circumspect. In addition to pressure from the media and NGOs, Mexican officials feared widening their already significant credibility gap with regard to the Zapatista movement. ECOSUR had applied for the first "biotechnology collections" permit in the history of the country, and after months of negotiations over the requirements of the permit during this very public debate it decided to withdraw that application. Various options for reformulating the project were considered. However, a year and a half of exhausting debate and continued disruption of ECOSUR activities, including those unrelated to the project, had taken its toll, and in 2001 ECOSUR reluctantly withdrew from the project altogether. Without a host-country institution in a leadership role, the project did not satisfy one of the minimum criteria for continued support, and the Maya ICBG grant was terminated.

The draft contracts in various stages of development by the Maya ICBG when it was terminated represented a coherent framework among scientific partners, with leverage assigned to the nonprofit organization being formed to represent the highland Maya (PROMAYA). The Benefit-Sharing and Protection of Intellectual Property Agreement outlined the objectives and responsibilities of the scientific organizations (including recognition of Mexico's sovereign rights over the genetic resources under the UN Convention) and committed them to sharing benefits equally among the four partners (including PROMAYA). The Biological Material Transfer

3. In addition to a barrage of press releases from RAFI and other NGO web sites and a few responses by the Maya ICBG, numerous other articles and commentaries appeared in Mexico in the daily newspaper *La Jornada* and the Mexican weekly *Milenio* and in the United States on National Public Radio, in the *Texas Observer*, *Time*, and *Nature*, and elsewhere. Michael Brown (2003) describes the dynamics of this media and NGO commentary.

Agreement established the basic terms under which ECOSUR would transfer samples to the University of Georgia and Molecular Nature Ltd. and tie any materials and derivatives that could enter the commercial research stream to a joint ownership and commercialization agreement that gave each partner an ownership stake in any intellectual property that emerged from the project, including veto rights over any proposed material transfer or commercial licenses. Near-, medium-, and long-term benefits for Mayan communities were outlined explicitly (Larson-Guerra et al. 2004; Berlin and Berlin 2005).

The termination of the ICBG represented the loss of a unique opportunity to attempt integrated and scientifically sophisticated ethnobotanical, biomedical, and biodiversity research and development that would be responsive to and dependent upon the participation of Chiapas Maya communities. In hindsight, the political, cultural, and governance context in which the members of the Maya ICBG chose to erect the project may have doomed it from the beginning.

Western-Style Governance as an Enabling Condition

While these two ICBGs differed in many ways, including their approaches to prior informed consent and the cultural and political context in which they worked, one factor seems fundamental in determining their different outcomes. That factor is the existence of an established, credible, and politically representative governance system of the indigenous communities involved. The preexisting federations of Aguaruna, despite internal differences, provided a foundation that gave the participating communities in Peru at least three key advantages unavailable to the participating Maya communities of Chiapas: increased autonomy, stronger ownership claims for the resources involved, and reduced transaction costs and greater stability for the partnership.

First, if indigenous communities are to find the space to negotiate on their own behalf with outsiders rather than through national governments, universities, or external NGOs, they will often need the authority that Western-style organizational and accountability systems provide. Otherwise they will continue to be susceptible to paternalistic efforts to exploit or protect their interests by the organizations they depend upon and those that identify themselves as their protectors. While an important part of the development community today, most NGOs represent special interests and are not generally accountable directly to communities. Similarly, universities often attempt to negotiate on behalf of indigenous communities with which they work and, while less prone to political agendas, may have a significant conflict of interest, especially if they are simultaneously negotiating with the same communities.

Because a key element in these partnerships is a culturally defined and maintained resource, traditional medical knowledge, there are both principled and practical reasons to look

for autonomous indigenous representational authorities rather than working through nationally defined institutions. Autonomy is a central concern of indigenous societies around the world and was a major component of the Zapatista rebellion and associated conflicts in Chiapas. Municipalities in Mexico and elsewhere in Latin America are experimenting with more participatory and deliberative municipal governance systems that share decision making with local and indigenous groups. However, these experiments still tend to be “low-intensity,” transient, or co-opted by national parties (Sellee and Santin n.d.). As a result, the representational authorities claimed by local and national governments for indigenous societies in much of Latin America still lack credibility. While credibility is, by definition, in the eye of the beholder, credible representative governance systems tend to have participatory processes that can be observed, have representatives that are accountable to community members, and persist over time. The semiautonomous political status of the Aguaruna federations provided them the flexibility under Peruvian law to enter into partnerships with international groups of their choosing, despite poorly defined legal rights to the land and genetic resources.

Second, organizations with networks of geographically contiguous communities represented in hierarchical governance systems are likely to be in a better position to represent the interests of the large number of people with valid claims to shared genetic and intellectual resources than are more dispersed groups. Although there is some fluidity of community membership between them, the smaller federations of the Aguaruna (OCCAAM, FAD, FECONARIN, OAAM) are essentially geographically bounded, clan-based clusters of communities. While neither their knowledge of medicinal plants nor the plants themselves are restricted to the federations’ zones of influence, they may have more politically defensible rights to develop these resources with outside partners than individual communities. When smaller federations band together for common interests, the case for representational authority becomes stronger still. The representational vacuum of the indigenous people in Chiapas put the Maya ICBG in the difficult position of having to work with widely separated communities that responded individually to invitations from the university participants.

Third, the existence of a coherent system for assessing and documenting the interests and concerns of communities, resolving differences internally, and authorizing a leader to negotiate on their behalf reduces the transaction costs of developing partnerships and provides for greater project stability. The flexibility of the ICBGs to make multiyear investments in obtaining prior informed consent before conducting research is, lamentably, rare among sponsored international projects. An attempt to negotiate separate multiparty formal contracts with each of 40–100 communities for a single project would quickly raise the transaction costs beyond that which most outside organizations are willing to support. Furthermore, when founded upon the formalized democratic

processes described above, a partnership is more likely to be able to negotiate with outside partners from a position of strength and withstand challenges from within or without.

In fact, many indigenous societies have traditional forms of deliberative democracy for internal decision making, at least at the village level. Attempts to stimulate broad public deliberation within communities have appropriately been part of the consent processes of both of these ICBGs. However, the highland Maya lacked the governance structures to enable this debate to take place at a politically and culturally relevant scale *among and between* communities and to produce credible representational authorities who could translate these discussions into communications and negotiations with Western-style governmental and nongovernmental organizations.

It would be naive to leap from these two experiences to a general statement about how scientists should relate to indigenous communities around the world. The enormous diversity of indigenous cultures and their diverse relationships to Western society and national governments would suggest that the thesis presented above should be treated as a hypothesis and will probably prove to be wrong in many, perhaps most, situations. However, it is fair to say that the involvement of a preexisting and broadly representative indigenous organization will often be important to achieving sustainable collaborative projects of mutual benefit. This hypothesis is primarily directed toward the research and development communities for their consideration of regarding selecting indigenous partners. *I do not wish to suggest that indigenous societies should compromise traditional governance systems in favor of corporate-style systems in order to participate in research projects on genetic resources.* Few if any bioprospecting projects can offer the sorts of reliable and sustainable benefits that would justify consideration of governance changes unless they are already desirable to the communities themselves for other reasons. In any case, debate about such significant social changes must take place fundamentally and broadly within the indigenous society rather than being dominated by advocates of one side or the other outside it (Sen 1999).

Implications for Applied Anthropology, Ethnobotany, Bioprospecting, and Development

How, then, can global research and development communities respond appropriately to the enormous needs and the scientific opportunities presented by indigenous communities that are neither credibly represented by governments nor organized into larger governance units? Berlin and Berlin (2005) point out that most of the world's indigenous communities do not have autonomous representational authorities. Many of these also have poor representation in their national and municipal governments. While not a completely satisfying response, perhaps the best answer today is that we have a

responsibility to help support their capacity to choose development paths that enhance their goals (Sen 1999). Practically oriented projects and publications such as the AAAS Project on Traditional Knowledge (Hansen and VanFleet 2003), WIPO's Project on Traditional Knowledge and Cultural Expressions (<http://www.wipo.org/globalissues/index.html>), the First Nations/First People's Worldwide series (<http://www.firstpeoples.org/index.htm>), and Sarah Laird's handbook on biodiversity partnerships (Laird 2002) are among a variety of resources that have emerged to facilitate the interaction of research and development professionals who work with traditional knowledge and biodiversity in indigenous communities. However, to the extent that the resources involved are communal and the potential for exploitation, real or perceived, is significant, researchers and their funders are functioning in an ethical and political minefield. Navigating it will require extraordinary efforts to develop prior informed consent that is based on broad participation and can rely on visible, credible indigenous representation in some form. It will also require that the benefits available to local participants are broad-based and address important local needs that are highlighted by the communities themselves. In some cases preserving local knowledge, strengthening biodiversity-based health care systems, forming partnerships with local universities, and defining a potential monetary benefit may meet these criteria. In other cases they may not.

As academic and industrial research have become more entangled in the past 20 years, anthropologists and ethnobotanists have frequently seized the opportunity to do research that broadened their work from a largely scholarly pursuit to one that might have a more direct impact on applied concerns such as human health through development of new drugs and in situ conservation of culture and biodiversity through social and economic valuation. The ICBGs that utilize ethnomedical knowledge have embraced this opportunity. The costs of this highly publicized trend in academic ethnobotany have been substantial. Today ethnobotanists are viewed by many indigenous communities, particularly in Latin America, with a mixture of suspicion and unrealistic expectations as pipelines to drug companies. Partly as a result, the field is in a state of crisis (Brown 2003). Medical anthropologists, especially those who collect human tissue for genetic studies, also contend with tremendous suspicion for similar reasons. Some lessons from the ethnobotany community may be useful to these scientists.

To address this issue, professional societies, government sponsors, and academic institutions, including botanical gardens, have begun to formalize and publicize policies that clearly separate academic and commercial research. One means of doing so, applying the lessons outlined in this paper, would be to declare that any projects that anticipate the possibility of developing a commercial product using genetic or intellectual resources from indigenous societies would be limited to working with societies that have formal systems of accountability and authorization and in which the resources

can reasonably be ascribed to their authority. The complement to this approach is for purely academic projects to declare their research objectives as strictly for basic knowledge and publication. For the reasons outlined near the beginning of this paper, this latter approach does not eliminate the potential for exploitation, but it significantly narrows the scope of concern. Ethnobotanists and their institutions should evaluate carefully whether they can do this effectively and ethically in today's politicized climate, and their conclusions may vary a great deal between projects. Critical to this approach is thoughtful discussion between researchers and communities about the implications of publication and databasing and what to do if intentions change in the course of a project.

The potential for international research and development partnerships and associated benefits to alter the power dynamics and membership of local political organizations, as in the case of the Peru ICBG and CONAP (Greene 2004), raises other important ethical concerns regarding the origins of social change in a traditional society. Investigators and their sponsors need to consider the possibility of such unintended consequences carefully in project planning and evaluation, but it is worthwhile to place the dynamic in a larger context. As Brown (1993) points out, indigenous organizations and their leaders in Peru have a long history of rising and falling tides in relation to their access to external funding and perceived influence over national and international arrangements. For governmental and commercial organizations, few would question the importance of success in developing and managing arrangements with partners; the strength and credibility of companies and governments regularly grow and decline with major contracts or trade pacts. Thus, an important question arises in the present context. Does the special status of indigenous societies require special protections that effectively minimize collaborations with external parties where these may have an effect on internal forms of social or political organization? Many cultural preservationists and others would say yes. However, designing and implementing such measures runs the risk of reducing autonomy for indigenous societies and could have significant disadvantages for other aspects of their well-being, such as those which may flow from development projects. While there are many unknowns and widely varying views on the benefits and costs to indigenous communities that collaborate with external organizations, one element of this dynamic is clear. The probability of influence on local community organization is strongly related to the size of the partnership and the nature of the resources entering and leaving the community.

In the past ten years the negotiations over the UN Convention on Biodiversity and the WIPO, as well as policy discussions within dozens of national governments, have struggled with the very complex policy questions of access and benefit sharing associated with genetic resources and traditional knowledge of indigenous peoples. A substantial portion of the discussion is aimed at achieving a policy environment that facilitates more equitable interactions between indige-

nous peoples and the scientific and industrial organizations of the world. The trend is toward construction of complex regimes empowered to make judgments regarding specific standards for prior informed consent, partnership makeup, benefit sharing, and related matters. The somewhat analogous history of the human-subjects research protection regime offers some insights in this regard. Over the past 30 years, research and regulatory agencies around the world have evolved a system of research oversight mechanisms that is increasingly rigid, detailed, and legalistic (Bhutta 2004), but this system has often proved inadequate to protect patients (Moreno 2001). It has promoted a mentality and practice that encourages researchers to adopt minimum standards of compliance rather than foster a sense of responsibility and thoughtful evaluation by the individuals and groups involved. Deciding whether a patient understands the potential risks and benefits in an experimental medical treatment and is therefore able to provide *informed* consent is a complex judgment that depends on many situation-specific parameters. Standardizing the information received and the manner in which it is transmitted clarifies the rules of engagement but does not necessarily enhance understanding or ameliorate the underlying inequities in researcher-subject relationships (Benatar 2004).

Lavery (2002) has very cogently argued that no matter how clearly we establish the rules of ethical research, international projects that involve human subjects in developing countries must be viewed in the context of development. In this context, it is critical to build a culture of responsibility that emphasizes dialogue and collaboration in the global research community (Benatar 2004) and a culture of ethical research in developing countries, including the social, technical, and institutional capacity for appropriate local evaluation and monitoring (Lavery 2002). However, Gross and Plattner (2002) argue that the development needs of a host community are frequently a separate question from that which is driving a research project, and it is therefore important that we not create unrealistic requirements regarding the role of the community in project design or the ability of a researcher to address its specific needs.

Access and benefit sharing are at least as complicated technically, politically, and ethically as biomedical research with human subjects. Adding the linguistic, cultural, and political layers characteristic of work with indigenous peoples and communal rights produces an extraordinarily complex package that requires tailored approaches to most situations and thoughtful consideration by all involved. There is a need for generally accepted principles, such as those embodied in the Bonn Guidelines (UNEP 2002), and national interpretations of those principles in policy measures. Clear and effective policies are important to give resource "providers" sufficient confidence to seek international collaborations and to give "users" clarity on how to approach the issues and confidence that they are operating within recognized principles and law. However, it seems likely that unless much more is done to

develop enabling conditions such as capable authorizing institutions and a culture of responsible research, few of these regimes will be able to provide the protections that many in the global community seek or to facilitate access to benefits for indigenous and scientific communities. The answers may often be local rather than global.

The Peru and Maya ICBGs have struggled very publicly with the definition and implementation of prior informed consent in attempts to build equitable and ethical research collaborations. An analysis of the contrasting political, cultural, and governance environments and the differential outcomes of the two projects suggests that the governance of potentially collaborating indigenous societies is key. The generality of this conclusion remains to be seen. Ultimately, conducting ethical research involving indigenous societies will depend a great deal on our ability to help create an enabling environment that includes appropriate local governance systems, well-defined national and international policies, and a culture of responsible research that incorporates locally defined priorities. In such environments we are most likely to achieve what most of us seek—research collaborations that advance science, strengthen human rights, and improve the health and well-being of indigenous peoples and the global community.

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Comments

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Vital learning opportunities continue to emerge from scholarly debate and reflective analyses of the Maya and Peru ICBG experiences, following the academic confusion and political turmoil that bioprospecting projects such as these catalyzed in the late 1990s/early 2000s. In this most recent assessment, Rosenthal significantly furthers our understanding in his val-

uable contribution from the perspective of a research administrator for the ICBG program.

Rosenthal focuses on the role of prior informed consent by “research subjects” as critical in providing an answer to the problem of developing projects “that minimize risks to participants and maximize the benefits to indigenous societies and the global community.” Drawing on both ethical and legal conceptions of prior informed consent, however, Rosenthal acknowledges the significant complexities of implementing the principle in bioprospecting projects when Indigenous peoples and their traditional plant knowledge are involved. On the basis of a comparative analysis of the two ICBG projects, he suggests that “preexisting and broadly representative indigenous governance” is key in “determining the feasibility and integrity of prior informed consent for the use of traditional knowledge.” A good match between project partners probably means sufficiently compatible institutional interfaces—that is, compatibility with Western-style governance. The Indigenous organizations involved in the “successful” (relatively speaking) Peru ICBG fit this bill better than the communities involved in the “unsuccessful” Maya ICBG.

A consideration in attempting to work institutionally rather than individually, however, is the potential distancing of the political decision makers from the ecological and cultural contexts and sources of the plants and knowledge that they aim to protect and/or negotiate benefits from exploiting. Significant tensions in this respect were expressed among the Aguaruna federation leaders involved in negotiating the Peru ICBG agreements (Tobin, Render, and Bannister n.d.; Bannister, unpublished interviews). Community assemblies could be employed for collective decision making about initial participation in the project, but formal negotiation of the complex agreements (including benefits) took place outside of the community contexts, among representatives of project partners and their legal counsels. Prior informed consent in legal terms may be about the negotiation of benefits by political authorities, but prior informed consent for the use of traditional knowledge within a research ethics framework is not.

Further examination of the relational implications of prior informed consent as an ethical principle of “human subjects research” may be useful. Prior informed consent is based on the concept of an *ongoing process* that begins with initial contact and continues throughout involvement in the project; it is through this continuing process of communication and information sharing that “subjects” are able to *continue* to choose to participate in research involving themselves (Tri-Council Policy Statement 1998, section 2; Alexiades and Peluso 2000). Prior informed consent in the context of research ethics, therefore, is premised upon the existence of a *relationship* between “researcher” and “researched” and is often situated within unequal power relations. Rosenthal and others have described the significant resources and multiple years of investment in prior informed consent by the ICBG program, but it is not clear whether this refers to legal or ethical conceptions of the principle.

In Canada the concept of relationship is fundamental to prior informed consent as well as more broadly to emerging Aboriginal research ethics standards under development—a subject of national debate and a priority topic for federal academic granting councils. In partial response, community-based participatory research paradigms have superseded subject-centered models of “studying Aboriginal cultures,” and the former will soon be supported by new ethical guidelines (requiring compliance for research funding) that designate the option of a participatory research approach as an Aboriginal right and call for the regulation of research within Aboriginal communities as enforceable under section 35 of the 1982 Constitution Act of Canada (CIHR 2005, section 2.3; Brant Castellano 2003). The policies will confer on researchers an obligation to understand their responsibilities in the research relationship *in the context of Aboriginal worldviews*, particularly when engaging the realm of traditional knowledge and the responsibility that possession of such knowledge involves in terms of accountability to the Creator, the land, and past and future generations (CIHR 2005, section 2.2). Furthermore, compliance with Aboriginal-community-level protocols and the Aboriginal research ethics review processes that are in place in some cases will be required.

The full implications of these new policies based on Aboriginal philosophies, including stringent prior informed consent requirements and the sharing of control of the research, have yet to be understood. As Rosenthal notes, many scientists who seek to use traditional knowledge in research would like to comply with culturally appropriate processes for obtaining consent, but they need to know what these are. At a minimum, the new Canadian policies will force researchers, universities, and funding bodies to address practical and political realities such as the need for adequate time and funds to build relationships, understand Aboriginal worldviews and local protocols, develop research agreements, and support participatory research processes. In many cases, capacity building may become a necessary prerequisite to research. Implementing the policies will also require confronting entrenched norms in academic reward structures, university intellectual property ownership policies, and academic publication practices—no small task but undoubtedly another vital learning opportunity.

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Rosenthal’s insightful historical account of the Peru and Maya ICBG projects is based on his firsthand knowledge of the facts, but we disagree with some of his interpretations of those facts. The Washington University Peru project ultimately succeeded because it was able to establish collaborative contractual agreements with 55 Aguaruna communities organized into four

loosely organized federations. These were represented by yet another umbrella organization that provided them with the institutional stability to withstand strong opposition from another indigenous federation that had aligned itself with a small but media-savvy international NGO—the Rural Advancement Foundation International (RAFI), now the ETC Group but referred to here by its original name. The Maya ICBG had established collaborative contractual prior informed consent agreements with 46 local autonomous Maya indigenous communities that lacked a form of shared governance. When a nonrepresentative indigenous organization, with legal advice and continual guidance from RAFI, attacked the Maya agreements as invalid, these 46 autonomous communities were unable to mount an effective defense, and the Maya ICBG faltered.

In our original proposal, we outlined a viable solution to the lack of an institutionalized Highland Maya political structure beyond traditional community-level governing bodies—the establishment of PROMAYA. As a civil organization under Mexican law PROMAYA, made up of elected indigenous representatives from the original 46 communities plus any others that joined later, would have had full legal status in all commercial negotiations and management of any future income through a trust fund. The numerous indigenous cooperatives in the region (e.g., coffee, mushrooms, weaving) would have served as a model with which the local Maya were familiar. PROMAYA was logical, feasible, and ethical. Our plans were cut short by the political controversy that engulfed the project from 1999 to 2001 (Berlin and Berlin 2002a, 2002b, 2004a, 2004b; Brown 2003, 109–25; Hardison 2000; Hayden 2003; Freese 2005).

The far-reaching policy recommendation that Rosenthal develops from his critique is the one he directs “toward the research and development communities [i.e., Western scientists and the funding agencies that support their research for their consideration regarding selecting indigenous partners.” Translated into formal language, the recommendation might read something like the following: “Where research will be conducted with indigenous communities, successful applicants must establish prior informed consent agreements with a preexisting and broadly representative indigenous organization of cooperating indigenous communities. When multiple organizations are involved, they must show credible leadership under an umbrella federation capable of arriving at demonstrable consensus on matters of shared concern among participating communities.” While perhaps a wise administrative consideration for a government granting agency, this recommendation is prejudicial to the thousands of indigenous communities of the world that are not now and unlikely soon to become members of representative organizations with Western-style systems of governance. It effectively excludes the communities most isolated from national and international markets and most in need of the benefits that would result from their involvement in ethical bioprospecting programs.

We also respectfully disagree with Rosenthal's conclusion that "the [Maya ICBG] may have [been] doomed . . . from the beginning." Sixty-five years of productive anthropological, ethnobotanical, and medical ethnobiological research in the region with scores of indigenous communities collaborating on multiple scientific projects shows this claim to be an overstatement. Instead of noting the fragility of autonomous Maya communities, it may be more productive to focus on the common negative factor affecting the whole ICBG program since its inception more than a decade ago—the active intervention of RAFI. The University of Arizona Arid Lands ICBG escaped with minor damage from RAFI, possibly because the Peru ICBG appeared more promising (B. Timmermann, personal communication). It is at least likely that RAFI was less than keen to pursue its attack on the Africa ICBG after a public confrontation with its Nigerian field leader, Maurice Iwu (personal communication). RAFI's involvement seriously threatened the viability of the Peru ICBG. With the Maya project, RAFI hit pay dirt.

Declaring that all forms of bioprospecting are biopiracy (RAFI 2000) and making effective use of the media and the World Wide Web, RAFI became expert in recruiting allies to its cause, including national and international NGOs. Among them were academics (some in our own back yard) who saw the project as an imposition of neoliberalist development policies, conservation activists, Mexican intellectuals, and popular journalists who stereotyped the conflict as one between *el indio* David of the South and gene-giant Goliath of the North.

In retrospect, the Maya ICBG's major failure was not its historically proven and ethnographically justified efforts to work with indigenous communities as much as its inability to mount a successful public relations program, implementing from the very outset the good advice of Vada Manager, Nike Company's director of global issues management—"Leave no charge unanswered, control the agenda" (<http://www.1worldcommunication.org/swooshwars.htm>), a strategy that might have allowed it to counter the well-organized media campaign against it. One lesson is that successful research and development projects on the commercial use of biological resources depend as much on astute management and wide dissemination of credible information as on developing and maintaining interpersonal relations of trust with our native collaborators on the ground.

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The Convention on Biological Diversity was presented as a framework that would reorder the acquisition of genetic resources and thereby address problems of conservation and equity. The perspective of a dozen years since its launch sug-

gests that the optimism of the 1992 United Nations Environment and Development (UNCED) conference in Rio de Janeiro was misplaced. Conservationists, researchers, and political leaders who expressed optimism in 1992 have been largely disappointed. The loss of biological diversity continues apace, the international system of research on and movement of biological resources from the tropics is all but gridlocked, and an equitable system for compensating the stewards of biological diversity seems as distant today as it did before. A recent survey of the experience of access and benefit-sharing regimes developed since the adoption of the convention (Brush and Carrizosa 2004) shows that problems in implementing new approaches to managing biological resources are common and widespread. Success in meeting the equity goals of the convention is more evident in efforts outside of the formal frameworks created in response to it.

Rosenthal's analysis of the fate of two ICBG projects provides an important piece of a larger explanation of the sources of failure of the convention. The problems confronted by the ICBG are similar to those of other programs that responded to the convention's call for a new international access and benefit-sharing regime for managing biological resources, and the Peru ICBG is a rare success. This paper's signaling of the importance of culture, governance, and politics is germane not only to issues of prior informed consent but also to many other elements that comprise the regime envisioned by the convention. Our study of access and benefit-sharing regimes among Pacific Rim countries (Brush and Carrizosa 2004) distilled several lessons that reaffirm Rosenthal's analysis: (1) agreements and implementation are most likely to succeed when the number of parties is minimized, (2) the determination of a competent authority or local focal point in granting access is critical, and ambiguity in this is problematic, and (3) governments need to build local capacity to facilitate the effective and efficient implementation of access and benefit-sharing laws and policies.

For many reasons, bioprospecting has broken down more than it has succeeded, and Rosenthal's paper cogently points to a set of immediate factors that contribute to success and failure. While this paper's goals do not include exploring the idea of reforming the international regime for accessing and conserving biological resources, its material is directly relevant because of continuing efforts to reformulate the place of "traditional knowledge" in the intellectual property arena (Brush 2005). In not mentioning such contested and fundamentally important issues as the public domain, the paper tends to understate the importance of the opposition to bioprospecting contracts. Indeed, the vigorous debate about the public domain (Brush 1999; Boyce 2003) suggests that the problems that beset the ICBG and other access and benefit-sharing schemes will not be entirely resolved by the measures suggested here. While returning to the preconvention common-heritage regime is impossible, the failure of bioprospecting to address the problems that led to the convention suggests that new approaches are needed. The contractual mode of providing access to genetic

resources that developed in response to the convention has proved particularly problematic because of the perception of expropriation of the public domain through the implements of intellectual property. The broader framework of indigenous political organization that allowed the Peru ICBG to succeed may be seen as a step toward partnerships for access and benefit-sharing that avoid the pitfalls of bilateral contracts. This approach is the fundamental breakthrough of the recent International Treaty for Plant Genetic Resources for Food and Agriculture (Fowler 2004). Future regimes for other types of genetic resources may also succeed by avoiding the contractual mode, but any access regime will have to be cognizant and inclusive of the interests of the stewards of genetic resources. The lessons of programs like the ICBG that are identified by Rosenthal will be valuable signposts in devising national programs that address the pressing needs of conservation and equity.

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Using two case studies, one among Aguaruna communities of lowland Peru and the other among Maya communities in Chiapas, Rosenthal argues that “the existence of an established, credible, and politically representative governance system” in the indigenous communities involved is the hinge upon which the success of collaborative bioprospecting projects turns. His article focuses upon issues of prior informed consent in the making and breaking of these projects. He has argued a good case, but I am anxious about some of the conclusions he reaches.

On the basis of the examples cited in the paper, Rosenthal suggests that it might be advisable for government and academic institutions to declare that “any projects that anticipate the possibility of developing commercial products using genetic or intellectual resources from indigenous societies would be limited to working with societies that have formal systems of accountability and authorization and in which the resources can reasonably be ascribed to their authority.” This proposal has at least two glaring problems associated with it. First, it is unclear who gets to decide what constitutes “formal systems of accountability,” with what criteria, and with what mechanisms for appeal to or at least dialogue with the funders on the part of the indigenous institutions concerned. Second, it has the potential to exacerbate inequalities between indigenous communities, in effect rewarding communities which already have their act together while punishing those that suffer from organizational maladies that are not necessarily their own fault.

Behind both the Peruvian and Mexican situations that Rosenthal describes are unspoken power relations which assign to the nonindigenous organizations and funders all of the tasks of analysis and assessment both of the projects and of the

“fitness” of their indigenous partners. To be fair, Rosenthal is describing real projects rather than developing an abstract model for such a partnership. In the Maya case, a process of encouraging community leaders to learn about both the research and the process of informed consent was, according to Rosenthal, derailed by “media-savvy” foreign NGOs and, in the end, by indigenous critics. Even though the project with the Aguaruna had a much more positive outcome, determining what went wrong and what went right with the project was exclusively the job of the funding agencies. The possibility that indigenous organizations could and, more important, might want to learn how to conduct impact and feasibility assessments of these projects that went beyond politically motivated critique is absent from Rosenthal’s presentation.

It has been my experience in working with indigenous communities in agricultural research that such communities are aware of scientific testing procedures and seek to learn how to design and perform them for themselves. I am not disagreeing with Rosenthal’s analysis in either example, but I do think that bioprospecting projects such as these may reify fundamental inequalities of knowledge and power which ultimately affect their outcome quite as much as the issues of leadership that Rosenthal emphasizes. Laying the groundwork for such projects may require the nonindigenous partners to go that much farther in supporting the educational empowerment of such communities.

My last concern has to do with the impact of armed conflict on the involvement of indigenous communities in bioprospecting and other research projects backed by foreign funders and interests. While Rosenthal notes that the conflict between the EZLN and the Mexican state is one factor in the situation facing Maya communities, it may in fact be the most important limiting factor, especially with respect to the development of the indigenous leadership that he considers crucial to the success of bioprospecting projects. (Since he does not mention the presence of Sendero Luminoso in the Aguaruna zone, we must assume that this conflict was not a factor for these indigenous communities.) Anthropologists conventionally focus upon community-level studies among minority peoples, but I think that the armed conflicts and civil wars affecting indigenous peoples in much of Latin America oblige us to broaden our scope to include the national-level politics that ultimately determine the possibilities for development in indigenous communities. With this in mind, it makes even less sense simply to avoid proposing projects in regions where indigenous communities and leadership are inchoate.

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Rosenthal’s comparative analysis of the two most controversial ICBG projects is a positive affirmation on many levels.

First of all, it serves to remind us that the suspicion and occasional knee-jerk cynicism with which certain sectors of anthropology view the institutions of development, policy making, and science are not always warranted. Second, it reaffirms the idea that anthropology can have immediate importance to the world of policy and action. After all, this article represents a policy makers' response to anthropological thinking on the complex problem of indigenous rights, international development, and traditional knowledge, even if a disclaimer is still needed to distance the author from the governmental institution he works for. This makes it well worth consideration by a discipline that struggles between the constant call to communicate its relevance beyond its borders and an occasional tendency toward overabstraction and incestuous intellectualism.

Having ventured into an ethnographic experiment with one of the indigenous groups discussed here, I find Rosenthal's paper to be an extraordinary confirmation of what I see as the Aguaruna project to "customize indigeneity" (Greene n.d.). The crux of his argument is that, while the ICBG Maya project collapsed, the Aguaruna salvaged the Peru ICBG from controversy because they possessed a pre-existing network of indigenous federations that facilitated the highly legalistic and delegational negotiations that bioprospecting ventures seem to demand. Yet, here we also have an international health policy maker stating that it was in significant part the historical adaptability of Aguaruna custom, specifically the consensus-building assembly known as the *ipaamamu*, that made the Peruvian ICBG controversy surmountable. Rosenthal declares that "resolution of the problems would not have been possible" in its absence. This too should make critics of development stop and think. What is at stake is not merely the politics of assimilating Aguaruna custom in the old sense of development as acculturation—Rosenthal's hypothesis about the apparent "necessity" of "Western-style" governance systems for successful indigenous negotiations—but also the Aguaruna's extraordinary ability to adapt their customs to that "Western-style" governance system. In doing so they not only modernize their customs but simultaneously customize their modernity and thus convince not only the anthropological traveler eager to find such cultural resilience but also the agent of development who operates without any such predisposition. This, I would argue, is testimony not only to the complexity of indigenous politics on the ground in the Aguaruna case but ultimately to the tenacity of indigenous cultures around the globe.

All of this is not to say there are no problems worth pointing out. While the paper makes some room for the "unintended consequences" of the ICBGs, there is considerably less available for the unimagined causes that contributed to the stories of Aguaruna "success" and Maya "failure." This is particularly clear in the overemphasis on the "preexisting" nature of "credible" leadership, somehow apparent among the Aguaruna and apparently lacking among

the Maya. Why such a stark contrast? Why, for example, does the Maya organization COMPITCH not count as a preexisting, Western-style governance structure? It sounds a lot like a Western-style professional association to me, and its representational structure may have been exactly what "the outside world" (as Rosenthal puts it) needed to achieve results, except that in this case it was RAFI's inflammatory antibioprospecting campaign, which needed its own "Western-style" governance structure to work with, that prevailed. In the case of the Aguaruna's federation structure, a broader anthropological understanding would also confront the fact that this "Western-style" governance structure is in a semipermanent state of crisis. At a minimum, it is worth recognizing that Aguaruna governance has had its ups and downs not only during the ICBG negotiations but long before them and long after the ICBG project was salvaged by CONAP and Co. Indeed, such vacillations in Aguaruna governance have coincided almost perfectly with the comings and goings of various development projects, research endeavors (including my own), advocacy organizations, state programs, and the like (Greene n.d.). Certain groups of Aguaruna have forged this governance structure only by excluding other Aguaruna, partly through historical contingencies and partly through political-economic influence (Greene 2004). This raises an issue that is never squarely discussed in Rosenthal's account. How is it that the myth of inclusion with which "Western-style" governance and development encounters are proffered so often comes to obscure the reality of exclusion on which they also rest?

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Rosenthal has written an interesting and informative paper about the difficulties surrounding negotiated agreements between international research teams and indigenous communities. The paper addresses a number of important issues, in particular in relation to benefit sharing and the use of intellectual property rights and prior informed consent. It is written from the perspective of a research administrator, a man who seems committed to solving the problems he describes. I find this commitment admirable, but I have some reservations about the paper.

Rosenthal is optimistic about the potential for using scientific collaboration to promote the interests of indigenous communities: local communities need to strike a hard bargain. However, he points out that it is difficult to define a community, and his material illustrates that different community members have different interests. Granted that the community cannot be clearly delineated and that, no matter how the delineation is made, there will be conflicting interests, how

should we determine whether “the community” has a good deal?

It is important to remember that the international opposition to intellectual property rights has developed for a reason. In the article this opposition is represented quite unfavourably by the organization RAFI, which is probably better known for its opposition to the patenting of a T-cell line from a man from Papua New Guinea (Cunningham 1998; Marks 2001). Of course, misplaced opposition should be criticized, but RAFI’s criticism of intellectual property rights rests on a general feeling that intellectual property rights as a property regime rarely serves the interests of marginalized people (Brown 1998). For example, it takes substantial resources to defend oneself against infringement (or, in fact, even to identify an infringement) of a patent. Accordingly, the notion of intellectual property rights seems more likely to serve the global actors of international science and finance than scattered villagers. Furthermore, the legitimacy of patents (to focus on the most relevant form of intellectual property rights in this context) rests on the idea of a contract between a creative individual/corporation that has invented (or discovered) something original, on one side, and the surrounding society that wants to use this invention (or discovery), on the other. Disclosure of information is rewarded with commercial rights. First, however, the originality of the information gained can be contested in the case of traditional knowledge. Second, the notion of disclosure is significantly transformed when we are dealing with knowledge which is (according to Rosenthal) “already in the public domain in one form or another.” What happens when we import this transformed intellectual property rights rationale back into Western societies, where the legitimacy of patents in relation to, in particular, genetic material is already seriously contested? I understand that Rosenthal may find it *fair* to grant local communities intellectual property rights, but I am worried about the international legal consequences of extending the use of them in this way.

Even if Rosenthal is right and shared intellectual property rights are the way forward, I am still reluctant to embrace the notion of prior informed consent as the solution to the problem of a fair deal. Rosenthal uses the IUCN’s definition of prior informed consent, which naïvely requires “full and complete information provided by the potential genetic resource user.” What is “full and complete information” about exploratory research? And how is a fair deal between two such unequal parties possible when the one is supposed to inform the other about practically every aspect of the arrangement? Furthermore, the legitimacy of informed consent can be seriously challenged for a number of reasons. For example, so-called substantive ethical principles such as human dignity and autonomy can hardly be transferred from the case of invasive medicine performed on the body of an individual to a community without some discussion of the way this changes their meanings.

As I read Rosenthal’s two case studies, I am convinced by his assertion that it is a “critical question” to figure out how to “maximize the benefits to indigenous societies” in this type of research collaboration, but I have found nothing to support his claim that prior informed consent “is a fundamental part of the answer to this question.” In fact, it remains a puzzle why a study of a “sophisticated” but *failed* consent process should make us want to put more emphasis on it, not least considering that it is expensive and fits only the project cycles of funding agencies. Is prior informed consent simply becoming a new mantra, replacing other organizational recipes such as participatory rural appraisal? Has the need for a “solution,” an *answer*, limited the opportunity for critical judgement? What about the need for broader infrastructural changes at the level of international law to complement the search for “local,” organizational solutions?

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Rosenthal’s argument is that a key difference between the successful Aguaruna ICBG in Peru and the failed Maya ICBG in Mexico is the engagement in Peru with broad-based, widely recognized Aguaruna organizations and the lack of such organizations representing Maya interests in Mexico. Yet, that such broadly representative indigenous organizations existed among the Aguaruna while the Maya peoples of the Chiapas highlands—the focus of the Maya ICBG—were represented rather by several dozen or several hundred independent local community assemblies is irrelevant to judgments as to the practical or moral value of the two projects.

Rosenthal’s suggestion that future proposals for collaborative scientific efforts involving indigenous partners should consider the institutional resources in place for representing indigenous interests to the outside world is certainly reasonable. Other factors, however, may well have been as critical if not more so in contributing to the success or failure of these two ICBGs, and the institutional contrasts emphasized by Rosenthal are somewhat exaggerated.

A key factor alluded to but not systematically analyzed by Rosenthal is the fact that the Maya ICBG was the target of a systematic and highly effective campaign of opposition and misinformation orchestrated by the Canadian-based NGO RAFI (Rural Advancement Foundation International, now the ETC Group [Action Group on Erosion, Technology, and Concentration]), which early on branded the project as “biopiracy.” To my knowledge no such campaign was directed at the Aguaruna ICBG, despite the fact that the Maya ICBG was in key respects more truly collaborative in its design and implementation. The political context of the Tzeltal and Tzotzil Maya was not significantly more volatile than that of the Aguaruna, nor were the Aguaruna free of internal dissent.

The exclusion of the Consejo Aguaruna y Huambisa from the Aguaruna ICBG compact might seem to have had even greater potential for undermining local support for the ICBG than the disaffection of COMPITCH in the Maya case. I suspect that the difference has more to do with the key role RAFI played in actively promoting opposition in the Maya case, though I have no idea why RAFI singled out the Maya ICBG for its attacks.

Rosenthal's characterization of the highland Maya as lacking effective political representation is an exaggeration. It is not generally the case, as he asserts, that "a lack of municipal institutional structure and truly participatory processes challenge(s) the authority of municipalities." Nor is it the case that "there are no indigenous political organizations that exist continuously and are authorized to speak on behalf of communities in relation to local or national resource issues." In my experience of southern Mexican indigenous communities—in highland Chiapas in the early 1970s and in Zapotec communities in Oaxaca during the past decade—the *municipio* is the most generally recognized indigenous unit of governance. In many Mayan and Zapotec communities, *municipio* boundaries closely correspond geographically, historically, and socially with indigenous communities with strong traditions of endogamy, shared language, collective worship, and local political autonomy. It is true that highland Chiapas Mayan *municipios* are today much more deeply divided than they were 30 years ago, largely because of dramatic population increases within a fixed land base and the correlated exacerbation of internal class divisions. Nor does municipal self-government by means of *usos y costumbres* (customary practices) guarantee "truly participatory practices." However, it hardly precludes that reality. *Parajes* or, in other contexts, *agencias* are administrative subdivisions of these *municipios* which in many instances replicate on a more local level the customary participatory political processes more formally recognized at the *municipio* level. Such communities may be the most effective level for negotiating prior informed consent, as they are small enough—numbering fewer than 1,000 residents on average—for true participatory democratic action.

Finally, to equate the Aguaruna—who number some 39,000 and speak a Jivaroan language—with the Maya—numbering over 2,000,000 and speaking over 30 distinct languages, living in four nations, and at home in a diversity of natural habitats—is quite misleading. RAFI's claim that consent must be obtained from all Maya, whatever their language or citizenship, on the assumption that all Maya people should be considered the collective "owners" of a common ethnobotanical tradition, is absurd. The Maya ICBG was quite reasonably limited to the Tzeltal- and Tzotzil-speaking communities of the central highlands of Chiapas, numbering approximately 600,000. Even so, it is clear that the simple demographic contrast between the indigenous populations addressed by the two ICBGs contributed substantially to the divergent outcomes Rosenthal seeks to explain, as sheer numbers greatly

complicate the political task of gaining consensus with respect to a collaborative venture.

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In his thoughtful analysis, Rosenthal calls attention to the complex and challenging issues associated with the discovery and development of pharmaceuticals and other products from biodiversity in developing countries. He illustrates the problems that arise in negotiating the difficult cultural and political terrain of biodiversity research with indigenous groups through two cases with very different outcomes. He focuses his attention specifically on the success and failure of processes for establishing prior informed consent and agreements with indigenous communities in Peru and Mexico. The case studies he presents are morality tales about the use and misuse of power and authority, the nature and consequences of the competing interests of stakeholders involved in research, and the profound influence of the globalization of scientific "progress" on indigenous populations throughout the world. He is correct in arguing that communities with established and credible systems of governance—systems that, not surprisingly, reflect Western approaches to organization and accountability—may be more successful in claiming ownership of indigenous resources and the benefits that accrue from research.

National and international guidelines for ethical conduct in research are well established and outline specific requirements for individual informed consent. In recent years scholars and policy makers have begun to give serious consideration to the ethical concerns underlying capacity building, benefit sharing, and the involvement of communities in research. Indigenous populations may be more vulnerable to exploitation because of their relative lack of social and political influence. Effective community engagement may diminish the potential for exploitation. However, community consultation can be daunting for researchers when they confront cultural beliefs that conflict with regulatory standards or face the pragmatic constraints of local power dynamics and forms of governance. Who is authorized to speak for the community? Where does this authority come from? What segments of the community are included or marginalized in community consultation?

As Rosenthal observes, his analysis has implications not only for biodiversity research but also for international genetic research. The failure of the Human Genome Diversity Project has been extensively discussed, and it is in part because of lessons learned from this experience that initiatives such as the International HapMap Consortium (2003) have required community engagement and consultation prior to implementing DNA sample collection with diverse world popula-

tions. The primary goal of the HapMap Project is to develop an international repository of DNA samples for research that will facilitate the development of pharmaceuticals and enhance our knowledge of genes and disease. Although patenting and intellectual property rights are not issues for researchers collecting the DNA samples, concerns about community “approval” for research, capacity building, and community benefits are certainly relevant. HapMap investigators working with local communities continue to face many ethical challenges (International HapMap Consortium 2004). Important issues have been the nature and scope of the “communities” involved, community representation for decisional authority regarding the project, the negotiation of community benefits, and the development of mechanisms for providing ongoing feedback to the communities.

Overall, I agree with Rosenthal’s critical assessment. However, I am perplexed by his suggestion that one method for clearly separating the goals and outcomes of academic and commercial research would be “to declare that any projects that anticipate the possibility of developing a commercial product using genetic or intellectual resources from indigenous societies would be limited to working with societies that have formal systems of accountability and authorization and in which the resources can reasonably be ascribed to their authority.” There are several problems with this approach. First, as Rosenthal points out, academic research conducted for basic knowledge and publication does not preclude the possibility of exploitation of indigenous populations. Second, genomic and biodiversity research sponsored by academic and commercial institutions is a global enterprise with a long history including both good and bad examples of the marriage between industry and academia. In some cases, the results of prior and ongoing research may indeed benefit populations throughout the world. Consider, for example, the potential benefits associated with the development of vaccines for infectious diseases such as malaria, tuberculosis, and HIV/AIDS—problems that disproportionately impact indigenous populations in resource-poor countries. It is naive to suggest that it might be possible to disentangle the interests and intentions of corporate and academic researchers and the institutions they represent. Third, anticipating the outcomes of genetic or biodiversity research is not always possible. Future applications of results may not be recognized or attainable until years after a study has been completed. Thus, research conducted for purely academic purposes may contribute to the development of technologies that result in commercial or monetary benefits whatever its original goals.

The development of effective strategies for engaging communities to promote understanding of research goals and equitable benefit sharing must be a high priority for researchers and policy makers representing both public and private sectors nationally and internationally.

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Rosenthal’s analysis of the strengths and weaknesses of ICBG Peru and ICBG Maya and the related process of prior informed consent raises critical questions in the practice of ethical anthropology, but he enters the debate several steps beyond where the ethical and practical dilemmas actually begin. This discussion is about questionable partnerships between academic institutions, individual researchers, and corporations forged without prior consent of the communities they expect to work with. It is also about a process of legal oversight of the entire endeavor that fails to accept the political reality in which we attempt to undertake our studies. The fate of current and future ICBG projects must be considered in relation to a complex web of social history and to the flawed logic imbedded in the language used to describe the components of prior informed consent.

Rosenthal attributes the “success” of the Peru ICBG project to “the existence of an established, credible, and politically representative governance system of the indigenous communities involved,” which was supposedly lacking in Chiapas. It is not quite that simple. In spite of a long record of research in Chiapas, the proponents of ICBG Maya failed to appreciate the implications of the historical moment in which they were working and the changes taking place as they worked. In connection with the 1994 Zapatista rebellion, a formalized process of consensus-based decision making was instituted in autonomous municipalities serving over 160,000 Maya. Since that time, whether represented by the Zapatistas, COM-PITCH, or a series of more recent “para-Zapatista” grassroots organizations that flourish in the aftermath of the rebellion, the Chiapas Maya have become increasingly capable of making their decisions felt. Indigenous communities are no longer the benign recipients of anthropological and other scientific research. Moreover, their governance systems are neither transient nor co-opted by national parties, nor are they likely to be susceptible to structural adjustment programs designed to make them amenable to bioprospecting partnerships.

Anthropologists of all people should understand the implications of negotiating treaties and entering into trust relationships with indigenous peoples. These nineteenth-century pastimes are currently being played out among twenty-first-century stakeholders who *have* learned from history. Why, then, is Rosenthal skeptical when they use “media-savvy” advisers and web sites and have indigenous spokespersons to evaluate the development initiatives of outsiders? As much as some might feel that only scientists should get to set the scientific agenda, potential researchers should begin to accept the fact that proposals for scientific research must also receive approval from the people who were formerly described as its “subjects.” This process can be as rigorous as

any National Science Foundation review. As Nigh (2002:963) notes, "Researchers cannot approach a community today without answering a series of questions about the uses to which their results will be put and the benefits or risks of the projects for the community." Indigenous organizations, whether attached to governmental bodies as in Peru or rejecting any national or state governance ties as in much of Chiapas, have the capacity to evaluate the projects we propose. They will agree to help with research as long as it helps them in their larger project in life. As observed in a commentary on the termination of ICBG Maya, "Ultimately, neither well-meaning anthropologists nor civil society organizations can make decisions for indigenous peoples; nor can outsiders appoint organizations to determine who will legitimately represent the interests of indigenous communities" (etcgroup.org n.d.).

The logic of prior informed consent is that preconceived projects are brought to communities and individuals who then agree to participate. To make this possible, many anthropologists use modified, verbal versions of prior informed consent, arguing that written documents simply will not work in politically volatile situations and among semiliterate people. Moreover, individual agreements are not part of the cultural logic in collectively governed communities. But regardless of the legal and liability protections for which prior informed consent is used, until the scientific community reevaluates the philosophy driving the process we will fail to receive the *informed permission* that we need to enter indigenous territories and carry out our *jointly* constructed and mutually beneficial projects. The notion of prior informed consent continues the asymmetry of elitist research, in which those who open their cultures and communities to us are viewed as subjects of our studies.

Giving agency to those to be "studied" as part of an equal partnership means that we bring to the partnership the skills that each of us has and from these devise a research design that emphasizes symmetry in the research endeavor and attention to community concerns surrounding how and when information should be shared. In this respect, Rosenthal could strengthen his conclusion by reversing the order of the purpose of collaboration: first, to improve the health and well-being of indigenous peoples and the global community and, in the end, to advance science.

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Historically, discussions of informed consent have focused upon seeking the consent of particular individuals. More recently, Charles Weijer (1999; Weijer, Goldsand, and Emanuel 1999; Weijer and Emanuel 2000) and other scholars have argued on behalf of obtaining community consent. Rosenthal

explores numerous challenges associated with obtaining the informed consent of indigenous communities prior to engaging in "bioprospecting" initiatives. He reveals how seeking prior informed consent of communities can pose challenges so overwhelming that some research initiatives are likely to founder even when key stakeholders agree that their benefits exceed their identifiable risks.

Informed consent is quite straightforward as a philosophical concept. In the clinical realm, informed consent should be voluntary, include a discussion of risks and benefits, outline treatment alternatives, and summarize the likely consequences of nontreatment. Informed consent to treatment can be distinguished from informed consent to research, but, recognizing these differences, the basic principles of informed consent are the same. Informed consent is a "democratizing" concept; it is intended to resist the "parentalism" of professionals and promote autonomous decision making.

Social scientists describe many barriers to obtaining genuine informed consent. Some patients express little interest in making health-related decisions. Some research subjects suffer from the "therapeutic misconception"; they believe that they are receiving beneficial treatment when they are participating in research without guarantee of benefit. Other observers note the complexity of information sheets and informed consent forms, linguistic barriers to communication, differences between the "explanatory models" of patients (or research subjects) and health care professionals, the failure of clinicians or researchers to disclose financial conflicts of interest, and differentials in power within the clinical realm. Other questions about the reliability of informed consent emerge when patients or research subjects express ambivalence about their choices, decision-making capacity fluctuates in response to the severity of illness or the influence of medications, or family members or health care professionals unduly influence deliberative processes and decision making. In short, there is a gap between informed consent as a relatively straightforward philosophical and legal concept and informed consent as a messy, complicated, multifaceted social process.

Rosenthal's article reveals the difficulties associated with seeking prior informed consent of entire indigenous communities. He identifies numerous barriers to obtaining prior informed consent of collectives. Abuses from the past can undermine efforts to negotiate agreements involving ethnobotanists, indigenous communities, various academic institutions, and pharmaceutical companies. Histories of colonialism can undermine trust amongst stakeholders. Cultural differences can pose challenges to seeking prior informed consent. Perhaps most important, two major problems will often confront researchers hoping to promote bioprospecting initiatives.

First, the diffusion of knowledge across various groups can raise perplexing questions about who ought to be involved in research initiatives and who can lay claim to being a stakeholder in the research process. The concept of prior informed consent is predicated upon the notion that there is

some identifiable collective from which informed consent can be sought. However, defining what counts as a relevant “community” can be a contentious process. Official bodies established by nation-states do not necessarily have credibility in particular communities. Sometimes various groups are engaged in a struggle for control of local resources or the support of different constituencies. Where the boundaries of groups are well-defined, obtaining prior informed consent can begin with some basic assumptions about whose consent should be sought. In other instances, it is not always clear who ought to be engaged in dialogue. The involvement of NGOs and other social actors purporting to “represent” the interests of various groups raises additional questions about whose “voices” should be given greatest consideration in negotiation processes.

Second, even if a “community” can be identified, it will not always be possible to identify authoritative bodies or leaders who can “represent” the interests of that community, engage in negotiations, support or question educational initiatives, and sign contractual agreements. Conflicts involving various governing bodies, disputes within these bodies, and questions about their legitimacy can undermine efforts to negotiate agreements with indigenous communities. Governing bodies can disagree about how to weigh risks and benefits and about what constitute appropriate forms of remuneration, capacity building, and local involvement in research activities.

As a philosophical concept, informed consent, whether at the level of the individual or of the community, is well defined and easily comprehended. Situated in time, located in particular places, inserted into narratives of colonialism, and connected to the interests, concerns, and local knowledge of particular groups, informed consent as a social process is often remarkably complex, murky, and convoluted. However, since bioprospecting occurs in complicated social arenas with specific actors, local histories, imbalances of power, conflicts over authority, and basic disputes about what counts as a particular “community,” Rosenthal performs an important service by drawing attention to the multiple challenges that efforts to seek prior informed consent with indigenous communities will often face.

Reply

I appreciate the diverse and thoughtful critiques of the experts in anthropology, bioethics, ethnobotany, and genetic resources who have taken the time and effort to respond to my article. Each of these commentators raises important points regarding either my analysis of the Peru and Maya ICBGs histories or my view of the lessons these projects provide for future research collaborations with indigenous communities. My response focuses principally on those comments that represent

disagreement or interpretations that differ from those I have offered. I should start out by emphasizing that my analysis should not be construed as a policy statement from my institution or even my program. Rather, it reflects a personal assessment of the ICBG experiences and suggestions to help the research community move forward in a constructive fashion.

Most commentators are largely supportive of my assessment of the central role of culturally relevant, credible representative democratic governance as an enabling condition that differentiates the two ICBGs, although several point to other factors that play important roles. I agree that the historical context of armed conflict (Field) and the growing empowerment of diverse indigenous voices in Chiapas (Simone) had a larger influence on the Maya ICBG than on the earlier project in Peru. However, we should recall that northern Peru during this period was experiencing a border war with Ecuador, ongoing violence from the Sendero Luminosa, and significant strife related to the coca trade. Furthermore, the political voice of the indigenous peoples in Peru at this time had been activated in numerous strikes and protests related to logging and oil concessions and by the Sendero movement, among other influences. Both Hunn and the Berlins point to the differences of sophistication and persistence in the negative campaigns waged by international advocacy groups against the two projects. Having lived through both of them, I can say that the campaigns were quite similar in argumentation and approach, but the greater reach of the Internet during the Maya ICBG enhanced the negative campaign against that project. This factor, in association with greater national sensitivity in Mexico to U.S.-led projects involving the nation’s patrimony, was certainly important in determining the Maya ICBG’s different fate.

While acknowledging the influence of background conflict and activism, I maintain that indigenous governance is key when working with outside organizations and communal resources. We can look to a third example that reinforces this view. The UZACHI-Sandoz project in Oaxaca, Mexico (1995–98), was a non-ICBG partnership between a preexisting cooperative organization of Zapotec and Chinantec communities in Oaxaca and a Swiss pharmaceutical company, Sandoz, to evaluate diverse fungi (without use of traditional knowledge) as a potential source of new pharmaceutical agents. UZACHI (a Spanish acronym for the Union of Zapotec and Chinantec Communities) was formed in 1992 to represent about six indigenous communities in a variety of natural resource issues and projects, including forestry management rights and the edible-mushroom trade (Larson-Guerra et al. 2004). They had formal community consultation, negotiating, and decision-making mechanisms and developed their own benefit-sharing plan among communities. The project with Sandoz was initially labeled “biopiracy” by RAFI(ETC.) on its web sites and in an international e-mail campaign similar to that targeting the other ICBGs. However, in this case UZACHI was able to generate an authoritative

representational response at the organizational and community level. Among those responses was a letter from two dozen community representatives declaring their support for the project and protesting the meddling of outside activist NGOs. The campaign was dropped, and the project continued.

This brings me to Greene's question whether I make too great a distinction between the Peruvian umbrella federation, CONAP, and the Chiapas healers' organization, COMPITCH, and the related implication by Simonelli that the COMPITCH/RAFI campaign represented the Maya people's will. Indeed, these questions go to the heart of the issue of representational authority that I point to and that Turner further articulates in his commentary. It is possible that my relative naiveté about the local conditions leads me to perceive clear differences where the reality is murkier, but it seems to me that there is a relatively straightforward and very important distinction between the two organizations that is independent of size, age, or strength. Rather, it is based on the nature of their missions and their degree of accountability. The Aguaruna federations under CONAP are authorized relatively directly by communities to negotiate on their behalf on a diversity of projects relating to the outside world. They assessed the popular will of the communities relative to the ICBG in a formalized process (similar in some respects to that of UZACHI) and acted accordingly, as they have done for a variety of unrelated projects regarding agricultural development, territorial disagreements, oil and gas leases, etc. In this way they approximate a community governance mechanism for development projects. By contrast, COMPITCH is a professional guild of healers and midwives. Their members are neither elected by communities nor directly accountable to them for their actions in relation to external projects. This is not to say that they are irrelevant to the discussion. However, giving such a guild veto rights over a project proposing to work directly with community members and communally held knowledge on local medicinal plant use is analogous to giving a carpenter's union the final voice on a neighborhood zoning plan or home sales. The guild is a relevant stakeholder, but I question whether it can speak legitimately for the citizenry. While acknowledging what Greene calls "the myth of inclusion" in democratic societies, I maintain that a professional guild is a special-interest group whereas a federation that formally assesses the popular will and is directly accountable is a more valid representative of community interests.

Hunn's view that *parajes* and their parent *municipios* in Chiapas represent a working governance system and the most widely recognized voice of the Maya is important. Indeed, this assessment was the basis of the Maya ICBG approach to community consent. I have no doubt that this was true in the 1970s and continues to be true to some degree today. However, in the context of the indigenous movement, the Zapatista rebellion, frequent corruption charges, and a host of human rights allegations, the state-organized bodies have much less credibility today in Chiapas and especially in the

national and international arena on matters as sensitive as the use of traditional knowledge and genetic resources. This raises the question whether the dynamics of the debate would have been altered in favor of the project if "bio-politically" savvy indigenous leadership could have mobilized a formal unified response from a critical mass of *parajes* on behalf of the Maya ICBG as UZACHI managed to do in Oaxaca. I suspect so, but I believe that both mobilization of a community response and a positive reception on the regional, national, and international stages would be much more likely with knowledgeable leadership in place and a preexisting framework for cooperation among the *parajes* or *municipios* on such matters.

Several commentators disagree with one or more aspects of my view of the implications of these two ICBG histories for collaborative research involving genetic resources and traditional knowledge. Brush and Hoeyer see the challenges faced by the projects largely in the global policy context of international treaties governing intellectual property rights and genetic resources, the UN Convention on Biological Diversity, the World Intellectual Property Organization, and the International Treaty on Plant Genetic Resources for Food and Agriculture and look to progress in these global discussions for resolution of conflicts. I agree that the global policy context is important. However, I am convinced that international discussions are much more productive when grounded in specific lessons such as those offered by the ICBGs. In this regard, I am much more confident than Brush is that locally negotiated solutions can be found to the challenges posed by communal resources for sustainable use, access and benefit-sharing, and conservation (Biodiversity Convention language), even in the current policy environment. I have focused on the two most controversial ICBGs because the controversies and their outcomes highlight important issues. But the vast majority of the projects we have supported in Suriname, Madagascar, Chile, Argentina, Costa Rica, Panama, Nigeria, Cameroon, Vietnam, Laos, Papua New Guinea, Uzbekistan, and Kyrgyzstan have functioned with broad support of local governments, local NGOs, and communities.

Field, Hoeyer, Bannister, and Simonelli all point to asymmetrical power relations and suggest that prior informed consent is an inappropriate framework with which to engage indigenous peoples in this type of research. Each, explicitly or implicitly, points to "participatory approaches" as more appropriate. In principle I agree. However, for better or worse, the terminology of "consent" and the regulatory framework it reflects are a function of the philosophical and political history of very diverse activities in biomedicine, anthropology, and sustainable development. This regulatory framework currently establishes the most generalizable minimum standards for the conduct of research (CIOMS 2002; NBAC 2001; UNEP 2002; but see Emmanuel et al. 2004 for a broader view of ethical research) and is not incompatible with participatory approaches (see Bhutta 2004). In fact, both ICBGs (and in particular the Maya ICBG) incorporated participatory elements in much of their research planning and execution.

Would the projects have been stronger with more initiative and leadership from the communities? Almost certainly. Most important, though, whether or not community members are actively participating in setting objectives and designing, conducting, and evaluating the research, if the project deals with communal resources it comes back to the same question that is at the heart of this paper. Who has the authority to collaborate and share these resources with outside researchers? Participatory approaches do not obviate this basic question. I am entirely in agreement that, in the long run, indigenous communities themselves must have the capacity to conduct and assess ethnographic and other types of research. Moreover, I believe that it is part of our responsibility as researchers to facilitate capacity-building in these areas.

Perhaps not surprisingly, my most concrete suggestion has drawn the most fire. This suggestion is that research institutions working with indigenous societies on genetic resources and communally held knowledge attempt to differentiate basic from applied research objectives and state their objectives in advance in order to minimize unnecessary anxiety when the project does not include commercial objectives such as drug development. Further, I have suggested that projects with commercial intent consider limiting their collaborations to indigenous societies that have governance bodies with systems of accountability and can reasonably demonstrate authority over the resources in question. The concerns expressed include the difficulty in differentiating basic from commercial research (Marshall), how to evaluate whether a given indigenous society satisfies this standard (Field), whether this would effectively withhold opportunities from societies that have not developed sufficiently to meet these standards (the Berlins and Field), and the possibility that such an approach would preclude projects, such as drug or vaccine research efforts, with great potential for public health (e.g., Marshall).

Indeed, it can be difficult to separate basic from commercial research in the early stage of many projects today. Most commercial products in the biomedical world began with a discovery made in a basic research project. Nonetheless, the overwhelming majority of ethnographic and environmental research projects involving traditional peoples are driven by basic interests and conducted by scientists with strictly non-commercial objectives. Given the suspicion that both greets and follows Western scientists working in indigenous societies today, is it not worthwhile to consider how to minimize that suspicion? Moreover, while we cannot predict the future, we can identify two clear decision points at which basic research becomes commercial. The decision to submit a patent application and the decision to share data or samples with an industrial company are both relatively unambiguous signals of commercial intent. I will not attempt to lay out any formal decision tree, but I think that, with the possible exception of human genetic research, this is more feasible than Marshall suggests. Greater complexities arise when a serendipitous and potentially commercial discovery occurs during a project or subsequent to publication. By considering these issues ahead

of time one can be honest about plans and potential outcomes with traditional partners and use this discussion to build trust.

Field asks who should evaluate an indigenous organization's authority and by what standards. Human subjects research protocols are already evaluated to one degree or another, generally by the independent scientific merit review committee, the advisory council of the funding agency, and the agency staff and subsequently by institutional review boards (often at multiple institutions), the local government, and in many cases the community itself. I would not suggest adding new bodies to this process. Rather I would suggest that those developing new projects as well as those involved in the above-mentioned review efforts ask themselves whether, given that communal resources are involved, the collaborating community is competent to authorize the proposed research. The question is analogous to the competence question regularly considered in classical biomedical consent but perhaps more complicated because of the political, cultural, and governance variables relevant to the resources in question. I am hesitant to consider standards for such complex questions and diverse situations. Rather, I would first seek to know that the participants and the evaluative bodies concerned are comfortable with the answer.

For the ICBGs that have worked with indigenous societies in recent years we have asked this competent-authority question directly and repeatedly of the investigators, the community representatives, and the local governments. Because the relevant policies for genetic resources and associated traditional knowledge are still evolving in most countries, the answers are sometimes ambiguous. However, asking the question is enormously important and stimulates all the participants and stakeholders to think about the nature of the collaboration, review their approaches, and revise relevant policies and procedures. I believe that this learning and evolutionary process is positive and congruent with the intent of the program.

Would strict application of the competent-authority principle (if standards could be identified) punish less-well-organized societies and prevent important medical or public health discoveries? This is a very difficult question but an extremely important one. Our inability to answer it argues that we should not apply this principle rigidly or universally. Rather, as in most research ethics decisions, we need to evaluate the potential costs and benefits of a given project to the immediate participants and the global community, as well as the quality of the research, the fairness of the project design, and the competence of the participants to give informed consent.

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