

Sample Genetic Policy Language for Research Conducted With Native Communities

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Abstract—*Background.* We have been repeatedly asked to clarify genetic issues that have cultural ramifications for Native communities. *Method.* In the following commentary, we explain selected genetic issues that may vary among tribal nations; nonetheless, scientists should allocate sufficient time to meet with the tribal leaders and/or members of the tribal institutional review board prior to designing a genetic study to learn how selected issues are perceived by that specific tribal nation. *Results.* Tribal nations generally encourage and mandate community-based participatory research methodology. *Conclusions.* We have included in this commentary draft language for study protocols to support researchers and tribal nations when developing studies pertaining to genetic issues. *J Cancer Educ.* 2005; 20(Suppl.):52-57.

Tribal nations have been involved since 1993 in numerous meetings about genetic issues (see Table 1). In response to concerns about genetic patenting, genetic research, and several other issues, meetings were convened. Studies such as the Human Genome Diversity Project added to concerns about tribal participation and risk to both individuals and community members. At these early meetings as well as present-day meetings, the dissemination of misinformation continues as though it is scientific knowledge (eg, the existence of an “American Indian gene”). Such misinformation contributes to great distrust by tribal nations of the majority of genetic studies. Nevertheless, not all tribes are opposed to genetic research, contrary to many people’s misperceptions; but almost all tribes that we have worked with agree that there has been insufficient effort by scientists to understand and learn how local communities perceive genetic research.

The subjection of Native communities to years of research without the benefit of study findings or perceived benefits has continued to occur. Indeed, the communities perceive research as solely benefitting the researcher with little or no regard for the impact on the community. Thus,

for this and many other reasons, the tribes who do wish to take part in research typically desire or mandate “community-based participatory research” (CBPR) methodology. Many scientists continue to misinterpret this methodology, yet descriptions of successful CBPR are well documented.¹⁻¹⁵ Among the more common erroneous interpretations is that if Natives are study participants, then the study was a CBPR project; this can be a false finding. CBPR requires that the community be equal partners for all the proposed study stages (eg, the development, refinement, implementation, assessment, interpretation of findings, and dissemination of findings). CBPR requires for each study phase that both community members and researchers have equal decision-making responsibilities. It also means that the study budget is comparable among all partners. This budgetary allocation is a way to begin to determine whether a study is really a partnership and/or CBPR.

A prior existing CBPR relationship among researchers and tribal leaders is obligatory for the release of a Request for Applications. The scientists and tribal leadership typically need a few years to develop trust, agree on priorities, and establish a working relationship among the regulating entities (eg, tribal review boards and institutional review boards [IRBs]). The following recommendations describe suggestions for protocol language to begin discussions on equal ground between community members and research institutions.

CULTURAL COMMUNICATION “PROTOCOLS” WITH TRIBAL MEMBERS

Examples of Cultural Issues

1. Obtaining tribal approval. Each tribal nation has a tribal council, health board, or some organized community body that must review and approve all research projects prior

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TABLE 1. Examples of Key Historical Events That Have Impacted Natives' Perceptions of Genetic Research (1983-1998)*

Year(s)	Event	Examples of Impact to Natives
1983-1984	John Moore and the Mo-line ¹⁶	Raised issues about ownership of body parts, cloning, informed consent process
1984	Genetic mutations caused from atomic bombing studied	Study unknown within general populations
1990	Congress approves Native American Graves Protection and Repatriation Act ¹⁶	The Act recognizes the right of ownership, respect for cultural perspectives of burial, and respect for the dead; some ancestors bones and artifacts returned to the descendants or their tribal Nation
1991	In 1991, organizers discussed the Human Genome Diversity Project (HGDP) in Sardinia, Italy (project formally organized in September, 1993)	Study unknown within general populations
1990	The Department of Defense and the National Institutes of Health announce the Human Genome Project	Study unknown within general populations
1993	Small groups of AIAN† become aware of the HGDP; meeting with HGDP principals in San Francisco ¹⁶	Insufficient informed consent of the study and potential outcomes; resulting in international Indigenous communities' fears related to (1) potential for stereotyping entire race based on one specimen from entire cultural group; (2) potential annihilation of entire race; (3) patenting issues; (4) specimens stored and used in studies of which tribal Nation has not approved; (5) insufficient protection of Indigenous knowledge of plants, healing, etc*; (6) fears of misuse and mismanagement of the new technologies; (7) interspecies hybridization
1993-present	American Indians meet to discuss genetic issues and numerous declarations are passed ¹⁶	Informed tribal communities about the HGDP and the potential harms; some tribes pass ordinances prohibiting all genetic research among their members
1993	National Congress of American Indians passes Resolution No. NV 93-118 condemning the HGDP ¹⁶	Patent from a indigenous male Hagahai from Papua New Guinea
1995	News of Papua New Guinea patent reaches Indian Country ¹⁶	General US population became aware of selected patenting concerns (not limited to Native peoples)
1995	80 American religious leaders released statement against patenting human and animal genes as a violation of the sanctity of life ¹⁷	Provided guidance to other communities on both the benefits and process of becoming partners in research and controlling how findings are used
1995	Akwesasne Mohawk publish article in peer-reviewed journal on community-based participatory research (CBPR) concepts and manual on how research, including genetics, should be organized, implemented, disseminated ¹⁸	First formal intertribal declaration opposing HGDP, patenting, cloning, etc
1997	"Heart of the Peoples" Declaration, first statement from the Indigenous Peoples of North America from a "Summit on Biological Diversity," Ft. Belknap, MT, August 7, 1997	Addressed patenting, cell lines, storage of specimens, cloning, repositories, need for CBPR
1997	Cold Springs Harbor Symposium on Human Evolution and the HGDP held in Cold Springs Harbor, NY, October 4-8; sessions on HGDP are held and AI invited to attend	Scientists stressed potential positive impact of genetic research; Natives raised cultural issues (eg, those listed previously)
1998	American Association for the Advancement of Science Conference, Philadelphia, PA, February; symposium on the HGDP held; AI invited to attend	AI representatives presented cultural issues
	National Bioethics Advisory Commission proposed that regulatory oversight be extended to include the protection of social groups (eg, AI)	Aboriginals from Canada, New Zealand, Australia, United States invited to discuss common issues of violation of personal property (e.g., specimens), patenting, fears of racial annihilation, etc.
	Rural Advancement Foundation International	Specific examples of plant genomics and patents highlighted
	Third World Network lauched international campaign against patents derived from the Neem tree (native tree of India)	Western scientists perceived as being "after Indian blood" to exploit the natural resources as well as Indigenous knowledge for monetary gains; "first they take your land, now they take your blood"
	Biocolonialism concept related to biotechnology disseminates throughout Indian Country	Genetic scientists recognize that many groups, not limited to Native Americans, need easy-to-understand language to enable informed consent processes
	Council for Responsible Genetics developed to translate scientific jargon into concepts understandable by communities.	

*AIAN indicates American Indian and Alaska Natives; AI, American Indian.

†Scientists, pharmaceutical companies seek plants for medicinal products along with the indigenous knowledge of their application and use, resulting in patents that prohibit communities from accessing plants for traditional uses—according to patenting language, these plants should be exempt from patents.

to implementation. The researcher needs to approach the tribe in a respectful manner that includes scheduling meetings with decision-making representatives from the tribal council, health board, or comparable body. Communication and approval protocols are unique to each tribal Nation and not easily accessed by an outsider of that community.

2. Prioritizing the research topic. Not all topics of interest to a genetic researcher are of equal interest to the community. The researcher needs to work with the community to understand and learn how the communities prioritize the genetic study. For example, research on migration patterns of ancient peoples are rarely of interest to tribal nations. Tribal nations often place higher priority on current relevant community issues such as diabetes, heart disease, and other health-related topics. Therefore, since there are limitations on available funding and resources for quality research studies, the efforts should focus on research issues that are of equal priority to the community and the investigator. CBPR protocols provide a means for establishing priorities.

3. Responsibility of academic and research institutions. Academic and research institutions need to invest the time and energy required developing a mutually trusting relationship with the tribal nation prior to developing a study protocol. Tribal nations reserve the right to issue sanctions against both the researcher and the sponsoring institution for violating tribal policies; such sanctions can extend beyond that current study and may prevent future contact between the institution and the tribal nation.

Draft Policy Language for CBPR

CBPR protocols used by and for the tribal nation require active partnership and joint decision making for all research project phases and components. The tribal nation and the researcher are both required to utilize CBPR prior to initiating a study.

DISCRIMINATION

Examples of Cultural Issues: Stigma

Genetic research can exclude individuals from medical care if they are associated with a particular disease. More important for Native communities, there is an additional concern that members of a particular tribe will be associated with a particular anomaly that results in stereotyping and stigmatization. The most obvious example of stigmatization is alcoholism. An additional Native American concern is the exclusion from the benefits of genetic research in the future due to some perceived stereotype. Therefore, the potential to be discriminated against for participation by one or a few tribal members risks the stereotyping of the entire tribe.

Draft Policy Language for Discrimination

None of the information learned from this research will discriminate against the individuals or the tribal Nations participating.

COLLECTION OF SPECIMENS

The Cultural Issue: The type of Specimen

Researchers are frequently unaware of cultural connotations of body parts for many tribes: One example is that selected tribal nations place great value on human hair. Thus, the cleaning out of one's hairbrush requires a culturally specified manner to save the hair and discard it. During the 1990s, researchers sent letters to tribal leaders requesting hair samples for genetic studies. Tribes for which hair holds a special significance received the letters and needless to say, the tribal communities were greatly offended by this cultural insensitivity.

The Cultural Issue: Blood Sample Collection of Genetic Material Versus a Blood Test for Routine Medical Care

A common question from researchers is how these two differ since they collect the same bodily fluid. For many Native tribes, the use of the specimen is why it is an issue (see discussion of storage, cell lines, and patenting following).

Draft Policy Language for Collection of Specimens

A portion of blood drawn for routine medical tests can be used for this and only this research project.

STORAGE OF SPECIMENS

Examples of Cultural Issues

Spiritual Issues

Some tribes have cultural beliefs like many other cultures that require the individual to leave the world whole. Thus, the significance is that if tissues are removed and remain on Mother Earth after one "walks on" or "passes," their ancestors will be unable to "find" them. This also prohibits the collection of genetic specimens from dead bodies.¹⁹

Long-term Storage

The most common concern about the storage of specimens relates to restrictions on the use of the specimen (described following). For those tribes who are participating in genetic studies, their specimens may be stored throughout the existence of that study only (eg, 5 years) and then must be discarded appropriately. Appropriate disposal may include return of the specimens to the tribe.

Making the Specimens Anonymous

Many research protocols require the removal of the phenotypic information from the specimens before storage. Since specimens would not be able to be identified to be re-

turned to an individual or a community (ie, the researcher may not know which specimens were from Native Americans), this type of protocol may exclude those Native Americans who want their samples back following participation. In addition, researchers, such as Fatimah Jackson, PhD, are raising issues about whether a sample of DNA is ever truly anonymous (ie, “anonymous DNA” is an oxymoron according to Dr. Jackson).

Storage of Tribal Specimens Without Tribal Knowledge

Indian Health Service (IHS) clinics collected specimens and maintained them in a repository managed by scientists or federal agencies without community knowledge. At the time of collection, blanket consents were common and included language such as “this information may be used for subsequent studies.” However, at the time of such blanket consents, genetic science was not as advanced as it is today. When these samples were used, it conflicted with the expectations of the original donation. Thus, many tribal nations have instituted policies requiring that they be notified if any specimens are to be placed in a repository.

Draft Policy Language for Storage of Specimens (Tumor, Blood, Saliva, Hair Follicle, DNA)

The specimens may be stored for use in this study only. All stored specimens will be anonymous (ie, phenotypes removed), and no personal identifiers will be retained, including geographic area or tribal affiliation.

CELL LINES

Examples of Cultural Issues

Native participants are opposed to the creation of cell lines because such research assumes the role of the Creator by creating DNA, messenger RNA, and so on. It is possible to perpetuate cell lines indefinitely, which contributes to the distrust by the Native community.^{20,21}

Draft Policy Language for Cell Lines

There may not be cell lines created to immortalize the specimens for additional studies. Additional specimens will not be collected for others to create cell lines or comparable repository storage protocols (ie, aliquots may not be distributed to nonapproved researchers).

SHARING OF SPECIMENS

Example of Cultural Issues

Anecdotal data was reported to tribal Nations about investigators sharing specimens for studies other than what was initially intended. Informed consent prohibits such sharing, and no permission had been requested of the tribal

leadership because the researchers or federal agencies claimed to have had a patient release from a decision-making body (eg, former trustee for the tribal nation) to use the specimens.

Presentation/Publication of Shared Data

Numerous reports were mentioned by tribal communities as well as college students participating in “Genetic Education for Native Americans” (R25 HG01866) GENA® about how specimens in laboratories where they were working were freely shared among investigators. The situation was even more inflammatory when Native students and community members attended meetings where genetic studies that included their tribe’s specimens were reported (orally, poster format, and reprints of peer reviewed publications). The tribal nation had no knowledge that these other studies had shared and used the specimens. In response to these situations, many tribal nations have instituted requirements for tribal approval of meeting abstracts and manuscripts prior to submission.

Draft Policy Language for Sharing of Specimens

No specimens collected for this study will be shared or accessible to any researcher other than those listed on the consent form. If the investigator should relocate or retire, the specimens will not be transferred without explicit permission from the tribal health board and/or tribal/IHS IRB. Sharing With Federal Agencies

Formal tribal approval is mandatory should specimens be shared with federal entities.

LIMITED USE OF SPECIMENS

Example of Cultural Issue

Based on our work with tribal Nations, it is almost unanimous that specimens collected for one study must be limited to that study. When researchers determine that an additional biomarker should also be examined, *active informed consent* (the individual must say “yes” to participate) is mandatory before the study can proceed. Thus, without active informed consent from the individuals, no specimens from one study may be used for any other purpose.

Draft Policy Language for Permission for Use of Specimens for This Study Only

If at any time these specimens are requested for other research, active informed re-consenting (ie, the participating tribal leaders must say “yes” to have their community included rather than *passive approval* that requires the individual say “no” to be excluded) is mandatory from the individual. If the specimens have had phenotypic information removed, then tribal health board and/or tribal/IHS IRB permission is required.

DISPOSAL OF UNUSED SPECIMENS

Example of Cultural Issue

For selected tribal nations, cultural practices exist to handle unused specimens. For example, a study was conducted in one tribal community that involved the collection of blood samples. This tribal community perceived that the remaining blood samples were to have been returned to the tribal healers for ceremony. However, the researchers discarded the blood with routine laboratory methods. The researchers in this case did not realize the cultural implications for the participants. The participants of this study subsequently had to spend several days preparing for a costly ceremony that could have been avoided (ie, the original ceremony for the tribal healers to discard the unused blood was short and relatively easy to do).

Draft Policy Language for Disposal of Unused Specimens On Completion of This Study

The investigators agree to discard unused specimens according to the local tribal community's restrictions. This may include returning the specimens to tribal leaders for ceremonies or other culturally specific practices. The community may elect to have the scientists dispose of the specimens by ordinary means.

PATENTS

Example of Cultural Issues

The cell lines, storage, and shared issues described previously are also related to patenting.

John Moore Case

Information about this case was widely publicized and orally shared during many Native meetings since 1993. This raised issues of who owns one's body tissue once removed from the body. Tribal nations generally disagree with the legal verdict from this case (ie, that once removed from the body, the researchers owned the tissue).

Contradictory Worldviews of Monetary Gain Versus Native Worldviews of Giving and Sharing

There is a fairly unanimous perspective from tribal communities, regardless of how diverse we are from one another, that it is inappropriate to restrict access to treatments, cures, and so on. Thus, patenting, particularly by private companies, directly violates the Native perspectives of sharing and helping people from all four directions and cultures of the world.

Patenting Products May Be So Expensive That Poor People Will Not Benefit From the Discovery

Once patented by companies, Natives will have limited access to plants and the Native knowledge of how to use plants and comparable products. Of particular concern is that patents by commercial companies may result in effective medications that will primarily be available to people who can afford to purchase expensive drugs and therapies rather than the less well to do.

Draft Policy Language for Patents

There is no expectation of the creation of patents resulting from this research. Moreover, should any patents occur resulting from the use of these specimens, the tribal community would share in the benefits and be a co-owner of a patent.

SUMMARY

Genetic research has multiple cultural ramifications for tribal nations of which most investigators are unaware. Prior to pursuing a genetic study with tribal nations, the investigator needs to develop a good, trusting, working relationship with tribal leaders. CBPR is the preferred method of conducting research with tribal nations as equal partners. Through such research designs, the tribal nations' cultural perspectives can be addressed and the subsequent study may be designed to be respectful and of high interest to both the investigator and the community. Disregard for the tribal perspectives can result in tribal sanctions against the researcher for subsequent studies. Furthermore, the tribe may refuse to conduct any research studies with any academic or federal institution that has sponsored unsanctioned research.

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