



## Research Regulation in American Indian/Alaska Native Communities: Policy and Practice Considerations<sup>1</sup>

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### Introduction: The Need for Research Regulation in Indian Country

Finding new ways to regulate research is becoming an increasingly important issue in Indian Country. American Indian/Alaska Native (AI/AN) tribal governments as well as urban Indian organizations are increasingly working to develop policies and institutional structures to regulate research. Such research review policies are important so that AI/AN communities have the means to protect themselves from harm in research, and so that they can gain the maximum possible benefits from research in using data to improve policies and practices. Furthermore, as sovereign governments, AI/AN communities have the legal authority and imperative to regulate research that is conducted on their lands. There has been a long history of research in AI/AN communities<sup>3</sup>, and AI/AN people are one of the most heavily-studied groups in the U.S. For example, a search on PubMed, one of the nation's largest search engines for medical science articles dating from the 1950s to the present, yields over 3,000 articles about AI/AN communities. The reasons for so much research in Indian Country are probably complex, and include (1) the high prevalence of certain health concerns in AI/AN communities, such as diabetes, heart disease, and alcohol use; (2) recent priorities in federal funding for research with ethnic minority groups; and (3) non-AI/AN researchers' interest in working with AI/AN groups who they view as "romantic" or "exotic."<sup>4</sup>

Unfortunately, the long history of research in Indian Country has included some instances of harm to AI/AN communities. The latest publicized example of harmful research in Indian Country is described in the now-infamous lawsuit the Havasupai Tribe has filed against Arizona State University (ASU).<sup>5,6</sup> In February 2004, the Tribe filed the lawsuit, charging that researchers from ASU misused blood samples taken from tribal members. The Tribe claims that tribal members were told their blood samples would be used for a study on the genetics of diabetes. However, the samples were also used for studies on schizophrenia, inbreeding, and possible

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<sup>3</sup>Davis, Jamie D. and Kelly Keemer. A Brief History of and Future Considerations for Research in American Indian and Alaska Native Communities. In Work Group on American Indian Research and Program Evaluation Methodology, Symposium on Research and Evaluation Methodology: Lifespan Issues Related to American Indians/Alaska Natives with Disabilities. Northern Arizona University, American Indian Rehabilitation Research and Training Center, 2002:9-18. <http://www.ncaiprc.org/index.php?todo=page&which=208>

<sup>4</sup>Brugge, Doug and Mariam Missaghian. Protecting the Navajo People Through Tribal Regulation of Research, 2003. <http://www.researchethics.org/articles.asp?viewrec=27>

<sup>5</sup>Rubin, Paul. Indian Givers. Phoenix New Times. May 27, 2004.

[http://www.phoenixnewtimes.com/issues/2004-05-27/news/feature\\_1.html](http://www.phoenixnewtimes.com/issues/2004-05-27/news/feature_1.html)

<sup>6</sup>*Havasupai Tribe vs. Arizona State University*, Case No. CV2005-013190, Superior Court of Arizona, Maricopa County. <http://www.superiorcourt.maricopa.gov/docket/civil/caseInfo.asp?caseNumber=CV2005-013190>

migration patterns of the tribe's ancestors from Asia to America. A number of papers were published discussing these topics, which Havasupai Tribe members say was humiliating and harmful to them.<sup>5</sup> This case sent waves throughout Indian Country, with many tribes and AI/AN organizations, including the National Congress of American Indians,<sup>7</sup> passing resolutions expressing support for the Havasupai Tribe's lawsuit against ASU. This case also caused many AI/AN communities to seek new ways to protect themselves from being deceived about the purposes of research projects and to control how their communities are portrayed in publications or presentations by researchers. This paper will present some of the strategies that AI/AN communities are now using to regulate research, and new ways that AI/AN communities might take control of research in the future.

This paper has three main sections: First, ethical and legal considerations for AI/AN communities in the regulation of research are discussed, including federal ethics frameworks for research, AI/AN models of research ethics, and the legal justifications for AI/AN governments to regulate research. Second, different mechanisms AI/AN communities might use to regulate research, such as Institutional Review Boards (IRBs), Community Advisory Boards (CABs), and other forms of research review committees, are presented. This section also includes a brief discussion of special considerations for urban Indian organizations. Finally, the last section of the paper delineates some of the broad policy issues that AI/AN community research review boards face, such as how to relate to federal research regulatory boards, the scope of research that should be subject to regulation by the AI/AN community review board, and methods of enforcing the review board's decisions.

## **Ethical and Legal Considerations for AI/AN Communities in Regulating Research**

### Ethics Codes

Research abuses in ethnic minority communities and other vulnerable populations (e.g., prisoners, psychiatric patients, etc.) were a major reason that the U.S. government formed the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974. This group of scholars and policy-makers drafted an ethics code that would guide the responsible conduct of research, which was published in 1979 as the **Belmont Report**.<sup>8</sup>

The Belmont Report presented three guiding principles that should be used in planning and regulating research projects:

*Respect for Persons:* This principle emphasizes the concept that individuals are "autonomous agents" capable of "self-determination." It also means that individuals should not be coerced into participating in research, and their decisions regarding research participation should be respected.

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<sup>7</sup><http://www.ncai.org/ncai/resolutions/doc/SAC-06-019.pdf>

<sup>8</sup>National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Department of Health, Education, and Welfare, 1979.  
<http://ohsr.od.nih.gov/guidelines/belmont.html>

*Beneficence:* This principle means that researchers have the “obligation” to not harm research volunteers and to maximize possible benefits while minimizing possible harms of the research.

*Justice:* This principle states that the burdens of research should be equally distributed amongst different groups, including individuals of different racial and socioeconomic backgrounds. The fairness demanded by this principle also means that “research supported by public funds” must ensure that the benefits of the research, such as new drugs or diagnostic tests, are equally available to all individuals, even those considered socially disadvantaged in any way.

While most researchers agree that these principles should be followed, advocates of AI/AN communities have argued that the Belmont Report does not go far enough in protecting AI/AN people. The main criticism offered by these advocates, along with many other scholars in bioethics, is that the Belmont Report focuses too much on the individual.<sup>9,10,11</sup> The Belmont Report does not include much discussion of the rights of groups or the need for protection of specific groups in research. AI/AN communities not only need protection of individual community members, but also of the tribe or community as a whole. As is evident in *Havasupai Tribe vs. Arizona State University*, the negative impacts of research can affect a tribe or community as a whole when its name is associated with certain claims of researchers. Although only some members of the Havasupai Tribe gave their blood for genetics studies, all members are harmed by researchers’ statements that the tribe as a whole is “inbred,” for example.<sup>12</sup> Thus, AI/AN communities must consider how to protect both their *individual members* and their tribe or community *as a group* when developing research regulation policies.

The three ethical principles of the Belmont Report are important, and it is ethically necessary for researchers to extend these values to apply to AI/AN communities as *groups*, according to William L. Freeman, former Director of the Indian Health Service (IHS) Research Program. In materials that Freeman wrote for the **Northwest Portland Area IHS Institutional Review Board (IRB)** manual, he explains that it is important for research review boards to ensure that the values of the Belmont Report – respect for persons, beneficence, and justice – are applied to protection of both individual research volunteers and AI/AN communities.<sup>9</sup>

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<sup>9</sup>Freeman, William. The Protection of Potential Individual Volunteers and Tribal Communities in Research Involving the Indian Health Service - in Guidelines for Researchers. Northwest Portland Area Indian Health Service Institutional Review Board, 2004. [http://www.npaihb.org/images/epicenter\\_docs/irb/docs/Protections\\_fr.pdf](http://www.npaihb.org/images/epicenter_docs/irb/docs/Protections_fr.pdf)

<sup>10</sup>Rhoades, Everett R., Rhoades, Dorothy A., and William Freeman. Research Ethics and the American Indian. In *American Indian Health: Innovations in Health Care, Promotion, and Policy*. Johns Hopkins University Press, 2000: 426-433.

<sup>11</sup>Quinn, Sandra Crouse. Protecting Human Subjects: The Role of Community Advisory Boards. *American Journal of Public Health*, 2004. 94(6):918-922.

<http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=15249289>

<sup>12</sup>Markow, Therese A. and John Martin. Inbreeding and Developmental Stability in a Small Human Population. *Annals of Human Biology*, 1993. 20(4):389-94.

For each of these three values, Freeman explains how they might apply both to the rights of individual members of AI/AN communities as well as AI/AN communities as a whole. For example, he expands the first principle to be “*respect for persons and respect for Tribal Community*.” For individuals, this principle means that people are autonomous and must be provided with all necessary information to give fully-informed consent for participating in research studies. Likewise, researchers must give AI/AN communities (and the governmental bodies that represent them, such as tribal councils) all required information and must obtain their informed consent for research conducted with their community members, because as sovereign nations, AI/AN communities are also autonomous. Furthermore, Freeman writes that the researchers must only do what the AI/AN communities specifically agree to in their consent. This means that AI/AN communities should not be identified in research results without their “explicit consent” and that, like individual research participants, they can refuse to participate in a study or withdraw at any time.

The second value, *beneficence*, means that the benefits of research should be maximized and the risks minimized both for the individual research participants and the AI/AN community as a whole. For example, in minimizing risks to AI/AN communities, researchers should “protect their privacy” to avoid causing AI/AN communities to be stigmatized. Finally, according to Freeman, the value of *justice* means that “people with less power should not be asked to undergo risky research that is of little benefit to them [but also] should be included in potentially beneficial research.” Along the same lines, AI/AN communities should not be asked to participate in research which is risky and is not likely to benefit them; yet, AI/AN communities should also be included in research that is potentially beneficial to them.

As AI/AN communities consider how to best regulate research conducted with their members, they may wish to adopt a set of ethical principles as guides for research regulation policy. These ethical principles can be then shared with researchers who work with AI/AN communities so that the researchers also understand which values they should honor in their work. As Freeman has argued, the Belmont Report may provide a useful set of values for AI/AN communities to adopt and then adapt to their specific needs. Another useful set of guidelines is the **Canadian Institutes of Health Research Guidelines for Health Research Involving Aboriginal People**.<sup>13</sup> Alternatively, AI/AN communities may wish to define their own set of ethical values that should guide research and research policy in their communities. These values might be based on traditional spiritual values, derived from healing ways, or collectively defined by the elders in an AI/AN community. For example, the Akwesasne Community of the Mohawk Nation formed the **Akwesasne Task Force on the Environment (ATFE)** to oversee research conducted in Akwesasne.<sup>14</sup> In its Protocol for Review of Environmental and Scientific Research Proposals, the ATFE includes a Preface with Guiding Principles for research. The values named are *skennen* (peace), *kariwiio* (good mind) and *kasastensera* (strength). These are the central ethical values to which both the ATFE and researchers must adhere when working in Akwesasne. The

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<sup>13</sup>Canadian Institutes for Health Research. CIHR Guidelines for Health Research Involving Aboriginal People, 2007. <http://www.cihr-irsc.gc.ca/e/29134.html>

<sup>14</sup>Quigley, Dianne. Compilation On Environmental Health: Research Ethics Issues With Native Communities, 2001. <http://www.researchethics.org/uploads/pdf/compilation.pdf>

ATFE Protocol, developed by and for members of the Akwesasne Community, sets out a comprehensive vision of how ethical research should be conducted at Akwesasne.

### Legal Basis for AI/AN Communities Regulating Research

As sovereign nations, AI/AN communities have the right and the responsibility to regulate research on their lands. Federal law provides some protections for AI/AN people that participate in research, but it is also important that AI/AN community governments formulate their own policies or laws regulating research. This section will first describe existing federal law on research regulation and then discuss the legal basis under tribal law for AI/AN communities to regulate research.

#### *Federal Law*

Under federal law, all research conducted or funded by federal departments and agencies must follow the requirements set forth under the federal regulations in Code of Federal Regulations, Title 45, Part 46, which is entitled Protection of Human Subjects (hereafter referred to as 45 CFR 46).<sup>15</sup> These regulations require that all research involving human subjects must be approved and continuously monitored by an Institutional Review Board (IRB). IRBs are committees which are found at most universities and other research institutions in the U.S. They usually include both members from the university and from outside the university (community members at large). The purpose of IRBs is to make sure that research volunteers are protected from harm. In order to do so, IRBs require that researchers submit a detailed application which explains the purpose of the research study, the procedures which will be followed in the study, the risks and benefits of the study for individual volunteers, ways that the risks will be minimized, and a copy of the informed consent form that the researchers will give to potential volunteers.<sup>16,17</sup> The federal regulations also include detailed requirements for what information must be included in the informed consent form, as well as who must serve on IRBs.

#### *Indian Health Service IRBs*

In accordance with these policies, the IHS has established IRBs for its Area Offices.<sup>18</sup> These IRBs oversee research conducted in IHS facilities. Some AI/AN communities served by IHS Area Offices have formal or informal agreements by which the IHS Area IRB oversees other health research conducted with AI/AN community members even outside of IHS facilities

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<sup>15</sup>Department of Health and Human Services. Code of Federal Regulations, Title 45, Public Welfare, Part 46, Protection of Human Subjects, 2005. <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

<sup>16</sup>For a list of required components for an IRB application, see: Northwest Portland Area Indian Health Board. Institutional Review Board (IRB), 2007. [http://www.npaihb.org/epicenter/page/irb\\_submitting\\_materials1](http://www.npaihb.org/epicenter/page/irb_submitting_materials1)

<sup>17</sup>For sample IRB application forms, see: Office of Research and Compliance Services, Creighton University. Institutional Review Board: Application and Reporting Forms, 2007. <http://www2.creighton.edu/researchcompliance/irb/irbforms/index.php>

<sup>18</sup>For a list of IHS and tribal IRBs, see: Indian Health Service. Human Research Participant Protection in the Indian Health Service, 2006. <http://www.ihs.gov/medicalprograms/research/irbTribal.cfm>

(personal communication, IHS staff, 2004).<sup>19</sup> The federal regulations for protecting human subjects in 45 CFR 46 do not specifically address the protection of communities. The IHS IRBs, however, follow specific policy provisions in addition to 45 CFR 46 that are designed especially to protect AI/AN communities. First, IHS IRBs include at least one AI/AN community member as part of the committee. In most IHS IRBs, more than half of the committee members are AI/AN individuals. Second, the IHS IRBs encourage researchers to provide certain information about the research (study procedures, risks, benefits, etc.) to the AI/AN communities who are involved, just as the federal regulations require that information about the research must be provided to individuals who volunteer to participate. The IHS IRBs also require proof that AI/AN governments included in the study have approved the research; this approval might be in the form of a tribal resolution or a letter of support from a tribal government.<sup>10</sup> Finally, the IHS IRBs require that researchers submit publication manuscripts for review to both the IHS IRB and the governments of involved AI/AN communities, and receive approval from both, before submitting the manuscript to a publisher. This function for publication review is not one required by the federal regulations on IRBs, and most IRBs at universities or other research institutions do not require that researchers submit publication manuscripts to the IRB for review. However, IHS IRBs and AI/AN communities with a process for research review often do require researchers to submit their publications for approval in order to give AI/AN communities more control over which information about them is published. This requirement for pre-approval of publications by IHS IRBs and/or AI/AN community research review boards may limit the academic freedom of researchers to some extent, but it also ensures that AI/AN community interests are considered in the publication process.

### *Tribal Sovereignty*

Although federal policies, particularly those of the IHS IRBs, provide some protection for AI/AN communities, these policies may not always be adequate to fully protect AI/AN communities in research. Given that AI/AN communities are sovereign nations (or have other forms of self-determination in the case of urban Indian communities) it is vital that they proactively develop ways to regulate research conducted with their members and they have full authority to do so.<sup>9</sup> Federal law Public Law 93-638, the Indian Self-Determination and Education Assistance Act of 1975, as well as the federal doctrine of Self-Governance, provides AI/AN communities with a legal basis for taking over the administration of health and social services provided to their members. Broadly defined, these services would include research related to health and social issues.<sup>9</sup>

As sovereign governments, AI/AN communities have the right to exclude outsiders from their lands and to regulate what happens on those lands, including research projects. Therefore, language in an AI/AN community's constitution or bylaws about promoting the general welfare of its membership or the right to exclude outsiders from the AI/AN community's territory can be interpreted as giving the community the legal right to regulate research.<sup>20</sup> Furthermore, AI/AN

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<sup>19</sup>Some of the individuals interviewed for this paper did not wish to be named. For further information on how to contact these individuals or obtain other relevant resources and information, please contact the author, Puneet Sahota, at [singhp@msnotes.wustl.edu](mailto:singhp@msnotes.wustl.edu).

<sup>20</sup>Deloria, Philip S. The Role of Tribal Government in Regulating Research. Northwest Portland Area Indian Health Service Institutional Review Board, 2003. [http://www.npaihb.org/images/epicenter\\_docs/irb/docs/deloria\\_fr.pdf](http://www.npaihb.org/images/epicenter_docs/irb/docs/deloria_fr.pdf)

communities may wish to pass a research regulation code as part of their laws in order to explicitly lay out their process of research review and the powers of the board that will review research. The Navajo Nation has passed such a code, entitled the **Navajo Nation Human Research Code**.<sup>21</sup> AI/AN organizations have also published model codes that AI/AN communities may wish to use as guides to developing their own research codes. One such model code has been developed by the **American Indian Law Center, Inc.**, and this document includes both a model code and a checklist of questions that AI/AN communities may wish to use in reviewing research proposals.<sup>22</sup> The **Indigenous Peoples Council on Biocolonialism**, an activist organization seeking to help AI/AN communities protect themselves from harm in genetics research, also has developed a model research code, the Indigenous Research Protection Act, that AI/AN communities may consider adopting or modifying for their needs.<sup>23</sup>

Deloria argues that the federal regulation of research does not and cannot completely protect the interests of AI/AN communities because the federal government has other interests in research.<sup>20</sup> The federal government has a responsibility to support research which is “in the public interest” and to support academic freedom. This obligation may be inconsistent with the federal government’s responsibility to protect AI/AN peoples in research, which might require restricting academic freedom, such as through preventing the publication of certain study results. The federal requirement for data sharing is one important example of how the interests of the federal government and AI/AN communities may not always be the same. The National Institutes of Health (NIH) adopted a data sharing policy in 2003 which requires that all researchers funded by NIH grants in the amount of \$500,000 or more in a single year must share data when possible.<sup>24</sup> Data must be made publicly available and shared with other researchers that request access to that data. Researchers applying for grants must describe a plan for data sharing or must justify why data cannot be shared.

The issue of data ownership and access is a critical concern for many AI/AN communities because when data is shared with researchers outside of the original research project team, how those data are used and interpreted is difficult to control. Publications which take the data out of context may make generalizations about AI/AN communities that are not true or are even stigmatizing to the community. As a result, it is important that AI/AN communities look carefully at the issue of data sharing when developing research agreements and that they closely examine the sources of funding for research, as accepting federal grants may obligate AI/AN communities to make data about their communities publicly available. There may be instances in which AI/AN communities wish to apply for federal grants despite a requirement for data sharing. Each research proposal’s potential benefits and risks to the community should be carefully considered, including the possible implications of data sharing.

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<sup>21</sup>Navajo Nation. Navajo Nation Human Research Code, 1996.

<http://www.nnhrb.navajo.org/pdf/NNHumanResearchCode.pdf>

<sup>22</sup>American Indian Law Center, Inc. Model Tribal Research Code, Third Edition, Albuquerque, 1999.

[http://www.ihs.gov/medicalprograms/research/pdf\\_files/mdl-code.pdf](http://www.ihs.gov/medicalprograms/research/pdf_files/mdl-code.pdf)

<sup>23</sup>Indigenous Peoples Council on Biocolonialism. Indigenous Research Protection Act, 2000.

<http://www.ipcb.org/publications/policy/index.html>

<sup>24</sup>National Institutes of Health. Final NIH Statement on Sharing Research Data, February 26, 2003.

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

AI/AN communities may develop their own policies for regulating research and require researchers to agree in writing to follow those policies. However, taking these steps does not ensure that AI/AN communities will be protected, according to a lawyer in the Southwest who has worked with tribes on issues of research regulation (personal communication, August 2006). He said that AI/AN communities must proactively monitor research while collection of data or blood/tissue samples is ongoing, and then continue to monitor the research study as publications are prepared. Regular communication with researchers and ongoing oversight by the AI/AN community of the research project is important. As this lawyer said:

You can put them [the requirements of researchers] in the documents, but the tribe needs to be vigilant. That's my lesson that I've learned: a tribe can't participate in [blood/tissue] samples being distributed to a research institution and expect that things will go according to the parties' intent at the beginning, because times change, and people's memories fade. Tribes need to be active in the research, and that's the best way I can think of to make sure problems don't arise in the future.

Thus, not only is there an ethical and legal basis for AI/AN communities to regulate research—it is vital that they do so in order to protect the interests of their members and their communities as a whole.

### **Approaches to Research Regulation for AI/AN Communities**

AI/AN communities can use a wide variety of methods to regulate research among their members. Some AI/AN communities choose to work with the IHS, tribal colleges, or other universities in their geographical area to regulate research. Other AI/AN communities have created their own research codes as part of their community laws, and have formed their own research review committees, either using the federal model of an IRB or another structure. AI/AN communities have also created Community Advisory Boards for each specific research project that is done with their members. Finally, there are informal mechanisms that AI/AN communities can use for gathering community members' input into how research studies should be conducted.

#### Using Existing IRBs

According to staff at a Southwest IHS IRB, some tribes that are served by that IHS Area Office have made arrangements for that Area Office IHS IRB to regulate research conducted on the tribe's land. These tribes have "contracted" with the IHS IRB to provide the service of research review and regulation to their community members. Another resource that is open to tribes is tribal colleges. In 2004, nine tribal colleges out of 35, or 25%, had IRBs, and some of those tribal colleges without IRBs were taking steps to establish them.<sup>25</sup> AI/AN communities might also consider "contracting" with the IRB of a tribal college in their area to review research proposals. AI/AN communities and organizations could also offer to provide cultural sensitivity training to

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<sup>25</sup>Hernandez, Juan A. Avila. Blood, Lies, and Indian Rights: TCUs Becoming Gatekeepers for Research. Tribal College Journal, 2004. 16(2).

<http://www.tribalcollegejournal.org/themag/backissues/winter2004/winter2004hernandez.html>



the outside IRB members in exchange for training in IRB research regulation procedures.<sup>26</sup> Finally, every university in the U.S., whether public or private, must have an IRB in order to receive federal funding for research. As a result, nearly every university in the U.S. which conducts research has an IRB. AI/AN communities might also consider ways to work with the IRB at their local university to regulate research in their community. There is usually an office with an administrative coordinator for the IRB that AI/AN communities may be able to work with in order to make that IRB more responsive to the concerns and needs of the AI/AN community. Each IRB at a university is required to have at least one member of the surrounding community as part of the committee. AI/AN communities could advocate for one of the IRB members from the surrounding community to be an AI/AN individual, or perhaps even a member of the AI/AN community's government or professional staff in the health services division. AI/AN communities that choose to contract with an outside IRBs might also consider selectively sending certain types of research proposals to those IRBs. For example, the **Alaska Area IHS IRB** generally reviews research proposals posing greater than minimal risk to research participants while Alaska Native communities review research proposals posing minimal risk.<sup>27</sup>

The approach of using an existing IRB at another institution (IHS, tribal college, or local university) may be attractive for those AI/AN communities with small populations or those that do not have the governmental resources to sustain a research review committee within the AI/AN community. Also, the volume of research proposals that are brought to the AI/AN community is another factor that may determine whether the community chooses to develop its own research review process or contract with an outside IRB. Communities that receive one proposal every few years, for example, may not wish to spend community resources on creating an IRB or research review committee. It may be more expeditious and cost effective for these communities to just work with an outside IRB to review research proposals. On the other hand, AI/AN communities which receive multiple project proposals from researchers every year may feel it is vital that they establish their own research review committee within the community's government.

The main advantages to the approach of using outside IRBs are: (1) this strategy can be implemented relatively quickly; (2) the IRB which will be used is already functional and has the infrastructure to review research; and (3) minimal resources are required from the AI/AN community. The disadvantages of this approach are that: (1) the AI/AN community has less control over the criteria that are used to review project proposals and the research review process as a whole; (2) the AI/AN community is dependent on the outside IRB for research review; and (3) the AI/AN community's interests may not always be clearly represented in IRB meetings or understood by IRB members.

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<sup>26</sup>This strategy has been used by the National Indian Child Welfare Association (oral presentation by Terry Cross: Models of Community-Based Research and Success Measures, National Congress of American Indians Policy Research Center, 2<sup>nd</sup> Annual Tribal Leader/Scholar Forum, Anchorage, AK, June 12, 2007).

<sup>27</sup>Terry Powell. Emerging Topics in Human Research (oral presentation). Research for Native Health: Strengthening Partnerships, Promoting Trust and Increasing Communication, Denver, CO, August 23, 2007.

## Creating an AI/AN Community IRB

Some AI/AN communities may wish to create their own research review boards. In a policy paper for the National Congress of American Indians (NCAI) Policy Research Center (PRC), Nicole Bowman argues that it is important for AI/AN communities to have their own IRBs because these research review committees are an important expression of tribal sovereignty.<sup>28</sup> Bowman points out that while some tribal colleges have their own IRBs, these review boards are not sufficient to protect AI/AN communities in research. Tribal colleges and AI/AN communities have different interests in research, and so it may be important for both entities to have their own, independent research review boards. AI/AN communities that choose to create their own research review process may choose to form a full, formal IRB that is modeled after federal IRBs, or may instead develop a research review process that is structured differently and is specific to the governing structure and needs of the AI/AN community.

AI/AN communities that choose to model their research review boards after the federal IRB process may also have additional requirements beyond those specified in federal research codes. For example, AI/AN community IRBs might choose to review research publications, although federal IRB requirements do not include this function. At least six tribal or inter-tribal IRBs (California Rural Indian Health Board, Cherokee Nation<sup>29</sup>, Chickasaw Nation, Choctaw Nation<sup>18</sup>, Ho-Chunk Nation<sup>30</sup>, and the Navajo Nation<sup>21</sup>) are modeled after the federal IRB framework.<sup>28</sup> In order to establish their IRB, called the Navajo Nation Human Research Review Board (NNHRRB), the Navajo Nation added a section to their laws (Navajo Nation Human Research Code) outlining the functions of the IRB and how it will operate.<sup>21</sup> Thus, this IRB is a formal part of the Navajo Nation tribal government. The Navajo Nation IRB follows the Belmont Report ethical values, like other IRBs, and asks researchers to go through a systematic process, submitting applications for review by the Navajo Nation IRB. Representatives from both the Navajo Area IHS and the Navajo Nation sit on the IRB, and so both interests are represented. This IRB, however, also has some provisions that are specific to Navajo Nation and are not used by other IHS IRBs. For example, the Navajo Nation reserves the right to petition Navajo Nation courts for judgment against researchers if any misconduct occurs or researchers violate the Navajo Nation Health Research Code. Under the Navajo Nation Health Research Code, section 21, the tribal courts may levy a fine of up to \$5,000 against a researcher for any misconduct. The **Northern Plains Tribal Epidemiology Center** also has developed trainings and a wide variety of resources related to tribal IRBs.<sup>31</sup>

The advantages of setting up a full IRB are: (1) that an AI/AN community would have a formal, structured, and comprehensive process by which research proposals are reviewed and tracked in

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<sup>28</sup>Bowman, Nicole. Tribal Sovereignty and Self-Determination through Evaluation. National Congress of American Indians, 2006.

<http://www.nbowmanconsulting.com/FINAL%20NCAI%20Policy%20Position%20Paper%207%202005%2006.pdf>

<sup>29</sup>For more information about the Cherokee Nation IRB, contact Dr. Sohail Khan, Epidemiologist/Co-Chair Cherokee Nation IRB, Cherokee Nation Health Services: [Sohail-khan@cherokee.org](mailto:Sohail-khan@cherokee.org)

<sup>30</sup>Ho-Chunk Nation Tribal Research Code.

[http://www.ho-chunknation.com/government/legis/code/Title%203%20Health%20and%20Safety/3HCC03\\_Research.pdf](http://www.ho-chunknation.com/government/legis/code/Title%203%20Health%20and%20Safety/3HCC03_Research.pdf)

<sup>31</sup>Northern Plains Tribal Epidemiology Center. Research Ethics and Institutional Review Board (IRB) Resources for Tribes and Researchers, 2005. <http://www.aatchb.org/epi/docs/ResearchEthics.htm>

the community; (2) federal models already exist for this type of review board and may be easily adapted to the AI/AN community's needs; (3) the IRB would represent the community's interests, since it is part of the AI/AN community's government and not just part of IHS; and (4) researchers understand the term "IRB," since many have IRBs at their own universities, and this may give an AI/AN community's research review board a certain legitimacy in the eyes of researchers. The main disadvantage to this approach is that considerable time and money may be required on the part of the AI/AN community to establish and maintain the IRB. Significant financial costs are required for hiring administrative staff and recruiting and training the members of the IRB. Public Responsibility in Medicine and Research (PRIM&R) offers different training opportunities for IRBs, ranging from \$700 per individual for conference registration to \$6,300 for a one-day customized training conducted on-site for a group of individuals. IRB training scholarships for AI/AN communities are available.<sup>32</sup>

### Community Advisory Boards

An alternative structure to an IRB that AI/AN communities may wish to adopt is a Community Advisory Board (CAB). CABs have more intensive involvement in research than IRBs. Whereas the focus of an IRB is to regulate research and perform continuing review of research projects to ensure they comply with ethical standards, a CAB's role is to help design the research study and documents from the beginning of the project. CABs have been commonly used in HIV/AIDS research studies conducted with different U.S. populations in order to give those communities involved in HIV/AIDS drug trials more control over research.<sup>33</sup> CABs are composed entirely of members of the community in which a research study is being conducted, and they serve as a liaison between the researcher and the community. CABs initially review the idea for a research proposal, and work with the researcher to make the research relevant to their community. This process includes reviewing the research protocols and informed consent forms and making suggestions about how to revise those materials in order to best meet the needs of the community. For example, an informed consent form might not contain certain information that the CAB believes is necessary for individuals in the community to know before they decide whether or not to participate in a study. The CAB can then make concrete suggestions to the researcher about how to improve the informed consent form. As the liaison between the researcher and the community, a CAB may also choose to formulate a set of recommendations to help community members decide whether or not to participate in a study. As the research study progresses, the CAB can serve as a forum through which the researcher can provide regular updates on the study. The CAB can then convey these updates to the community, serving as the main mechanism by which the researcher communicates their interim findings. It can also be a place for research volunteers to come to report any concerns they may have about the study in a safe and anonymous way. If the CAB deems those concerns to be important to the research

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<sup>32</sup>For more information on IRB training programs and costs, see: <http://www.primr.org/education/overview.html>. PRIM&R offers scholarships for AI/AN communities wishing to attend their annual IRB training conference in December, consisting of a registration waiver and a travel stipend. The deadline for scholarship applications is in August. For more information, contact Maeve Luthin: [mluthin@primr.org](mailto:mluthin@primr.org), (617) 423-4112, ext. 217.

<sup>33</sup>Strauss, Ronald P.; Sengupta, Sohini; Quinn, Sandra Crouse; Goepfinger, Jean; Spaulding, Cora; Kegeles, Susan; and Greg Millett. The Role of Community Advisory Boards: Involving Communities in the Informed Consent Process. *American Journal of Public Health*, 2001. 91(12):1938-1943.  
<http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=11726369>

project, it can then work with the researcher to rectify problems before they become too big to handle. Finally, at the end of the study, the CAB can take the responsibility of helping to disseminate the researcher's findings in a way that is helpful and comprehensible to the members of the community.<sup>33</sup>

CABs can be established for each specific research project, in which case they would be disbanded once the research is over. One advantage of this approach is that members of the CAB can be selected for expertise that is relevant to specific research projects in areas such as data collection methods, the subject matter of the research, etc. Alternatively, AI/AN communities may choose to establish a standing CAB which oversees all research projects happening in the community and works with all researchers who approach the community with project proposals. This latter approach has been successfully used by research institutions working with urban ethnic minority communities.<sup>11</sup> The model of a CAB may be very attractive to some AI/AN communities because it provides control over and input into a research project throughout the process, from the initial development of informed consent forms to the dissemination of research findings at the end of a study. Another advantage of the CAB model is that it encourages dialogue between the researcher and the community, rather than serving mainly as a body designed to enforce ethical principles of research like an IRB. One disadvantage to using this model is that it requires a good deal of time from the members of the CAB to meet periodically, review research documents, make recommendations, etc. Since a lot of time may be required to perform the extensive functions of a CAB, involving one may slow down the progress of a research project. Finally, another possible disadvantage is that researchers may view AI/AN community CABs as merely advisory bodies, rather than boards with real power, like federally-recognized IRBs. This potential disadvantage may be overcome, however, if an AI/AN community chooses to establish a CAB as a formal part of its governing structure by passing a code or law that includes methods for the CAB to enforce its decisions (see Enforcement section below).

### Other Forms of Research Review Committees

AI/AN communities may also choose to establish a research review board with a different structure than either an IRB or CAB. It is possible to take aspects of both models and create a hybrid research review board that includes whatever functions an AI/AN community views as important to meet its needs. In addition, AI/AN communities that have small populations and do not have the resources to form their own IRB or CAB may wish to partner with other neighboring AI/AN communities and form a consortium, which then could establish a research review board to regulate research in all communities that are part of the consortium. Inter-tribal organizations which represent multiple communities may also wish to consider the option of forming a research review board that could serve as a resource for the individual communities that belong to the inter-tribal organization. Even if individual communities choose to maintain their own research review processes, having an inter-tribal consortium IRB or CAB to serve as a resource and possible place where AI/AN communities could refer research proposals for review may be very helpful for smaller AI/AN communities.

## Using Existing AI/AN Community Committees

Rather than establishing a new research review board, some AI/AN communities may choose to delegate the responsibility of overseeing research to a committee or department that already exists as part of the community's government. For example, rather than having a full, formal IRB, some AI/AN communities have chosen to delegate a subcommittee of their Health and Social Services Committee or Health Department that assembles on an ad-hoc basis to consider research proposals whenever they are brought to the AI/AN community. This committee might choose to use many of the same criteria as an IRB in evaluating research (risks and benefits of the study, ethical considerations, informed consent, etc.), and then might refer the proposal to the tribal council or other governing authority with a recommendation to either approve or not approve the project. The advantages of this approach are (1) AI/AN communities do not have to invest the time and money that may be required to establish a full, formal IRB; (2) it is not necessary for the AI/AN community to draft a new law, as may be required to establish an IRB; (3) this research review board, like a AI/AN community IRB, would be part of the AI/AN community governing structure, and so would represent the AI/AN community's interests, not those of IHS or a tribal college; and (4) health care/social services providers in the community are familiar with the community's needs and local health issues, and so are well-informed about what types of research might be useful to the community. A disadvantage of this approach is that most committees within AI/AN communities are already overworked and stretched thin, particularly in the areas of health and social services, which are significantly under-funded and under-staffed.<sup>34,35</sup> Given more immediate community needs and the nature of jobs related to service provision, research may not be a priority. Delegating research review to an existing health/social services committee may cause the process of research review to be slow, cumbersome, and inefficient, as the committee must make room in a busy agenda for careful review of research. Another disadvantage of this approach is that health care/social services providers in the AI/AN community may not be completely unbiased in their evaluation of research projects, in the sense that they have their own interests and ideas about what will benefit the community, and may give priority to research projects in the specific area of services that they provide. For this reason, it may be important to include members of the AI/AN community who are not service providers on any research review board whether it is a full, formal IRB or not.

## Special Considerations for Urban Indian Communities

All of the models for research review boards described above can be used by urban Indian communities. Urban Indian organizations that provide health or social services, or those that represent the political interests of urban Indians, may choose to set up IRBs, CABs, or use existing committees/boards to oversee research that is conducted with the populations they serve. The main difference between urban Indian communities and AI/AN communities with governments is the legal mechanisms by which these research review structures would be adopted. While urban Indian organizations do not have a sovereign governmental structure

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<sup>34</sup>U.S. Commission on Civil Rights. Broken Promises: Evaluating the Native American Health System. 2004. [www.usccr.gov/pubs/nahealth/nabroken.pdf](http://www.usccr.gov/pubs/nahealth/nabroken.pdf)

<sup>35</sup>U.S. Commission on Civil Rights. A Quiet Crisis: Federal Funding and Unmet Needs in Indian Country. 2003. [www.usccr.gov/pubs/na0703/na0204.pdf](http://www.usccr.gov/pubs/na0703/na0204.pdf)

within which they could amend a constitution or enact laws the way a tribal government would, they could draft bylaws or policies on research which are adopted by the organization.

It may be helpful for urban Indian organizations to communicate closely with neighboring AI/AN communities from which some of the urban populations they serve originate. Researchers whose proposals are rejected by AI/AN communities may attempt to recruit urban Indians for their study, because urban areas are not under the jurisdiction of an AI/AN government. Urban Indian organizations need to ensure that researchers who approach them are not trying to circumvent the authority of an AI/AN government. Furthermore, researchers who wish to avoid dealing with tribal governments' regulation of research altogether may attempt to conduct research in urban Indian communities, assuming that they will not face restrictions on their research. Like tribal governments, urban Indian organizations should carefully evaluate research proposals they receive, and need to adopt measures to protect the populations with which they work. On the other hand, urban Indian communities may also need to consider whether an AI/AN government's rejection of a research proposal limits the choices of urban Indian people who are enrolled tribal members: is the freedom of those members to choose whether or not to participate in a research study constrained because their tribal government has rejected the research proposal? It is to the benefit of enrolled tribal members living in urban areas for urban Indian organizations to work closely with relevant AI/AN communities in regulating research. Ideally, urban Indian organizations and related AI/AN communities should notify one another of their decisions regarding specific research proposals and the status of on-going research involving enrolled tribal members living in urban areas. In some circumstances, urban Indian communities may even wish to partner with neighboring AI/AN governments to form a research review board that oversees research that is conducted both in the urban area and on AI/AN community lands. Finally, urban Indian communities may wish to collaborate with tribal epidemiology centers that are part of a partnership between the IHS and the Centers for Disease Control (CDC).<sup>36</sup> These epidemiology centers may serve as a helpful resource in reviewing research proposals or regulating research in urban Indian communities.

### **Policy Considerations for AI/AN Community Research Review Boards**

Establishing a research review process is a fairly complex undertaking, regardless of which model an AI/AN community chooses for a research review board. In considering how to regulate research, AI/AN communities face a number of important policy considerations. These include how to relate to the federal government on the issue of IRBs; the jurisdiction the AI/AN community research review board has in relation to IRBs at universities and in IHS; how to enforce decisions made by AI/AN communities' research review boards; and what types of research should be subject to the authority of AI/AN communities' research review boards.

#### Relationship with federal IRB structures

There are a number of policy issues that AI/AN communities face in choosing which model of research review to adopt, many of which involve how to relate to the federal government model of an IRB and federal offices which regulate research. If an AI/AN community does create its own research review board, there is the question of whether or not to have the board registered

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<sup>36</sup>For a list of tribal epidemiology centers, see <http://www.cdc.gov/omh/Populations/AIAN/AIANEpiCntrs.htm>

with the federal government as an IRB. The U.S. Department of Health and Human Services has an office called the Office of Human Research Protections (OHRP). This office serves several functions related to IRBs.<sup>37</sup> First, it provides registration for IRBs with the federal government, certifying that these IRBs are in compliance with federal law (45 CFR 46 and related codes) on the protection of human research subjects. This certification is necessary for IRBs at research institutions that receive any federal funds. Research institutions receiving federal research funds must also obtain a federal-wide assurance (FWA), which is a document on which they must list a federally-recognized IRB that reviews their research. Second, OHRP sets the guidelines for how these federally-recognized IRBs must function. Third, OHRP provides some limited training and auditing services to federally-recognized IRBs free of charge. Finally, OHRP audits IRBs in cases where research misconduct is reported for a project that an IRB reviewed, and may impose penalties on IRBs or their institutions, including halting all research conducted at that institution, if violations of federal law dealing with human subjects protections are found (personal communication, OHRP staff, 2006).<sup>37</sup> AI/AN IRBs are welcome to apply for federal registration and to affiliate with OHRP (personal communication, OHRP staff, 2006). AI/AN communities also may obtain an FWA, which allows them to directly apply for and receive federal research grants. AI/AN communities that do not wish to set up their own IRB can also obtain an FWA but list an outside federally-recognized IRB on that document.<sup>38</sup> This outside IRB would need to review all federally-funded research projects that are conducted in the AI/AN community.

The advantages to registering an AI/AN community IRB with OHRP and/or obtaining an FWA are: (1) AI/AN communities can apply for and receive federal funds to conduct research themselves (i.e., where a member of the AI/AN community is a principal investigator on a project, rather than a researcher from a university or other institution); (2) OHRP provides technical assistance in the form of training and auditing services to IRBs, which may be helpful as AI/AN communities establish their own research review boards; and (3) it may give an AI/AN IRB legitimacy in the eyes of researchers if that IRB is federally-registered.

One potential disadvantage of registering the AI/AN community's research review board with the federal OHRP is that the AI/AN community may have needs and priorities that do not match federal requirements for IRBs. For example, AI/AN communities might have different needs for IRB membership than specified in federal requirements. Federal law requires that IRB membership must include: (1) at least five members, (2) both men and women, (3) at least one scientist and one non-scientist, and (4) at least one member not otherwise affiliated with the institution (or AI/AN community) (personal communication, OHRP staff, 2006).<sup>15</sup> An AI/AN community may wish to have a different membership, for example, less than five members, or a committee that does not include anyone from outside the community. Thus, having a research review board registered as a federal IRB with OHRP can provide an AI/AN community with significant benefits, but it is important to consider whether or not federal IRB requirements fit the needs of the AI/AN community. One option AI/AN communities may wish to consider is calling their review board an "IRB" in order to gain legitimacy in researchers' eyes and impress

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<sup>37</sup>Department of Health and Human Services. Office of Human Research Protections, 2006.  
<http://www.hhs.gov/ohrp/>

<sup>38</sup>Trachtenberg, Alan. Institutional Review Board Expectations and Regulations (oral presentation). Research for Native Health: Strengthening Partnerships, Promoting Trust, and Increasing Communication, Denver, CO, August 22, 2007.

upon the researcher that their review board has authority, but to not register with OHRP. A review board may be called an IRB without registering with the federal government (personal communication, OHRP staff, 2006).

### Jurisdiction of AI/AN Community Research Review Boards and Outside IRBs

Many AI/AN communities will have research projects that are submitted both to the AI/AN community's research review process as well as an IRB at the researcher's institution. Some research projects may even involve three separate research review processes: the AI/AN community's, the IHS Area IRB, and the researcher's institutional IRB. Negotiating the relationship between these different review boards can be a complex and cumbersome process. It is important for AI/AN communities to carefully consider how they wish to relate to outside IRBs. If an IRB outside the AI/AN community requires a change to a research protocol or informed consent form, then will the AI/AN community automatically accept that change? Or will the community require the researcher to resubmit his or her research project to the AI/AN community for a second review? Determining an order for research review by different IRBs and deciding which IRB will have final authority over the project can be complex.

It may be advisable for the AI/AN community to review the research proposal first. IHS IRBs require written proof, such as a signed letter from a government official, that an AI/AN community has approved a research project before IHS IRBs will approve the research. For this reason, it is usually simpler for the AI/AN community to review research before an IHS IRB does. For university IRBs, it may also be better for the AI/AN community to review the proposal first. Some university IRBs, although not all, require proof that the community has approved the research before they will do so. Even if university IRBs do not require community approval, it is likely that AI/AN communities will request more changes to a research proposal than a university IRB, because AI/AN communities know best how to ensure that the research meets their community's norms and priorities.

If an AI/AN community does review a research proposal first, it is possible that the IHS IRB or researcher's institutional IRB will still require other changes to the research protocol or informed consent form. If this is the case, AI/AN communities may wish to consider how they will handle such requirements imposed by other IRBs. One option is that AI/AN communities will accept any changes required by outside IRBs. Another option is that any such required changes must be submitted to the AI/AN community's research review board, with written proof that the outside IRB has requested this change. The AI/AN community's research review board may then wish to review those changes using the same full procedure and detailed requirements they use in evaluating new research proposals. A third option is for the AI/AN community to create an expedited procedure for review of any changes required by other IRBs. For example, an administrative staff person in the AI/AN community's health department or one member of the research review committee might be charged with reviewing any changes required by outside IRBs. If that reviewer deems the changes to be minor, then he or she might approve them rather quickly. However, if those changes are determined to be major ones, then the reviewer might refer them to the full research review board for consideration.



It is also possible that AI/AN communities' research review boards and IHS IRBs will have different changes they require researchers to make to publication manuscripts. IHS IRBs require that researchers submit manuscripts to the IRB for review prior to publication, and many AI/AN community research review boards also have this requirement. For this reason, AI/AN communities may need to consider the same options delineated above for publication manuscripts, in the event that a researcher must submit the manuscript for review to both the AI/AN community's research review board and the IHS IRB. In sum, given that researchers often must work with multiple IRBs when conducting research with AI/AN communities, it is important for AI/AN communities to determine how they will relate to outside IRBs in the research review process.

### Enforcement of AI/AN Community Research Review Decisions

Some AI/AN communities have found that it is difficult to enforce their decisions about research projects. If an AI/AN community disapproves a research project or takes many months (or years) to make a decision about a project, impatient and/or unethical researchers may try to find a way "around" the AI/AN community's research review board (for example, by approaching AI/AN community members who live in urban areas and asking them to participate in the research, as mentioned above). Most researchers are ethical and those that work with AI/AN communities generally have a deep respect for the authority of AI/AN governments and decision-makers. However, for the rare researchers that seek to do their projects at any cost, it is important for AI/AN communities to consider how to best ensure that researchers abide by AI/AN community decisions.

One method is to have penalties in a research policy for those researchers that violate the agreed-upon terms for conducting research in the AI/AN community or conduct research that has not been approved by the AI/AN community. According to the Indigenous Peoples' Council on Biocolonialism, one strategy AI/AN communities might consider for research projects they approve is to have the researcher pay a fee or a deposit at the beginning of the research project that will be returned at the end of the project if the research is conducted without any ethical violations.<sup>23</sup> If violations of research agreements occur, then the fee could be held by the AI/AN community and not returned to the researcher as a penalty. Alternatively, AI/AN communities could levy a fine against a researcher through tribal courts if there is misconduct or unethical behavior in the research. This method is one used by the Navajo Nation, as mentioned above.<sup>21</sup> Another possible penalty is to exile the researcher from the AI/AN community. As sovereign nations, AI/AN communities have the power to determine who is and is not allowed on their lands. AI/AN communities may also choose to lodge a complaint against unethical researchers with OHRP and the researcher's institution of employment or professional associations (for example, the American Medical Association for physicians; the American Anthropological Association for anthropologists). Finally, complaints may also be registered with the National Congress of American Indians (NCAI) Policy Research Center (PRC) at <http://www.ncaiprc.org>. The NCAI PRC maintains a database of tribal complaints in order to share information about unethical researcher conduct with other tribes who may want to contact the Center about any potential complaints prior to agreeing to work with a particular researcher or institution. In order to make researchers aware of these possible penalties for any misconduct, AI/AN communities might consider including details on possible penalties in the approval letter they send to a

researcher when permission is granted for a study. Alternatively, if an AI/AN community does develop a written code or set of guidelines for their research review process, a copy of this document might be provided to the researcher, with the requirement that the researcher sign a pledge committing to abide by these policies.

Another method of enforcement is a legal contract between the AI/AN community and the research institution. AI/AN communities might require researchers to sign a contract agreeing to specific terms about the research project, such as the research protocol that will be followed, how data or biological samples will be handled, intellectual property considerations, details on who owns the data and/or biological samples, guidelines for review of publications and authorship of publications, and what penalties may be imposed if the contract is broken. AI/AN organizations have published model contracts that AI/AN communities may wish to use or adapt for their own needs in forming relationships with researchers. One model contract has been developed by the Indigenous People's Council on Biocolonialism.<sup>39</sup> Another one has been developed by the **Canadian Aboriginal AIDS Network**.<sup>40</sup> One advantage of a legal contract is that the requirements of the researcher and the AI/AN community are both in writing. Requirements of both parties are clearly stated by having a contract, and if staff from either the AI/AN community or the research team change, there is a written document about the terms that have been agreed upon. In addition, if either party violates the agreement, there are written terms for the penalties that will be imposed. A written contract can also serve as important evidence in the unlikely (and unfortunate) situation where litigation might be required. The only disadvantage of using a research contract is that significant resources may be required from the AI/AN community in order to draft a contract, including financial resources to hire a lawyer or time required of in-house counsel.

Urban Indian organizations can use many of the same mechanisms as AI/AN governments in enforcing their decisions on research. Urban Indian organizations can sign contracts with researchers, and can report researchers to their institutions, professional associations, OHRP, and/or the NCAI PRC if there is misconduct or unethical behavior discovered. However, urban Indian communities may not have all of the possible penalties for researchers available to them that AI/AN governments have, such as levying a fine or exiling the researcher from a specific geographic territory. In addition to the methods of enforcement described above, pursuing legal action serves as a final resort for AI/AN communities and urban Indian organizations that have unsuccessfully attempted to resolve disputes with researchers in other ways. Litigation requires significant financial resources on the part of AI/AN communities and urban Indian organizations, and is not a guaranteed way of rectifying wrongs committed by researchers. It is best for AI/AN governments and urban Indian organizations to develop policies and methods of preventing harms from occurring to the populations they serve that participate in research.

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<sup>39</sup>Indigenous Peoples Council on Biocolonialism. Model Academic Research Agreement, 2000.  
<http://www.ipcb.org/publications/policy/index.html>

<sup>40</sup>Canadian Aboriginal AIDS Network. Principles of Research Collaboration, 2006.  
[http://www.caan.ca/pdf/Principles\\_of\\_Research\\_Collaboration.doc](http://www.caan.ca/pdf/Principles_of_Research_Collaboration.doc)

## Scope of Oversight of AI/AN Community Research Review Processes

An important issue for AI/AN communities to consider in developing a research review process is which types of research will be regulated by the research review board. Many AI/AN communities conduct their own internal needs-assessments and evaluations of their health care or social service programs. Examples include surveys on housing needs and focus groups with community members about their opinions on a specific health program. AI/AN communities may choose to conduct such assessments themselves, perhaps having their own staff do those assessments, or might instead contract with outside researchers and/or consulting firms for those assessments. One question for AI/AN communities developing a research review process is whether or not these internal forms of research need to be approved by the community's research review board. Nicole Bowman points out it is important for AI/AN communities to be in control of their own process of evaluation (internal assessment of programs and services).<sup>28</sup> One way to keep track of all of the assessments happening in a community might be to include those evaluations as part of the jurisdiction of the AI/AN community's research review board.

Another question AI/AN communities may wish to consider is whether only research studies including living human volunteers should be subject to the authority of the research review board, or if there should be a broader scope for research regulation. For example, many AI/AN communities have extensive archaeological research that happens on their lands. It is possible that a research review committee's authority could be expanded to include all forms of research that happen in a AI/AN community, whether they involve living human volunteers or not. The advantage of expanding the scope of a research review board's authority to include all research in an AI/AN community is that there are a standardized set of guidelines that researchers must follow and there is a centralized body overseeing all research. On the other hand, the main disadvantage of expanding the jurisdiction of a research review board to include all types of research is that extensive regulations may be required for the research review board, which would require additional resources for the AI/AN community to develop. Regulating all research that happens in the community may be overly burdensome to the review board, and might slow down the process of research review and the conduct of research. Finally, another possible disadvantage is that the members of the board may not have the expertise to evaluate such diverse kinds of research as health research and archaeology. This problem may be rectified by having members on the research review committee with knowledge of diverse forms of research, or by having technical experts on-call for the committee to consult with for specific types of research.

### **Conclusion**

There are many options open to AI/AN communities that wish to create a process for research review. IRBs and CABs present formal models of boards that have the sole function of overseeing research. AI/AN communities may also choose to form other kinds of research review boards that meet their specific needs, or instead might delegate the task of reviewing research proposals to an existing committee in the community. There are a number of important policy issues that AI/AN communities need to consider when deciding what type of research review process to adopt, including how they will relate to the federal government's research review models, how their research review committees will relate to IRBs outside the community,

how they will enforce the decisions of their research review committee, and what the scope of oversight will be for the research review committee.

Regardless of how AI/AN communities choose to regulate research, it is vital that they do so. There have been some instances in the past of AI/AN communities being harmed in research. The Belmont Report's ethical principles may not always offer adequate protection for communities, as those principles are mainly focused on the protection of individual research volunteers. As sovereign governments, AI/AN communities have the authority and the responsibility of protecting their community members and their communities as a whole from harm in research. Furthermore, finding better ways to regulate and take control of research will increase the ability of AI/AN communities to better use research as a tool for gathering important information which is needed to improve policies and services provided to their members.

*Note: The author would welcome any feedback, comments, or questions on this paper. Please email feedback to [singhp@msnotes.wustl.edu](mailto:singhp@msnotes.wustl.edu).*