Research Regulation in American Indian/Alaska Native Communities:
A Guide to Reviewing Research Studies[1]

By Puneet Chawla Sahota[2]

Introduction

Regulation of research is becoming an increasingly important issue for many American Indian/Alaska Native (AI/AN) communities. This paper will provide a step-by-step guide for tribal governments, community boards or other AI/AN entities reviewing potential research projects, particularly those studies including living human volunteers (e.g., health or social research). This paper does not address other kinds of research (e.g., environmental, economic, archaeological, etc.) in detail. Careful review of a research proposal is often the best way to prevent any harm to individuals or communities that are participating in a study. AI/AN communities should carefully regulate research projects throughout all phases: in the initial stage of reviewing proposals, while the research is ongoing, and finally in dissemination and publication of the research findings.

There are many models for regulatory boards that AI/AN tribal governments or urban Indian organizations might use to oversee research, as is discussed in another paper published by the National Congress of American Indians (NCAI) Policy Research Center (PRC).[3] Regardless of how the research review process is structured, there are a number of issues AI/AN communities may need to consider when evaluating a research proposal, as will be discussed in detail in this paper. Some of the recommendations included in this paper have been influenced by the Indian Health Service (IHS) Institutional Review Board (IRB) checklist,[4] which is used by IHS IRBs to review research proposals, and the checklist found at the end of the Model Tribal Research Code, published by the American Indian Law Center, Inc.[5] Both of these checklists are outstanding resources for AI/AN communities and may be good tools to use in the review of research proposals. For a summary checklist of the review criteria described in this paper, see the Appendix. This checklist may be used as an interactive guide for communities reviewing research projects.

Components of Research Proposals

AI/AN communities have the most power in regulating research at the beginning of a project, when a researcher and the community are still negotiating the terms of their collaboration. Once a research project has begun, it can be more difficult to negotiate changes to the project.[6] It is important that the research review board be provided with all necessary information to make a decision about whether or not a research project will be allowed in a community. Reviewing the detailed information provided in a research proposal can take a significant amount of time, and working through the process of reading a proposal, negotiating necessary changes, and agreeing on a research protocol may take months or years. However, research proposals sometimes must be reviewed quickly in order to meet deadlines for funding or other time constraints placed on the researcher(s). AI/AN communities may wish to consider these timing issues when designing their own processes for research review. Delegating different aspects of research review to specific groups of community members or staff (as discussed below in *Publication Review*) may be one way of expediting the process. Communities may also wish to institute time limits for different stages of research proposal review and notify researchers of these timelines (e.g., all research proposals will be evaluated within 90 days of receipt).

A detailed written research proposal should be required of all researchers requesting permission to conduct research in the community. This proposal should include several documents, which are described below. Many Institutional Review Boards (IRBs) (boards that review research proposals at universities, the IHS, and other research institutions) require a similar set of documents. One option AI/AN communities might consider is to require a researcher to simply submit a copy of the application s/he sends to an IRB. Some AI/AN communities, however, may want specific information that is not required by the research institution's IRB. In that case, AI/AN community research review boards could require an entirely separate application from the researcher, or they could ask that the researcher submit a copy of the IRB application as well as answer some additional questions in an addendum. Recommended research proposal components are described in detail below.

Narrative of Research Proposal

This document should describe how the research will be conducted, from start to finish and should include:

> -Background: review of relevant literature and an explanation for why this research project is important.
> -Research question: an explanation of the central question(s) the researcher is investigating.

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[6]Philip S. Deloria. Research for Native Health (oral presentation). Research for Native Health: Strengthening Partnerships, Promoting Trust and Increasing Communication, Denver, CO, August 22, 2007.

-Recruitment: an explanation of how the research study will be publicized in the community and how research participants will be recruited for the study.

-Informed consent: an explanation of how research participants will be given sufficient information in order to make a knowledgeable decision about study participation; how consent to be part of the study will be obtained from participants (see *Recruitment and Informed Consent Documents* below).

-Incentives/compensation: a description of the method and amount of compensation that will be provided to research participants, if any (e.g., a meal, gift certificates, check for certain dollar amount, etc.).

-Sampling frame: detailed information about the group of individuals from whom data will be collected. Includes how many community members will be part of the study; the criteria for including or excluding certain individuals from the study; how representative of the community the sample will be; and how generalizable the data collected from this sample might be for the community and AI/AN people more broadly.

-Data or specimen collection: a detailed explanation for how data will be collected from study participants including copies of relevant research tools (e.g., questionnaires, surveys, interview questions, etc.) or information on how data will be extracted from biological specimens (e.g., blood and tissue samples).

-Data storage and handling: an explanation for where, how long, and in what way data or biological specimens will be stored after they are collected. Includes information on how confidentiality of the research participants will be maintained; who will have access to the data and under which conditions; whether or not data will be destroyed at the end of the study; and if so, who will destroy the data (communities could request that data or specimens be returned to them so they can destroy them, or could require written proof from the researcher that data/specimens have been destroyed).

-Data analysis: information on how data will be analyzed (e.g., will data be analyzed quantitatively using statistical tests, etc.).

-Publication/dissemination of data: how data will be used during the study and afterwards; who will control the data; how the research findings will be conveyed back to the AI/AN community and to the public at large; what types of publications or presentations are expected, both for community members (e.g., articles in the community newspaper, presentations at community meetings) and academic audiences (e.g., journal articles, book, etc.).

-Opportunities for community input: what mechanisms will be provided for community input on the study (for more detailed information, see *Relationship Between Researcher and Community* below).

Recruitment and Informed Consent Documents

For any study involving human volunteers, researchers will need to advertise the study in the community, find willing participants, and then enroll them in the study. Depending on the method of recruitment, appropriate documentation of how study participants will be recruited should be provided. For example, if the study will be advertised in the community newspaper or on fliers, copies of the advertisement text and fliers should be

submitted to the community's research review board. Sometimes, the process of recruiting participants and securing informed consent is closely intertwined. If the researcher will recruit potential participants by verbally telling them about the study and then asking them if they would like to participate, then a script of what will be said should be submitted.

The process of informed consent is designed to ensure that potential research participants are provided with all necessary information to decide whether or not to participate in the study. This process also is intended to make sure community members who agree to participate in the study do so out of their own free will and without any coercion. Researchers should be required to submit a copy of an informed consent form to the AI/AN community research review board. Informed consent forms should be written in simple language that participants can comprehend. If needed, the informed consent form should also be translated into the AI/AN community's native language(s). The informed consent form should have several components:[7]

> -background and description of why the study is important
> -study design, including different treatment groups (or placebo/control groups[8]) to which participants may be assigned
> -detailed description of research procedures (what the research participant will be required to do as part of the study; any procedures they will undergo)
> -procedures that will be followed to protect the confidentiality of the research participant
> -description of the risks and benefits of the study (including a statement that there is no direct benefit of the research to the participant if that is the case)
> -alternatives to participating in the study
> -a statement that individuals have the right to refuse to be part of the study and the right to withdraw from the study at any time
> -information on how the participant will be compensated in the event of injury
> -whom to contact with questions about the study
> -place for the participant to sign if they agree to be part of the study

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[7]Lahl, Lyndi. Basics of Human Subject Protection (oral presentation). Respecting Tribal Nations and Members When Conducting Research, Tulsa, OK, July 26, 2007.

[8]Research studies testing a new drug or medical intervention are called randomized clinical trials. A placebo is a pill that has no biological effect, such as a simple sugar pill. Randomized clinical trials are often split up into two groups: one receiving the experimental drug/intervention and one that does not. The group that does not receive the experimental drug or intervention is sometimes called a control group or a placebo group. Previous studies have shown that when people think they are taking a medicine, their own mind can impact their body's healing. This phenomenon is called the placebo effect. In order to control for this effect, researchers testing a new medication often include a placebo group of research volunteers and then compare the results from this group to those from the group which is taking the experimental medication. It is helpful for AI/AN communities that are reviewing potential research projects to know how the proposed study is designed and to which possible groups community members may be assigned, including control or placebo groups. Community members assigned to a placebo or control group will not receive the experimental medication. Research participants usually will also not be told whether the pill they are taking is the experimental drug or a placebo. This information is important for potential research volunteers to know as they consider whether or not to enroll in a study.

Additional elements of informed consent that may apply for certain studies include: risks related to pregnancy, reasons that participants might be withdrawn from the study by the researcher(s), costs of the study the participant may have to pay, relevant findings from recent research, and the number of participants who will be enrolled in the study.[7] In some studies, it may be possible to give participants choices about what happens to their data or biological specimens. For example, participants might have the choice about whether their biological specimens are to be used for one research study only, or whether they are willing for those specimens to be stored for future studies. In cases where participants need to make decisions about multiple issues (e.g., whether or not to participate in the study at all; whether or not to have the specimen stored, etc.) the informed consent form should have places for each of these decisions to be specified. An informed consent form could have a checklist where participants check a "yes" or "no" box for statements about each specific study procedure.[9]

In some cases, IRBs at the researcher's institution may waive the requirement for written informed consent or certain elements of informed consent. Federal guidelines state that the requirement for written informed consent may be waived if the study poses no more than minimal harm to the participants and does not involve procedures for which written consent would be required outside of research. Another circumstance under which informed consent may be waived under federal guidelines is if the consent form is the only written record linking the participant to the research study and a loss of confidentiality is the main risk of the study.[10] Federal guidelines also state, however, that local laws may require additional elements of informed consent beyond those in federal regulations. Thus, AI/AN communities may need to decide whether a waiver of informed consent requirements granted by a researcher's institution is consistent with the community's laws and needs or whether the community wishes to require written informed consent in all studies.

Budget and Funding Sources

AI/AN communities should carefully evaluate what sources of funding are being sought or are awarded for research projects, and whether the purpose of the study that is stated in the grant application is consistent with the researcher's proposal to the community. Researchers should be required to submit a detailed budget for the research project. This budget may be a copy of that submitted to a funding agency if the researcher has applied for grants. Copies of grant applications may also be required of the researcher so that the community review board knows the sources of potential or received funding for the project. AI/AN community research review boards might also consider asking a researcher to submit a "master budget" which details all sources of potential or received funding and the amounts from those sources. Potential funding agencies' policies on data ownership and sharing should also be detailed in this section (see *Data Control and*

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[9]For a model informed consent form for genetics research that includes options for how biological specimens should be handled, see Oregon Health and Science University, Genetic Consent Form Sample: http://www.ohsu.edu/research/rda/irb/docs/sample_forms/gene.doc.

[10]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

Ownership below). Researchers should be asked to explain funding agencies' expectations for access to and use of data collected in the research project. Funding or in-kind resources the researcher is requesting from the AI/AN community, if any, could also be included in this section. Resources requested from the community might include office or clinic space, supplies, staff time or other resources. Communities may wish to consider whether the budget and grant applications include funds specifically allocated to cover such costs, particularly if substantial staff time or other resources will be required of the community.

Professional Qualifications of Research Team

Researchers and any other research staff (recruiters, surveyors, etc.) could be required to submit resumes or *curricula vitae* with their relevant previous job experience and professional qualifications. Researchers that have already published papers could be asked to submit copies of their previous publications, particularly those conducted with AI/AN communities or relevant to the proposed topic. Reviewing the researcher's previous publications may help the AI/AN community research review board to anticipate what kinds of publications may result from the proposed research project. AI/AN communities could also consider requiring researchers to submit letters of support from their research institutions or departments endorsing their research proposals. Requiring letters of support may encourage researchers to notify their departments and research institutions of any proposed research projects with AI/AN communities early in the process of seeking the community's approval of the project.

Review of Research Proposals

The decision about whether or not to move forward with a research proposal can be complex, with many issues to consider. Some key areas which should be considered when reviewing a research proposal will be discussed in this section.

Risks and Benefits of Study

___ Do the potential benefits of this study outweigh the potential risks?

This question should be weighed for both the individual research participants and the community as a whole.[11] For individual research participants, some potential benefits might include free testing or medical care, access to a new treatment for a disease, new knowledge they might gain from educational aspects of the study, or simply a sense of satisfaction that they are assisting in the gathering of new knowledge that may help their community. There are also many possible risks in research study participation, including loss of confidentiality of personal information and negative side effects of new medications that are not yet known. The community research review committee should

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[11]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

assess whether the potential benefits are maximized and the potential risks are minimized for individual research volunteers.

The same principle applies to the community as a whole, not only those individual community members who participate in the research. For example, one potential benefit of research to a community is the gathering of new data that can be used to improve services or advocate for increased funding of programs. One of the risks of research to a community is stigmatization, which may occur if research publications or presentations portray a community in a negative light. There can also be indirect benefits and risks of research. One example of an indirect benefit to a community might be job training for community members. Community members who are hired as part of the research team may gain new job skills, education, and income, while also providing the researchers with important knowledge about the community. Other indirect benefits could include supplies or access to technology that the community might gain.

Data Control and Ownership

___Does the community have adequate control over how biological specimens and data are collected, used, stored, and destroyed?
___Is there a contract or other legal tool that ensures the community has adequate control over data/biological specimens?

For researchers, sharing data is often a scientific norm. The main reasons researchers share data are to replicate and validate one another's findings as well as to avoid duplicating one another's efforts in data collection. Researchers try to efficiently gather information by analyzing existing data sets rather than re-collecting data for each new research question. However, sharing of data may also result in research studies being done that were not originally authorized by an AI/AN community. For this reason, AI/AN communities should carefully consider what level of control they will have over biological specimens and data. Control of biological specimens and data includes how they are used; how, where, and for how long they will be stored; who will have access to them; and how and when they will be destroyed, if at all. In reviewing research proposal documents, including the research protocol and informed consent forms, AI/AN communities should carefully consider language related to each of these issues. The terms of use for data and biological specimens should be as specific as possible. For useful sample policy language on the use of biological specimens, see *Sample Genetic Policy Language for Research Conducted With Native Communities*, by Linda Burhansstipanov and colleagues.[12] Data and biological specimens should be stored securely, under lock and key. AI/AN communities could consider having data and/or biological specimens stored in their own facilities, although special technology may be required for storage of biological specimens.

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[12]Burhansstipanov, Linda; Bemis, Lynne; Kaur, Judith; and Gordon Bemis. Sample Genetic Policy Language for Research Conducted With Native Communities. *Journal of Cancer Education.* Spring;20(1 Suppl):52-7, 2005. http://www.informaworld.com/smpp/content?content=10.1207/s15430154jce2001s_12

AI/AN communities could even maintain their own specimen bank. The Alaska Native Tribal Health Consortium, for example, manages the Alaska Area Specimen Bank, which includes biological specimens donated by nearly 92,000 people, most of whom are Alaska Native.[13] This specimen bank was originally managed by the Centers for Disease Control and the IHS. Specimens were collected in research studies, public health investigations, and clinical testing beginning in the early 1960s. The specimen bank is housed at the Alaska Native Health Campus in Anchorage, AK. Researchers submit applications to a committee that determines whether or not to grant access to the specimens. One of the challenges of maintaining a specimen bank is building appropriate laboratory facilities with the correct temperature and other specifications to keep specimens viable. Creating a specimen bank could thus require significant time and resources from communities. Rather than having biological specimens stored, some AI/AN communities may require researchers to destroy specimens at the end of a study. Those communities pursuing this option may wish to require that researchers provide written proof of specimen destruction. For example, the Navajo Nation IRB requires that researchers provide a "certificate of destruction" documenting the time and place that the specimen was destroyed and stating that procedures required by state law were followed.[14]

AI/AN communities should also carefully examine the data sharing requirements of potential funding agencies for the research project (see *Budget and Funding Sources*, above). In some cases, funding agencies may require that data is made publicly available or shared with other researchers. For example, NIH-funded studies with grants of $500,000 or more in a single year are required to share data when possible.[15] The NIH does, however, accept data storage options which are highly controlled. For example, in the NIH's *Data Sharing Workbook*,[16] data enclaves are described as one option. In the case where there is a risk of individual research participants' identities not being kept confidential, data may be stored in a restricted-use dataset. Through a data enclave process, researchers outside the original team would submit requests for specific analyses to be conducted, and the original research team would provide the results of analysis. In this manner, only the original research team would have direct access to the data. If a community wishes to pursue the data enclave option, then the researcher could describe that strategy in the grant application for NIH. AI/AN communities might consider negotiating with potential funders about data control if they are concerned that data sharing might cause the release of sensitive information or stigmatization of the community. If it is not possible to negotiate adequate community control of data or a funding institution unequivocally requires that the data be made publicly available, then

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[13]H. Sally Smith. Genetics, Serum Banking, and Specimen Collections (oral presentation). Research for Native Health: Strengthening Partnerships, Promoting Trust and Increasing Communication, Denver, CO, August 23, 2007.
[14]Becenti-Pigman, Beverly. Genetics, Serum Banking, and Specimen Collections (oral presentation). Research for Native Health: Strengthening Partnerships, Promoting Trust and Increasing Communication, Denver, CO, August 23, 2007.
[15]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
[16]National Institutes of Health. Data Sharing Workbook. February 13, 2004. http://grants1.nih.gov/grants/policy/data_sharing/data_sharing_workbook.pdf

AI/AN communities must carefully weigh the benefits of the research against the risks of data sharing. There may be research proposals that a community chooses to accept even if there is a data sharing requirement because of the potential benefits of the study. In working with researchers, AI/AN communities should seek the maximum possible control and input into how biological specimens and data are used. Two useful legal approaches for accomplishing this goal are written contracts and tribal law.

Written Contracts

Within current legal frameworks, written contracts may be the most effective way for AI/AN communities to control how data and biological specimens are used and to ensure the community will receive benefits from the research.[17] One example of a successful contract that limits the use of data is the Collaborative Agreement between the Northwest Portland Area Indian Health Board, the National Cancer Institute, and the Nova Research Company.[18] This agreement specifies what type of data will be shared with the research group and how long data will be stored after the study analysis is completed. The contract also explicitly states that approval is required by all relevant Tribal or IHS entities for publication of any results. Useful contract templates have also been developed by the Indigenous Peoples' Council on Biocolonialism[19] and the Canadian Aboriginal AIDS Network.[20] Contracts can be adapted to the specific needs of each community and/or research project. Communities may wish to develop a template contract that all researchers working in the community must sign. Specific provisions of this contract may need to be altered for each research project. Contracts may include any terms that the community desires regarding data control and benefit sharing in research. For example, the contract can stipulate that the AI/AN community owns the data (or co-owns it with the researcher), and can describe how the data will be collected, used, stored, accessed, destroyed, etc. Contracts might also stipulate benefits the AI/AN community will receive if any products of the research are patented. Finally, contracts could include provisions stating that the researcher agrees to abide by all relevant tribal laws, such as research regulation codes, and that any disputes between the community and the researcher will be adjudicated by tribal courts.

Tribal Law

AI/AN communities or organizations might also pass resolutions or tribal laws stipulating how data and biological specimens collected in the community may be handled. Such resolutions or laws may be effective when used in conjunction with written contracts. As noted above, contracts could state that researchers agree to follow any applicable tribal

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[17]Greaves, Tom. IPR, A Current Survey. In Intellectual Property Rights for Indigenous Peoples: A Sourcebook. Ed. Tom Greaves. Society for Applied Anthropology, Oklahoma City, 1994: 9.
[18]Northwest Portland Area Indian Health Board, Tribal Epidemiology Center, Multi-Agency Collaborative Agreement Recommendation, 2007. For more information, contact Victoria Warren-Mears, PhD, RD, email: vwarrenmears@npaihb.org, phone: (503)-416-3283.
[19]Indigenous Peoples Council on Biocolonialism. Model Academic Research Agreement, 2000. http://www.ipcb.org/publications/policy/index.html
[20]Canadian Aboriginal AIDS Network. Principles of Research Collaboration, 2006. http://www.caan.ca/pdf/Principles_of_Research_Collaboration.doc

laws including those on data control. The Northwest Portland Area Indian Health Board recently passed such a resolution.[21] This resolution stipulates:

1. that investigators will not transfer the data to any other party without formal agreement from the tribe (and oversight by the PAIHS [Portland Area Indian Health Service] IRB [Institutional Review Board], if involved) and
2. that no secondary analyses are performed on the data that are different than those proposed in the original research protocol without a formal request to the affected tribe (and PAIHS IRB, if involved), and
3. that there are measures taken to meaningfully inform the community of the results of research, and
4. that the tribe has the opportunity to benefit from gains that come out of the research (whether that means monetary profits or benefits in terms of better health), and
5. that the tribe has control over how and when data is disposed of (meaning that the storage of data is explicitly laid out, as are the plans for where and when and how it will be destroyed when no longer needed).

Other excellent examples of tribal research regulation codes are the Navajo Nation Human Research Code[22] and the Model Tribal Research Code by the American Indian Law Center, Inc.[5] Thus, both written contracts and tribal law can be useful legal tools for ensuring community control of data and biological specimens in research.

Relationship Between Researcher and Community

____ Is there a trusting relationship between the researcher and the community?
____ Is the community treated as an equal partner in the research project?

Communities may choose to use a variety of different mechanisms to regulate research and enforce their research policies (for more information see the NCAI PRC publication *Research Regulation in American Indian/Alaska Native Communities: Policy and Practice Considerations*[3]). However, regardless of what written guidelines or contracts are in place, the most important element of successful research collaboration is the relationship between a researcher and a community. If the relationship is based in trust and goodwill, it is more likely that the intent of written guidelines and contracts will be followed by both parties. There are many aspects of a trusting relationship between a researcher and a community.

One key element is an avenue for community control and input into the research. Some research designs involve the community more than others. Many researchers state that they take a community-based or participatory approach. Unfortunately, research studies claiming to be participatory are not always truly collaborative. Carolyn Smith-Morris

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[21]Northwest Portland Area Indian Health Board. Tribal Ownership of Health-Related Data (Resolution # 05-04-04), July 19, 2005.
http://www.westerntobaccoprevention.org/documents/Tribal%20Ownership%20of%20Data.pdf
[22]Navajo Nation Human Research Code. http://www.nnhrrb.navajo.org/pdf/NNHumanResearchCode.pdf

notes that the phrase "participatory" can include models in which communities have only a nominal role.[23]   The ideal participatory research study does not simply name the community as a collaborator, but truly includes the community at all stages of a research project. As Barbara Israel and colleagues point out, community-based participatory research is not simply a method, but rather is a broader orientation in doing research that follows several key guiding principles.[24] Community-based participatory research studies vary in their design, and so it is important for communities to carefully evaluate exactly *how* the study proposes to collaborate with the community. Some possible mechanisms for community involvement might include regular community meetings soliciting input; a community advisory board that works with the research project; community members/staff that serve as co-principal investigators on a research project; or other kinds of community-researcher partnerships. In some cases, AI/AN communities may wish to engage in a research study even if they are not fully collaborating with the researchers at each stage of the project. Communities may make this decision for a variety of reasons, including not having adequate staff time or expertise to fulfill certain roles on the research team. In reviewing research proposals, communities should carefully consider whether the mechanisms proposed for their involvement meet their needs and priorities.

The researcher's history in working with AI/AN communities may also indicate trustworthiness. Successful relationships between researchers and communities are often long-term and are built over several research projects. AI/AN communities that are approached by a new researcher may wish to know whether other communities previously experienced problems with him or her. Communities may contact the NCAI PRC for this information, as the PRC is now keeping a registry of researcher misconduct in Indian Country (http://www.ncaiprc.org).

The researcher's sensitivity to community culture and values is another important aspect of a trusting relationship. Researchers' willingness to learn about community worldviews, traditions, and daily life may be an important indicator of cultural sensitivity. For example, communities may have spiritual or ceremonial concerns over how biological specimens are treated in research.[12] Researchers that are willing to modify laboratory procedures to accommodate these concerns may be easier to work with than researchers who are inflexible. More broadly, a researcher's willingness to change the research design to accommodate a community's wishes may be an important indicator of a truly collaborative relationship. In some cases, these kinds of changes might include adding new research questions or specifically prioritizing certain questions that the community feels are important. For example, in behavioral health or social services research, community definitions of "success" may be driven by particular community norms or cultural values.[25] Thus, the definition of "cultural sensitivity" is highly contextual and

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[23]Smith-Morris, Carolyn. "Community Participation" in Tribal Diabetes Programs. American Indian Culture and Research Journal, 2006. 30(2): 85-110.

[24]Israel, Barbara, et al. Critical Issues in Developing and Following Community Based Participatory Research Principles. In Community-Based Participatory Research for Health. Ed. Meredith Minkler and Nina Wallerstein. Jossey-Bass, San Francisco, 2003.

[25]Cross, Terry. Models of Community-Based Research and Success Measures (oral presentation). National Congress of American Indians Policy Research Center, 2nd Annual Tribal Leader/Scholar Forum, Anchorage, AK, June 12, 2007.

will depend on the topic of research and the relevant values of each community. In order to enhance a researcher's knowledge about their cultures, AI/AN communities could consider providing an orientation for research staff. This type of training could be in the form of a guided tour of the community; suggested reading of exemplary books or articles about the community; or informal conversation with community elders.

In sum, the relationship between the researcher and the community should be a partnership. In evaluating whether or not a researcher/research institution would be a good partner, John Phillips recommends that AI/AN communities ask themselves the following questions[26]:

-Would the researcher value Indigenous knowledge and consider it valid?
-Would the researcher be culturally understanding and respectful?
-Would the researcher help protect tribal interests in the research?
-Would the researcher acknowledge tribal sovereignty in all their activities?
-Would the researcher ensure that the research benefits Native people?

If communities cannot confidently answer "yes" to all of these questions, Phillips recommends they continue evaluating the research partner, and perhaps ask for further references, especially from other AI/AN communities.

Possible Outcomes of Proposal Review

Once an AI/AN community has reviewed a research proposal, there are three main possible outcomes: (1) the research proposal may be approved as written, (2) the proposal may be sent back to the researcher with requests for additional information or revisions, and (3) the proposal may be rejected. AI/AN communities should notify researchers in writing of their decisions. All written notifications should include contact information for an individual in the community who serves as a point person for communications with researchers (e.g., a staff member, community government official, etc.) Notification letters could also contain other important information related to the process of research review. For example, if a proposal is approved, then the AI/AN community might include deadlines and instructions for progress reports that will be required from the researcher(s) (see *Regular Research Reports* below for details on report content). This letter might also include other information that the researcher will need to know as the project moves forward, such as requirements for publication review by the community and criteria under which publications might be approved or rejected (see *Publication Review* below). AI/AN communities that have drafted their own codes or sets of regulations for research review may wish to provide a researcher with a copy of these and perhaps require the researcher to agree in writing to follow all relevant community laws.

In reviewing research proposals, communities may find that they need additional information to make a final decision. Another possible scenario is that the community supports the overall goal of the project but that significant changes are needed in the

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[26]Phillips, John. Lesson Five: Conducting Research With Others. Responsible Research for Tribal Communities, NCAI Research Curriculum Draft, 2008.

research methodology (e.g., data collection procedure, etc.) before the project can be approved. In either of these cases, the community might consider sending a detailed letter to the researcher requesting necessary information or changes to the proposal. If the community requests that the researcher make revisions to the proposal, the notification letter should include detailed information about why the proposal was unacceptable as written along with an itemized list of required revisions. Letters should include deadlines for the submission of additional information or revised proposals, as well as a commitment that the community will review the received information within a certain time frame (e.g., 45 days). Finally, there may be some research proposals that do not meet community needs and priorities and thus are rejected. For research requests that are denied, it may also be useful for the notification letter to include the reasons why the community did not accept the proposal. AI/AN communities that review a large volume of proposals may also find it helpful to develop template notification letters for each of the scenarios described above.

Monitoring Ongoing Research

After an AI/AN community has approved a research proposal, there are still important landmarks in the study that require community oversight. Ongoing monitoring of the research project is vital to protecting community members participating in the study. The results of research also should be carefully evaluated by AI/AN communities, including how those results will be used and disseminated. The sections below address each of these project stages in more detail.

Regular Researcher Reports

After a research project commences, the community research review board may wish to maintain continued oversight of the project. One method of doing so is to require periodic reports from the researcher. In the initial approval letter sent to the researcher, the community research review board may wish to specify how often regular reports will be required. The frequency of these reports may depend on the type of research or the risk/benefit ratio of the study. For example, the community might require frequent reports for a study on a new experimental medication, and for a less risky study, might only require bi-annual or annual reports. Progress reports should be made in writing and perhaps in person also, if the community research review board wishes. The researcher could also be asked to provide regular reports to the tribal government. One forum for regular reporting could be an annual community conference, where all researchers conducting ongoing projects provide reports.[27] Reports should include information about the progress of the study, such as how many community members have been enrolled or how many biological specimens have been collected. The reports should also contain an assessment of whether the risks and benefits of the study have changed in any way since the initial application. Another important component of reports is a description of any unexpected problems or obstacles the researcher has encountered while conducting the study. An honest assessment of problems in the study may help both the community and the researcher, as the community research review board members may have suggestions

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[27]The Navajo Nation IRB has an annual research conference: http://www.nnhrrb.navajo.org/

on how to solve these problems. Finally, the report might contain a timeline for the remaining work of the study and an assessment of the expected outcome(s), particularly if they have changed since the study began.

Adverse Events

The community's research review board should be notified immediately of any unexpected, serious adverse events, such as a study participant's bad reaction to an experimental drug. The board can then decide whether or not the study will be allowed to continue. Federally-funded drug trials are required to have a data safety monitoring board (DSMB), which is a separate board apart from the research team.[28] The DSMB is made up of scientists or other experts in the field that have no conflict of interest (that is, vested interest in the research study). This board periodically reviews the progress of a study and any unexpected adverse reactions to the experimental drug(s). If the board decides there is adequate evidence to halt the study or stop using a particular drug because of safety issues, the researchers must abide by that decision. AI/AN communities should inquire about DSMBs when reviewing research proposals on new experimental drugs or medical devices. AI/AN community research review boards should make sure that all federal protections required for research participants, including DSMBs, are in place and should require written proof that these requirements have been met. Furthermore, it may be helpful for community research review boards to have a direct line of communication with the DSMB and/or the researcher's institutional IRB. If a DSMB determines the research procedure should change or that the drug trial should be halted, the researcher's institutional IRB will be notified of this decision. Similarly, community research review boards could also request that the DSMB directly notify them of any decisions. Direct coordination with outside research review boards enables the AI/AN community to work with those boards on regulating the study.

Besides bad reactions to experimental drugs, other types of adverse events could include any unexpected discomfort or problem experienced by a research participant. AI/AN community research review boards should consider what they define as an "adverse event" and develop a definition which makes sense for their community priorities, perhaps even on a case-by-case basis for each research study. Researchers and community research review boards should agree on what constitutes an "adverse event," and researchers should be required to report any such events to the community's research review board immediately. Community research review boards might also consider providing contact information for a community representative on the informed consent form so that participants who experience problems in the study may contact the board directly. In this way, the community research review board serves as a liaison between community members participating in research and the researcher, both through regulating the research and advocating for participants' needs.

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[28]National Institutes of Health. NIH Policy for Data and Safety Monitoring. June 10, 1998.
http://grants.nih.gov/grants/guide/notice-files/not98-084.html

Review of Research Results

At the end of a research study, researchers should provide a report of the results to the tribal government or community governing board. Like research proposals, results reports should be written in clear language that is relatively easy to understand. These reports should include a summary of the findings; resulting recommendations to the community for improvements in policies or services; benefits the research study provided to the participants and to the community as a whole; any problems that occurred in the research study; and a timeline for anticipated follow-up steps (such as papers to be submitted for publication or possible proposals for future studies that will build on the original research). AI/AN communities may also wish to work with the researcher to disseminate the results of the study in the community. Results could be shared in public meetings, articles in a community newspaper, or by distributing copies of the study report throughout the community. If research participants have shared their contact information with the researcher, they could be mailed copies of the study report also.

Publication Review

Publications and oral presentations are an important end product of research projects. Researchers use publications and presentations to communicate their findings with one another and the general public. For this reason, publications are an integral part of the research process. In this section, "publications" are defined as written publications like journal articles or books as well as oral presentations such as those that are given at research conferences. AI/AN community research review boards may need to decide whether or not to review manuscripts for research publications. IRBs at universities generally do not review publications, but IHS Area IRBs do. Review of research publications ensures that AI/AN communities are informed about the research findings and how those results will be portrayed to the research community and the public. There have been instances where publications have been harmful to AI/AN communities because findings were reported in a manner that stigmatized or misrepresented the community. The most recent highly-publicized example of this problem was the lawsuit the Havasupai Tribe filed against Arizona State University (ASU).[29] The lawsuit alleges that researchers collected blood samples from tribal members for a study on the genetics of diabetes, but then instead used the genetic material for other studies on schizophrenia, inbreeding, and the Bering Strait migration theory.[30] Having the power of review and approval of publication manuscripts provides AI/AN communities with some level of control over how they are portrayed in publications.

One challenge AI/AN community research review boards may face is making time for review of publication manuscripts on an agenda that is already full with research

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[29]*Havasupai Tribe vs. Arizona State University*, Case No. CV2005-013190, Superior Court of Arizona, Maricopa County.
http://www.superiorcourt.maricopa.gov/docket/CivilCourtCases/caseInfo.asp?caseNumber=CV2005-013190
[30]Rubin, Paul. Indian Givers. Phoenix New Times. May 27, 2004.
http://www.phoenixnewtimes.com/2004-05-27/news/indian-givers

proposals. One solution to this problem is to delegate the responsibility for reviewing publication manuscripts to a tribal staff person or to one member of the community research review board. Asking the entire board to review the publication manuscript may be overly cumbersome and time-consuming. It may be advisable instead for one individual to review the publication manuscript and only refer it to the entire board if there are major problems with it. AI/AN communities also must decide whether manuscript review by a staff member or the community's research review board is sufficient, or whether a government representative, such as a Tribal Council member, will also need to review the manuscript.

Another challenge AI/AN communities may face in review of publication manuscripts is the interpretation of highly technical language which is used in many scientific fields. One way to solve this problem is to refer highly technical manuscripts to members of the community's staff, such as a physician in the case of a medical research article. If there are no members of the community's staff that can interpret an article's language, the community might consider asking an outside expert in the field to review the article. Another possible way to deal with a manuscript which is hard to understand is to ask the researcher to provide a summary of the manuscript's main content in layman's terms. While it is helpful for the reader reviewing the manuscript to be able to understand the technical language used, it should be noted that the main purpose of community review of publications is not to evaluate them for scientific merit—that is the role of the publisher and peer reviewers. The main goal of community publication review should be to ensure that the manner in which the community is portrayed is not harmful or stigmatizing.

Researchers may be reluctant to relinquish full control over their publication manuscripts and submit them for community review. One reason for this reluctance is the value of freedom of expression. An uncensored disclosure of research results is an important part of academic collaboration. Researchers publish information as a way of sharing it with each other so that they can successfully build on one another's work. It is also necessary for most researchers to publish as much and as often as possible in order to advance their careers. One way that AI/AN communities can partially address researchers' needs is to place a time limit on review of research publications. In the written agreement between the researcher and the community, a timeline for review of publication manuscripts (e.g., 45 days) should be stated. Written research agreements should also include guidelines for manuscript review and criteria for the disapproval of a publication manuscript (e.g., a list of specific issues that the community feels are stigmatizing and should not be discussed, etc.), which should be stated as clearly and specifically as possible. AI/AN community review policies for publication manuscripts should be geared towards protecting the community from stigma but should avoid putting up unreasonable roadblocks for researchers trying to publish their findings. If there is an irreconcilable disagreement over how a manuscript is written, rather than disapproving a manuscript AI/AN communities could require researchers to add a disclaimer stating that the publication does not represent the opinion of the community.[31] In general, researchers whose proposals are approved in the first place should be individuals that the community trusts. As a result, publications should be a process of collaboration between the researcher and the

community rather than a struggle. It is ultimately beneficial to the community if a research study is completed successfully and the data are published, because then other AI/AN communities, researchers, and policy makers can learn from the findings.[31]

The possibility that a manuscript would not be published because the AI/AN community disapproves it may seem too risky to some researchers. However, if the researcher truly views the community as a partner, then the community should have input on how the research results are portrayed and disseminated. Furthermore, there is a very real risk of stigmatization of communities in publications. AI/AN communities have been stigmatized because of research publications in the past.[30, 32] Many tribal communities are small with just a few hundred members, and so stigmatizing research publications may harm both the AI/AN community as a whole and its individual members. One advantage to community review of publication manuscripts is that publications may be improved as a result. Community members or staff that review the manuscript may be able to verify that they have observed the same phenomena described by the researcher, or might be able to provide additional interpretations of the research findings that are informed by their knowledge of the community. The community and the research team might even consider co-authoring publications, with at least one co-author being a community member or staff person that worked on the research study. Co-authorship brings with it the right and the responsibility to review and help write publication manuscripts, and so this is one mechanism by which communities can have input into research publications and have their contributions acknowledged publicly.

Finally, another decision AI/AN communities face in the review of publications is how specifically they wish to be identified. For example, a community might be willing to be named by tribe but may not want the specific villages where the research was conducted to be named. In some cases, a community may not wish to even have the tribal affiliation known, and might instead want to be identified only by region (e.g., a Southwest Tribe). The question of how specifically to identify an AI/AN community in a research publication is a complicated issue with compelling arguments on both sides. Ilena Norton and Spero Manson argue that it is unnecessary to name AI/AN communities in research reports, and that being named often has the potential to harm these communities.[32] Norton and Manson also point out that research publications which have associated AI/AN groups with certain issues, such as alcoholism, have contributed to negative stereotypes about AI/AN people. Therefore, if the topic of the research is one which the community feels might marginalize or stigmatize its members, the community may wish to remain anonymous in the publication.

On the other hand, being identified in a research publication may be one way of acknowledging an AI/AN community's contribution to research. If an AI/AN community is identified, other AI/AN communities might look to that community for assistance if

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[31]Khan, Sohail. Roles of Tribal, Regional, and National IHS IRBs (oral presentation). Respecting Tribal Nations and Members when Conducting Research, Tulsa, OK, July 26, 2007.
[32]Norton, Ilena and Spero Manson. Research in American Indian and Alaska Native Communities: Navigating the Cultural Universe of Values of Process. Journal of Consulting and Clinical Psychology, 1996. 64(5): 856-860.

they have similar issues as those described in the publication. Naming the community involved in the study helps other communities to contextualize the research results and to better evaluate how the findings might apply to them. Some communities may also feel it is important that they are identified in publications so that other researchers who read the reports can contact the AI/AN community in the future about new projects. By the same token, some AI/AN communities may wish to remain anonymous in publications to prevent researchers from approaching them in the future with proposals, particularly those communities that are reluctant to participate in a large number of studies. Some researchers might argue that not naming a community in a research publication decreases the scientific credibility of a study, in that it is necessary to know all possible information about a group when considering the results of a research project. AI/AN communities must balance these complicated issues when deciding whether or not to be named in publications. Communities might adopt a global policy to be named (or not to be named) in research publications or might instead make this decision on a case-by-case basis. Communities choosing to be named on a case-by-case basis might be identifiable in publications where they are not explicitly named if there have been other similar publications in which they are identified. This possibility might be more likely if publications about the community are all on a similar topic or are written by the same author. Thus, when reviewing new publication manuscripts, communities may need to consider the broader context of literature that has already been published about them.

In sum, publication review is a complex process that requires thoughtful negotiation of many issues. AI/AN communities must protect themselves and their members from harm when reviewing research publications. However, this interest must be balanced against the principle of freedom of expression and the importance of publishing for the advancement of researchers' careers. With a carefully crafted publication review process, it is possible to meet both the needs of researchers and the communities with whom they work.

Conclusion

It is vital that AI/AN communities carefully review research proposals and research results. The best way of ensuring that AI/AN communities are not harmed by and benefit to the greatest extent from research projects is for communities to be involved throughout a research study. Prevention of problems in research studies is much easier than attempting to rectify them after they occur. Effective partnerships between AI/AN communities and researchers are key to ensuring successful research projects which benefit communities. Through creating a comprehensive research review process and detailed guidelines for review of research projects, AI/AN communities can facilitate these partnerships.

The author welcomes questions and comments about this paper. Please email feedback to: singhp@msnotes.wustl.edu.

APPENDIX

Research Review Checklist

The checklist below summarizes key components of research proposals that are discussed above. This checklist may be used as an interactive guide for AI/AN communities reviewing research proposals. Communities are encouraged to use this checklist as a template for developing their own, and to add any components they feel are necessary for their specific needs. Each community is unique. While there may be overarching themes that are important in reviewing research proposals, individual communities will need to determine what specific criteria for research review work for them.

Reviewing Research Proposals

<u>Possible Components of Research Proposals</u>

___ Narrative of research proposal:
     ___ Background, literature review
     ___ Research question(s)
     ___ Recruitment procedures
     ___ Informed consent procedures
     ___ Incentives/compensation procedures (if any)
     ___ Data/specimen collection procedures
     ___ Data storage/handling procedures
     ___ Data analysis procedures
     ___ Plan for publication/dissemination of data

___ Informed consent form:
     ___ Clear, understandable language
     ___ Background and significance of study
     ___ Description of research procedures
     ___ Confidentiality procedures
     ___ Options for data/biological specimen handling (if applicable)
     ___ Description of risks and benefits of study
     ___ Alternatives of study participation
     ___ Right of individuals to refuse study participation or to withdraw at any time
     ___ Information on compensation in the event of injury
     ___ Contact person for questions about the study
     ___ Signature line if individual agrees to participate

___ Budget and funding sources:
     ___ Detailed budget for research project
     ___ Copies and status of grant applications submitted
     ___ Information on data ownership and sharing requirements of potential funders
     ___ Funding and/or in-kind resources being requested from the AI/AN community

      ___ Funding and/or in-kind resources available to the AI/AN community

___Professional qualifications of research team:
      ___*Curricula vitae* for researchers and research staff
      ___ Copies of relevant previous publications by researchers
      ___ Letters of support from researchers' institutions or departments

Questions to Consider:

___Do the potential benefits of this study outweigh the potential risks?
      ___ For the community as a whole
      ___ For individual community members

___ Does the community have adequate control over data/biological specimens in the following areas?
      ___ Collection
      ___ Use
      ___ Storage
      ___ Destruction

___Is there a contract or other legal tool that ensures the community has adequate control over data/biological specimens?

___ Is there a trusting relationship between the researcher and the community?

___ Is there an avenue for community input and feedback during the research project?

___ Is the community treated as an equal partner in the research project?

Monitoring ongoing research

Once a research project has been approved, the community may wish to continue monitoring the project through requiring regular reports from researchers. The following components may be included in interim or final reports provided by researchers:

___ Clear, understandable language

___ Summary of current findings

___ Resulting recommendations to community for improvements in policies/services

___ Benefits the study provided to participants and community

___ Problems that occurred in the research study (if any)

___ Timeline for anticipated follow-up steps (e.g., future proposed research studies, manuscripts that may be submitted for publication).

___ Report of how results have been disseminated in the community (e.g., articles in community newspaper, presentations at community meetings).

Review of publications

___Do proposed publications represent the community without unfair stigma?

___Has the community tried to constructively support the researchers' needs for publication?