How to Build and Sustain a Tribal IRB

The Partnership for Native American Cancer Prevention, U54CA143924

Hopi NARCH, S06GM128012

February 2019 | **Volume I, Issue II**

Contents

Why a Review Board?	1
Research Review Board	2
Decisions Needed	2
Membership	2
Documentation	2
Elements of a Review	3
Voting Decisions	3
Registration	4
Resources	4

This document is a guide for American Indian and Alaska Native (AI/AN) tribal communities on:

- How to build a Tribal research review board or an Institutional Review Board;
- How to conduct protocol reviews;
- How to register a Federalwide Assurance (FWA) or an IRB; and
- Additional resources.

Tribal research reviews are important because they can ensure research benefits

Why Have a Tribal Research Review Board or a Tribal Institutional Review Board?

It is important to have a tribal research review board to ensure tribal members and the tribal community are protected, from a tribal perspective, and have optimal benefit from a research project. It is also a right of tribal sovereignty to govern the activities, i.e., research, that occurs in tribal communities. Not every tribal community may need a research review committee however. For example, if a tribe is not going to participate in research, a research review committee may not be necessary.

Questions to ask when considering a research review committee:

- Are researchers coming to our tribal community to introduce research projects?
- What type of research is being proposed? For example, surveys, interviews, screenings, etc?
- Who is being involved within the community? Existing programs, community at large?
- Who should serve on the review committee? How do we support the review committee?

In this guide, we offer a brief outline of basic items needed for a tribal research review board and offer resources that go into more detail (pg. 4). This guide is part of a series that the University of Arizona NACP Outreach has created. The other guides in this series are focused on:

- How to Review Research to Benefit Tribal Communities, Volume II
- How to Conduct Research, Volume III
- Guidelines for Researchers, Volume IV

These resources are intended to provide and useful and pertinent information to tribes and researchers so that outcomes can benefit tribal members and tribal communities. These guidelines are written specifically for research that would involve people, usually called human subjects. Most of the procedures and policies contained within these guides are based on current federal regulations, called ***Code of Federal Regulations*** (CFR), 45 CFR 46, for ***human subjects protection***.

Since most research is initiated by personnel at University settings, the Universities call their research review boards, ***Institutional Review Boards*** (IRBs). A University IRB conducts reviews but their reviews are focused exclusively on the protections of individuals, not communities. Since University IRBs may not know much about tribal systems and values, the assessment of risks and benefits may not be adequate or complete.

Suggested Citation: Gachupin FC, Molina F. How to Build and Sustain a Tribal IRB, VI(1). Tucson, Arizona: University of Arizona, Department of Family and Community Medicine, College of Medicine, February 2019.

The Tribal Research Review Board

The tribal research review board are a group of individuals that have interest in ensuring tribal members and the tribal community are receiving the most from a research project and are willing to volunteer time to review a lot of written materials. It is ideal to have a person who is in charge of the board, i.e., a Chair, and someone to take minutes and to take care of all the written materials. Unfortunately, most tribal research review committees are voluntary and do not receive any financial compensation.

Decisions need to establish a tribal research review board:

- Tribal leadership should formally recognize and authorize the research review board, i.e. receive permission to have authority to review and approve research projects
- Decisions on the operations of the review board should be established, for example, where will the meetings be held? Where will the documents be received and stored?
- Decisions on how expenses will be handled need to be determined. Who pays for copies, phone calls?
- Decisions on who will be responsible for ensuring everything is secure and protected need to be made
- Decisions on how board members are selected need to be made, for example, appointment, volunteer?
- Decisions on who will be responsible to set up the review committee, for example, policies and procedures.
- Decision on how researchers will be notified that the review board exists.
- Decision on how review board will receive continuing human subjects protection training.
- Decisions on whether tribe will own the data. If so, how should the data be received (format) and where and for how long will it be stored? Who will have access?

If federal regulations are to be referenced, **the research review board must have**:

- At least five members, both men and women
- One member must be non-scientific (for example, a community member)
- One member must have science based training background, or at least know about the area that the research involves. For example, if the research involves a medical condition, a physician should be present for the review.
- One member who is not directly affiliated with the tribe.
- The board members should not have conflicts of interest. For example, if the researcher is related to one of the board members, the board member should not vote.
- All board members must be trained in human subjects protection, at least every three years.
- For official decisions to be made during a meeting, there must be a quorum and at least one community member and one

It is important for the tribal research review board to **keep documents and store correspondence**, such as:

- Meeting minutes that includes who was present, time the meeting started and ended, and decisions made, including summary of discussion.
- A list of board members and a copy of their resumes.
- All correspondence with researchers including copies of submitted protocols, consents, surveys, interview or focus group questions, and letters going to and from the review board.
- Written policies and procedures of the research review board.

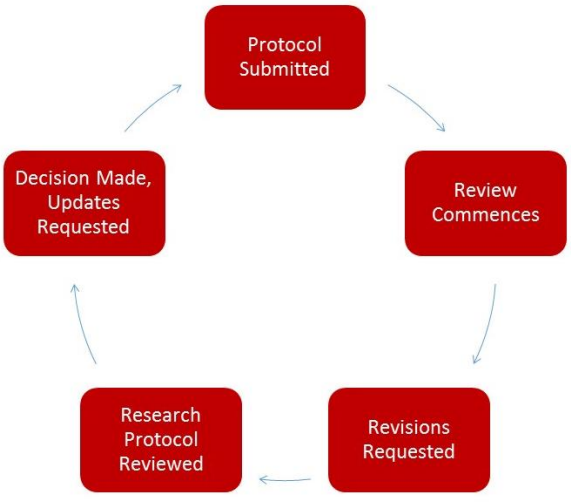
Elements of a Review

1. **Understand the research**
   Understand the type and purpose of the research being presented. This is achieved by reading through all of the materials submitted by the researcher. The review board should identify the risks and benefits for both the individual participants and the tribal community. The review board should look at who is included or not included in the research and why. Special attention should be paid to how individuals are being consented and whether the process is sufficient. For example, is a translator or interpreter needed? All information that is being collected should be protected and kept secure. The review board should assess how the tribal community is involved. Are all these adequate and sufficient?
2. **Ensure the consent process fully informs and freely consents potential participants**
   Decide whether or not the consent form explains all parts of the research in easy and understandable ways.
3. **Minimize potential harms**
   Consider potential cultural/traditional, biological, medical, spiritual, psychological, and social harms to the individual, family, and the community, and require steps to ensure potential harms are minimized.
4. **Maximize potential benefits**
   Consider potential cultural/traditional, biological, medical, spiritual, psychological, and social benefits to the individual, family, and the community, and require steps to ensure potential benefits are maximized.
5. **Ensure justice**
   Look at who is being included in the study and assess that all those who could benefit from participation are being included.
6. **Obtain additional information**
   Decide if additional expertise is needed to understand what is being proposed. This may include involving additional experts (researchers, health educators, administrators, etc.) to clarify or provide assistance with the review.

Tribal Research Review Board Decisions

When a Tribal Research Review Board has reviewed a research protocol, they vote and the decision could be to:

- **Approve the Research.** The research can start and the board can request that a researcher provide updates with the time specified, for example, annually.
- **Approve with Recommendations.** The research can start and there are items given to the investigators to make the research project more responsive to local tribal circumstances.
- **Approve with Conditions.** The research cannot start and there are concerns that must be addressed first. The revised research protocol is reviewed once changes have been made.
- **Defer.** The research cannot start and a decision is not made at all because there are key elements missing. The revised research protocol is reviewed once changes have been made.
- **Disapprove.** The research is disapproved and cannot proceed.



Federalwide Assurance Registration and IRB Registration

A Federal Wide Assurance (FWA) is documentation of an entity's commitment to comply with Federal regulations and maintain policies and procedures for the protection of human participants. Tribes can complete FWA registration for the Tribal Research Review Board. An FWA application can be obtained from and submitted to: https://ohrp.cit.nih.gov/efile/FwaStart.aspx.

If and when a tribe feels their review board is established enough to become a registered IRB, an application is completed online and registration is active for 3 years. The registration is through the Office for Human Research Protections (OHRP) (the federal agency that is responsible for IRBs across the country), www.hhs.gov/ohrp/assurances/irb/register/index.html

Resources

This guide provides information in brief and there are other resources available that provide more in-depth background, templates, regulations and support. Following are links and a brief sentence explaining what the respective resources provides.

The University of Arizona Human Subjects Protection Program provides information on IRB Assurance and Registration, IRB Roster, Statements of Regulatory Adherence, and fee charges at: https://rgw.arizona.edu/compliance/human-subjects-protection-program/about-the-irb

The University of Arizona Native Peoples Technical Assistance Office provides research support; training and education; and technical assistance for tribal community development at: https://nptao.arizona.edu/

The Indian Health Service provides additional resources regarding IRBs, grants, research studies, and programs at: https://www.ihs.gov/dper/research/researchresources/

The National Congress of American Indians has information about the foundations, ethics, and practices of research resulting in the construction of AI/AN codes, contracts, and IRBs at: http://www.ncai.org/policy-research-center/initiatives/research-regulation

The Office for Human Research Protections issues written guidance's, registers IRBs and FWAs, and provides information about the New Common Rule at: http://www.hhs.gov/ohrp/

PRIM&R is a leader for public responsibility in medicine and research providing educational programs and professional development opportunities that can be found at: https://www.primr.org/

For further information about the Belmont Report, the Nuremberg Code, and Helsinki, please visit the "Ethical Codes & Research Standards" section of the OHRP website at: https://www.hhs.gov/ohrp/international/ethical-codes-and-research-standards/index.html

For more information, please contact:

Francine Gachupin, PhD, MPH
Office: 520-621-5072
Email: fcgachupin@email.arizona.edu

University of Arizona
Department of Family and Community Medicine
PO Box 210491
655 N Alvernon Way, Suite 228
Tucson, AZ 85711

COLLEGE OF MEDICINE TUCSON
Family & Community Medicine

Fatima Molina, BSc
Office: 520-621-5920
Email: fatimamolina@email.arizona.edu

The-Partnership-for-Native-American-Cancer-Prevention

@NacpOutreach