

STARTING AN INSTITUTIONAL REVIEW BOARD [IRB]:
Suggestions for Tribes and Tribal Colleges
*** draft ***

[all URLs were accessed on April 7, 2006]

A. Why should a tribe or TCU start up and register an IRB, and obtain a Federal Wide Assurance [FWA]? There are several reasons.

1. Tribal governments and TCUs apply for and receive increasing numbers of federal grants that include research involving human participants. Such grants require that all applications be reviewed by the tribe's or TCU's human research protection system, and if, not exempt, be approved by its IRB.
2. IRBs protect human participants in research from possible harms.
3. IRBs of non-tribal universities and institutions are less likely to consider and know what potential research harms are in the local tribal situation and how to minimize them, and what potential benefits are and how to maximize them. For that reason, many tribes and TCUs do not rely solely on the IRB of a non-tribal institution.
4. The federal regulations permit IRBs to consider possible harms to tribes in research. TCU & tribal IRBs will often be the only IRBs to do so.
5. TCU/Tribal IRBs have the best and most complete knowledge of their local situation. TCU/Tribal IRBs know best how to minimize potential harms and maximize potential benefits to the tribe, tribal members, TCU students, and the TCU itself.
6. Because many tribes, tribal governments, and tribal people mistrust research, they may trust a research project more if a TCU/tribal IRB reviews and approves it.
7. All federal funders recognize those IRBs with a Federal-Wide Assurance [FWA] as appropriate to review and approve/disapprove the research. IRB decisions are final.
8. A TCU and tribe can easily form and register its IRB.
9. A TCU/Tribal IRB can easily obtain an FWA -- but that IRB must first be registered.

B. What are the major resources and advisers for a TCU/Tribal IRB?

1. Resources in Indian Country

Three people with much knowledge of and long experience on IRBs related to Native health are important resources. **Bill Freeman** was Chair of National IHS IRB for 11 years; he now staffs the NWIC IRB. **Sayaka Kanade** has much experience and knowledge, as both staff and member of IHS IRBs. **Terry Powell** [Chugach] and **Francine Romero** [Jemez Pueblo] each have served / are serving as Chairs and co-Chairs of three IHS IRBs.

Bill Freeman wfreeman@nwic.edu and WilliamLFreeman@att.net

Sayaka Kanade epikanade@aatchb.org

Terry Powell tjpowell@anmc.org

Francine Romero Francine.Romero@jemezpueblo.us

Bill Freeman is willing and available to help any TCU or tribe to:

- * learn about protection of Native individuals and communities in research;

- * form an IRB;
 - * educate members of its IRB;
 - * apply for registration of its IRB;
 - * apply for an FWA; and
 - * review a particular protocol, or understand particular questions about the regulations.
- Bill's full contact information is at the end of this document.

2. Area or regional resources

Most IHS Area Offices have an IRB, and an Epi Center. The Chair or staff of the Area IHS IRB is an experienced source of suggestions and advice. Many Epi Centers will also help.

Most universities have IRBs. The Chair or staff of the IRB of a university nearby, or that the TCU or tribe works with, may be an experienced source of suggestions and advice.

3. National resources

Office for Human Research Protection [OHRP] is a major resource of the federal government. (Until 2000, it was "Office for Protection from Research Risks" [OPRR]. You may still see "OPRR" in older documents.) OHRP helps organizations establishing an IRB, and IRBs themselves. OHRP issues written guidances, registers IRBs, and issues FWAs.

<http://www.hhs.gov/ohrp/>

1101 Wootton Parkway, Suite 200

Rockville, MD 20852

Toll free within USA 866-447-4777

Telephone 240-453-6900 fax 240-453-6909 ohrp@osophs.dhhs.gov

OHRP staff listing, with e-mail & telephone #: <http://www.hhs.gov/ohrp/about/staff.html>

PRIM&R (Public Responsibility in Medicine and Research) and **ARENA (Applied Research Ethics National Association)** hold a large annual national educational meeting for IRB members, researchers, and others. The meeting is held in late fall.

<http://www.primr.org/>

PRIM&R has scholarships to attend that meeting with all expenses paid for institutions that serve populations with health disparities and need to establish an IRB. TCUs and tribes are eligible for that scholarship program. Contact PRIM&R or Bill Freeman for information.

C. What is the structure and membership of a TCU/tribal IRB?

In many tribes, the Executive Officer nominates, and the tribal council probably approves, the IRB members. In most TCUs, the president appoints the members. The IRB should have at least 5 members, both men and women. The IRB may have alternate members.

- * The IRB must include at least one member "whose primary concerns are in nonscientific areas," such as nonscientist tribal community members, spiritual leaders, lawyers, etc.-- often called "community members."
- * The IRB must also include at least one member "whose primary concerns are in scientific areas" (including people whose training is science based), such as physicians, nurses, psychologists, social workers, ethnographers or anthropologists, geographers, science teachers, some counselors, etc. Good guidance for IRB membership is to have at least: one physician member, if the IRB will review any health protocols; one behavioral member [social worker, counselor, psychologist, anthropologist] if it will review behavioral protocols.
- * Many new IRBs have an experienced member or staff of a nearby IRB.
- * The IRB must also include at least one member--scientist or community--who is

unaffiliated with the TCU/tribe. That means at least one member must be not employed by (part-time or full-time) or consultant to the TCU/tribe, not a student of or on the Board of the TCU, and not part of the immediate family of a person in those categories. (The NWIC IRB is stricter: a person who is affiliated with neither the NWIC nor tribal government of Lummi [the tribe that chartered the NWIC].)

The quorum must include at least one community and one scientific member; without at least one person present from both types, the IRB cannot hold a meeting or make decisions. (The NWIC Policy is that, although nonscientist members may be non-Native, quorum requires at least one nonscientist who is an American Indian or Alaska Native enrolled tribal member.)

D. Basic steps to form and develop an IRB

1. The TCU or tribe decides and commits itself to have an IRB.

An IRB may not be sustained if it is formed and developed by only a local champion, without the support and commitment of the TCU or tribe itself.

2. Members of the future IRB and others learn about human research protection.

Likely members of the future IRB, and key supporters in the tribe/TCU, learn about:

- o human research protection for individuals and communities;
- o the federal regulations about human research protection; and
- o the additional concerns a tribal/TCU IRB will likely have.

The "Resources in Indian Country" and "Area or regional resources" (above), and PRIM&R and ARENA, can help with this step. Bill Freeman will visit any TCU or tribe to provide such education. Some Epi Centers also provide on-site education.

3. Form and develop the IRB, by starting to work.

This large step typically include the following suggested substeps.

- o Solicit people interested in serving on the IRB.
- o Ask the responsible tribal/TCU official to appoint the members to the IRB.
- o If the host organizer is a TCU, consider discussing with the chartering tribe what the relationship should be between tribe and TCU IRB. If the organizer is a tribe with a TCU, consider discussing with the TCU what the relationship should be between tribal IRB and TCU. (An IRB, either conjoint or with both tribal government and TCU members, does not violate the arms-length relationship in **governance** between tribe and TCU required by accreditation.)
- o Develop the IRB's Policies and Procedures. The development can be started by examining and modifying a P&P from an IRB of similar size and function. Pay special attention to certain sections, and decide if your IRB wants to follow the same procedures or modify them for:
 - _ initial screening of the protocol (who does it, what decisions are made);
 - _ protocols judged to be "Exempt" under the federal regulations;
 - _ protocols judged to be "Expeditable" under the federal regulations;
 - _ review, discussion, and decision-making in the IRB meeting; and
 - _ periodic re-reviews (done at least annually).

The development of the P&P provides important education about human research

protection, tribal/TCU values and concerns, and the federal regulations. If the entire IRB develops its P&P, the IRB educates itself about those matters while achieving a practical task. Having an experienced member of another IRB may assist the IRB's education and decision-making.

- o Educate the host tribal government or TCU about the purpose and function of the IRB. (If staff and potential researchers in the organization are not aware of human research protection, research may occur without IRB review.)
- o Review protocols. The IRB can treat each review as an opportunity for IRB self-education. In each review, the IRB can discuss relevant basic issues, such as the applicable principles of human research protection, research methods that might carry less or more potential harms and potential benefits, etc.

E. How does a tribe or TCU first register its IRB, and then obtain an FWA (Federal-wide Assurance) for its registered IRB?

Register an IRB:

<http://www.hhs.gov/ohrp/assurances/index.html>

Click on "New IRB/IEC Registration":

<http://www.hhs.gov/ohrp/assurances/index.html#registernew>

Instructions for registering an IRB:

<http://www.hhs.gov/ohrp/humansubjects/assurance/regirbi.htm>

Apply for a Federal-Wide Assurance:

http://www.hhs.gov/ohrp/assurances/assurances_index.html

Click on "Domestic (U.S.)":

http://www.hhs.gov/ohrp/assurances/assurances_index.html#domestic

Instructions for filling out an FWA application:

<http://www.hhs.gov/ohrp/humansubjects/assurance/filasuri.htm>

Terms of the FWA:

<http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>

TCUs & tribes may quote this document without prior permission from the author.

William L. Freeman, MD, MPH, CIP

Director of Tribal Community Health Programs, & Human Protections Administrator

Northwest Indian College <http://www.nwic.edu> (Lummi Nation <http://www.lummi-nsn.gov>)

2522 Kwina Road

Bellingham, WA 98226-9217

360-758-2175 (360-392-4284) fax 360-647-7084

wfreeman@nwic.edu and WilliamLFreeman@att.net