

# Native STAND

*Students Together Against Negative Decisions*

## **IRB 101 and Native STAND IRB Review Qualifier**

Many American Indian and Alaska Native (AI/AN) people are wary of research and do not trust researchers. This is largely due to the fact that ‘research’ generally reminds Native people of the myriad of projects conducted by outsiders that did not benefit Native communities and sometimes caused harm. As Indian health policy and strategic planning increasingly rely on evidence-based data & statistics, Native communities are engaging more with Community-Based Participatory Research (CBPR) and program evaluation activities. However, the Native research process requires specific approaches and methods that are necessary to gauge the impacts and the benefit of particular Native-focused projects.

### What is an IRB?

An Institutional Review Board (IRB) is charged with protecting the rights and welfare of people involved in research. An IRB reviews plans for research involving human subjects which is required by federal law. Federal laws and regulations regarding human subjects have specific requirements for IRBs and study administration. IRBs look closely at the negotiation between researcher and each potential volunteer, called the “informed consent process.”

### What is the purpose of an IRB?

The IRB is intended to protect the rights and welfare of human research subjects recruited to participate in research activities. Institutions that accept research funding from the federal government must have an IRB to review all research involving human subjects (even if a given research project does not involve federal funds.)

### How Do IRBs work in Indian Country?

Much research is done in AI/AN communities by outsiders such as universities, by Tribes and Indian Health Service (IHS) Service Units, and by the IHS Research Program. IRBs help ensure that all research observes three ethical principles: (1) respect for persons; (2) beneficence (to do no harm, and to maximize benefit); and (3) justice. AI/AN communities use a wide variety of methods to regulate research. Some AI/AN communities choose to work with the IHS, tribal colleges, or other universities in their geographical area to review and approve proposed research. Some 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. In addition, some AI/AN communities have created Community Advisory Boards for each specific research project that is done with their citizens. Finally, there are informal mechanisms that AI/AN communities use for gathering community members’ input into how research studies should be conducted.

### **Why does the IHS IRB Review and Approve research for AI/AN people?**

The IHS has primary responsibility for health services for AI/AN people based in Federal law. The IHS is committed to the self-determination and cultural integrity of AI/AN communities; this includes the IHS IRB. Due to concern about tribal sovereignty and self-determination, the IHS IRBs look both at the negotiation between researcher and each potential volunteer (“informed consent process”), and also that between researcher and the tribal community. That is, IHS IRBs help ensure that all research in AI/AN communities observes the three ethical principles – respect for persons, beneficence, and justice. The IHS IRBs ensure protection not only of the individual volunteers in research, but also of the tribal communities in which the research takes place.

The IHS has established IRBs for its Area Offices. 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. The IHS has 12 IRBs, one for each Area and a Headquarters IRB (known as “National IHS IRB”) that also covers the Albuquerque Area. The Navajo Nation has its own IRB, whose IRB members also hold appointments on the IHS Navajo Area IRB.

### **Native STAND participants and the Portland Area IHS IRB review qualifier**

Communities that participate in Native STAND are recommended to recognize the Portland Area Indian Health Service’s IRB (PAIRB) review of the protocol to assure human and tribal protections. This qualifier has been discussed and approved by the Co-Chair of the PAIRB, Tom Weiser, MD, MPH, Medical Epidemiologist. The PAIRB will inform the National IHS IRB (NIRB) of all participating sites located outside the Portland Area, and will also inform all local IRBs about the presence of the study in their region. For those Area Offices that have their own IRB, that local IRB Chair will be asked to email the PAIRB ([pairb@ihs.gov](mailto:pairb@ihs.gov)) and the NIRB ([irb@ihs.gov](mailto:irb@ihs.gov)) indicating that they agree to recognize the review provided by the Portland Area.

### **What are the advantages of deferring IRB review to the Portland Area versus my own tribe’s IRB or my regional Area IHS IRB?**

There are some complexities in the multi-site, multi-geographical IRB protocol review for communities outside of the Pacific Northwest that choose to participate in the Native STAND program. Deferring review and approval to the PAIRB has several advantages: (1) this strategy can be implemented relatively quickly; (2) the IRB has the experience and infrastructure to review multi-site research projects; (3) all manuscripts will be reviewed by experienced researchers before publication; and (4) fewer resources are required from the tribal communities that participate. For expedited Native STAND application processing, deferral to PAIRB is the preferred option.

### **What if I opt out of the Portland Area IHS IRB review and decide to use an alternative IRB approach?**

An alternative 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. This approach, although acceptable, may delay and defer Native STAND application consideration into the next year and ultimately, implementation of the project in your home community

### **Human Subjects Protection Training & IRB 101 -- a part of Native STAND Summer Training?**

Community professionals who attend the Native STAND training at the Portland Summer Research Institute will receive training on the protection of human subjects in research, and IRBs. The Native STAND Project is committed to building the capacities of tribal communities to engage in research, allowing individual communities to better access and understand data that would benefit their communities toward eliminating health disparities, and potentially affect Federal Indian policy, budget & appropriations efforts.