

# Frequently Asked Questions about the Southwest Tribal Institutional Review Board

## Frequently Asked Questions

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### Question: What is an IRB?

An institutional review board (IRB), also known as an independent ethics committee or ethical review board, is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. They often conduct some form of risk-benefit analysis in an attempt to determine whether or not research should be done. The number one priority of IRBs is to protect human subjects from physical or psychological harm. In the United States, the Food and Drug Administration (FDA) and Department of Health and Human Services (specifically Office for Human Research Protections) regulations have empowered IRBs to approve, require modifications in planned research prior to approval, or disapprove research. IRBs are responsible for critical oversight functions for research conducted on human subjects that are "scientific," "ethical," and "regulatory."

### Question: What is research?

Federal research regulations and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) define research as a “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

A project is research – It is possible that a project is public health practice or non-research. Examples of non-research include public health practice, quality assessment and quality improvement programs, Resource/utilization reviews, and outcome analyses.

**Question: What is the purpose of the Federal Wide Assurance?**

The Federal-wide Assurance (FWA) is the only type of assurance of compliance accepted and approved by the Office of Human Research Protection (OHRP) for institutions engaged in non-exempt human subjects' research conducted or supported by the Department of Health and Human Services (DHHS). There are a number of DHHS programs that fund or conduct research in Native communities – Indian Health Service (IHS), Centers for Disease Control (CDC), Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institutes of Health (NIH). Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in the Code of Federal Regulations (CFR), Department of Health and Human Services Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR Part 46).

**Question: Does the AAIHB have a FWA?**

Yes, AAIHB is required to register for a FWA because the organization sponsors several programs that conduct health-related research in tribal communities – Albuquerque Area Southwest Tribal Epidemiology Center (AASTEC) and the Southwest Tribal Native American Research Center for Health (NARCH). AAIHB's FWA number is FWA00010285.

**Question: Why does the AAIHB sponsor the SW Tribal IRB?**

Until mid-2009, there was not a local tribal-based IRB to serve Southwest tribes participating in health-related research activities. The national IHS IRB in Rockville, MD, has served as the reviewer of research in the Albuquerque Area. AAIHB Directors recognized the need to provide critically needed support for tribes to approve, require modification to, or disapprove all health research activities taking place in southwest tribal communities. At their March 2009 meeting, the AAIHB Board passed a resolution to establish the Southwest Tribal IRB to provide IRB services to AAIHB and AASTEC research projects.

**Question: What tribes are served by the Southwest Tribal IRB?**

The consortium tribes of Ramah Navajo, Tohajiilee Navajo, Mescalero Apache Tribe, Jicarilla Apache Nation, Ute Mountain Ute Tribe, and Southern Ute Tribe are served by the Southwest Tribal IRB. Laguna Pueblo submitted a resolution that authorizes the Southwest Tribal IRB to review their health-related research protocols. Other southwest tribes are indirectly served by the Southwest Tribal IRB if they collaborate with AASTEC or NARCH on projects that may result in research.

The Southwest Tribal IRB is available to collaborate with southwest tribes to conduct a supplemental review of research projects based on federal code and regulations specific to human subjects' protection. The Southwest Tribal IRB does not supplant or replace local tribal review but is meant to provide additional insight and recommendation. It was determined that Tribes will be required to submit a resolution from their tribal government indicating the approval and authorization of Southwest Tribal IRB services.