



For Tribes: How to Build and Sustain a Tribal Institutional Review Board

July 11-13, 2005
Rapid City, South Dakota

Hosted by:

Northern Plains Tribal Epidemiology Center

Sponsored by:

Indian Health Service

Spirit of E.A.G.L.E.S.-Mayo Clinic NCI 86098-05
University of Nebraska Medical Center

TRAINING AGENDA

This 3-day training will provide tools to help tribes and tribal colleges establish and administer an IRB. Topics to be covered include: role of IRBs, review of the federal regulations under which IRBs operate; IRB structure including membership and meetings; IRB administration including receiving, reviewing, and tracking protocols; and obtaining a Federalwide Assurance and registering an IRB. Participants will become familiar with the nuts and bolts of IRBs and receive the materials necessary to build and maintain an IRB.

DAY 1: MONDAY, JULY 11 Principles of Research Ethics

7:00am Registration

8:30am Welcome & Introduction
Chairman John Blackhawk, Winnebago Tribe
Francine Romero, PhD, MPH, Director, Northern Plains Tribal Epidemiology Center

9:15am Keynote Address- IRBs: Contributors and Resolvers of Problems
Bernard A. Schwetz, DVM, PhD, Director
Office for Human Research Protections, Department of Health and Human Services

Institutional Review Boards (IRBs) are the single most important element in our efforts to protect human subjects of research. Federal regulations and applicable state and local laws, regulations, and policies provide a comprehensive articulation of society's expectations for the responsible use of human subjects in research. Implementation of these regulations and guidelines, however, rests largely in the hands of IRBs in the US and their equivalent outside the US.

The flexibility that IRBs have as they perform their responsibilities has created a diversity of approaches to comply with the regulations. In some cases this has created burdens that do not necessarily result in additional protections for research subjects, for example, overinterpretation of the regulations or treating guidances like regulations. In other cases, IRBs have

become quite innovative in ways that have improved their efficiency and effectiveness, resulting in better protection of subjects of research.

Lack of public trust in the research enterprise is a significant problem, especially among minority populations and communities. Abuses of the past have eroded confidence in researchers and the federal government. Rebuilding the trust of the public will be essential for the success of the research enterprise and the continued development of new medical products, improved medical procedures, and knowledge that will translate into better lives for Americans.

10:30am Break

11:00am Guiding Principles of the Belmont Report are the Cornerstones of Human Subject Protection Research
Ernest Prentice, PhD, IRB Chair
University of Nebraska Medical Center
This session presents the events leading to the development of the Belmont Report, the guiding principles of human research protections. The principles and application of the Belmont Report are reviewed.

12:00pm Lunch (provided)

1:00pm Participant Introductions

1:30pm Research Types and Potential Harms and Benefits
Terry Powell, IRB Administrator
Alaska Area Institutional Review Board
Potential harms and benefits may vary depending on whether the research is a survey, screening, clinical trial, intervention, quality assurance, or another type of project. This session will explore the potential harms and benefits for the different types of research.

2:00pm Inside the Research Process and Protocol
Marianna Kennedy, MSW, MPA, MPH, Executive Director
Albuquerque Area Indian Health Board
The current research process will be described, including designing of the research plan or protocol, obtaining tribal approval, collecting data, conducting data analysis, and publication of results.

2:45 pm Break

3:15pm Breakout Session #1
Mock Review using 45 CFR 46 guidelines & combined Tribal Review Checklist

5:00pm Group Discussion

5:30pm Adjourn

DAY 2: TUESDAY, JULY 12th Building Your IRB

- 8:30am Learning from Local Tribal and Tribal College IRBs
We will hear from local tribal and tribal college IRBs on why they decided to develop their own system, about their structure and procedures, and about some of the successes and challenges of managing an IRB.
- Winnebago Tribal IRB
John Blackhawk, Chairman, Winnebago Tribe
- Mandan, Hidatsu, and Arikara Tribal IRB
Deborah Hall-Thompson, MBM, RN, Tribal Health Director, Mandan, Hidatsa, & Arikara Tribes
Renee Mayer, MSW, Director of Social Services, Mandan, Hidatsa, & Arikara Tribes
Jody Gillette, Native American Training Institute
- Northwest Indian College IRB
William Freeman, MD, MPH, Director of Tribal Community Health Programs & Human Protections Administrator, Northwest Indian College
- 10:15am Break
- 10:45am IRB Meeting Process
William Freeman, MD, MPH, Director of Tribal Community Health Programs & Human Protections Administrator, Northwest Indian College
This session will provide an overview of the IRB process, including details on administrative activities before, during, and after an IRB meeting.
- 12:00pm Lunch (provided)
- 1:00pm Breakout Session #2
Mock IRB Meeting
- 3:00pm Break
- 3:30pm Planning Your Tribal or Tribal College IRB
Francine Romero, PhD, MPH, Director
Northern Plains Tribal Epidemiology Center
This session will be a very interactive session in which participants brainstorm ideas and discuss various ways of establishing an IRB and the advantages and disadvantages of the each. This exercise will help participants work with key players in their community to plan an effective IRB.
- 5:00pm Adjourn

DAY 3: WEDNESDAY, JULY 13 Sustaining Your IRB

- 8:30am Keeping track of your protocols and meetings: Database of the IRB
Sayaka Kanade, Academic Liaison
Northern Plains Tribal Epidemiology Center
Record-keeping is important in administering an effective IRB. A Microsoft Access database will be demonstrated as a potential tool to track and store information on protocols, principal investigators, IRB members, and meetings.
- 9:30am Registering your IRB and obtaining a Federalwide Assurance (FWA)
William Freeman, MD, MPH, Director of Tribal Community Health Programs & Human Protections Administrator, Northwest Indian College
The purpose of this session is to introduce the process of registering an IRB and obtaining an assurance with the Office of Human Research Protections. This session will help participants navigate the various forms and requirements.
- 10:00 am IRB resources
William Freeman, MD, MPH, Director of Tribal Community Health Programs & Human Protections Administrator, Northwest Indian College
There is a multitude of resources available to IRBs and IRB members on research ethics and IRB administration. This session will showcase various websites, manuals, and agencies that can assist you as you plan, implement, and maintain an IRB.
- 10:30pm Closing Discussion
- 11:00pm Adjourn

ACKNOWLEDGEMENTS

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Guest Speakers

Bernard Schwetz, DVM, PhD

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Winnebago IRB

John Blackhawk

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Mandan, Hidatsa, & Arikara Nation IRB

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Presenters and Moderators

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