



ORIENTATION AND TRAINING FOR TRIBAL IRB MEMBERS

This orientation and training consists of three steps. We recommend facilitated in-person meetings for step I and III. Step II is self-paced and may be completed online in an individual or group setting.

Step I. In the first step, participants will be introduced to the history of human subjects' protections in general and as it relates to American Indian communities.

1. History and Purpose of Human Subjects Protections

Duration: 22minutes 13 seconds.

<https://www.youtube.com/watch?v=174SkSszRVg>

Module 1 of this 3-video series outlines the history of ethics in research and the criteria for protecting human participants in biomedical and behavioral research. Provided by the Health Resources and Services Administration of the U.S. Department of Health and Human Services.

2. LaFrance, Joan and Cheryl Crazy Bull. "Researching Ourselves Back to Life: Taking Control of the Research Agenda in Indian Country".

In *The Handbook of Social Research Ethics*, 3-27. Ed. Donna M. Mertens and Pauline E. Ginsberg. Thousand Oaks, California: SAGE Publications, Inc, 2009

Duration: self-paced

Facilitated discussion of article which outlines the history of unethical research activities involving American Indians, the history of the tribal IRB movement, and key topics relevant to this movement and research in "Indian country".

3. What is an IRB?

Duration: 7 minutes

<http://www.youtube.com/watch?v=nRhxq-caHXY>

Viewing followed by discussion of brief video created by a Purdue University student providing an overview of the function of an IRB for American Indian Tribal Nations and for researchers working in 'Indian Country'.

4. What Values Will Guide Us?

Duration: self-paced

<http://genetics.ncai.org/which-values-will-guide-us.cfm>

Discussion relevant to topics in this resource created to provide American Indian Nations with guidance for determining which values may drive their process of research regulation. Developed by the National Congress of American Indians.

Step II. Following the introduction to human subjects' protections training, participants should obtain a human subjects research certification and complete additional trainings listed below.

1. Human Subjects Research Training Certification

Duration: self-paced

<p>National Institutes of Health (NIH) Protecting Human Research Participants (PHRP) Tutorial (FREE)</p> <ul style="list-style-type: none">• Access here.• This 7 module training outlines the principles used to define ethical research using humans as well as the regulations, policies, and guidance for the implementation of the ethical principles.• Includes certification of completion.	or	<p>CITI Program 'Human Subjects Research' course (FEE BASED)</p> <ul style="list-style-type: none">• Collaborative Institutional Training Initiative (CITI) is a provider of research education content. Relevant courses offered include a 'Human Subjects Research' series. More information here.• Fee information here.
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2. [Is it Human Subjects Research PART 1: Determine if Activity is Research](#)

Duration: 15 min 48 seconds, but self-paced

Developed by CRCAIH, this training uses case studies to provide basic understanding of how to determine if an activity is research, as defined by the Office for Human Research Protections (OHRP). Using an interactive format, participants can learn and test their knowledge in this topic area.

3. [Is it Human Subjects Research PART 2: Determine if Research Involves Human Subjects](#)

Duration: 26 min 22 seconds, but self-paced

Developed by CRCAIH, this training uses case studies to provide basic understanding of how to determine if an activity involves human subjects. Using an interactive format, participants can learn and test their knowledge in this topic area.

4. Mock Convened IRB Meeting

Duration: 28 min 44 seconds, but self-paced.

Read this [overview](#) and watch this [video](#) of a live role play of a convened IRB meeting. Demonstrates the process for initial review of a research protocol.

5. [Introduction to Research Data](#)

Duration: 10 min 46 seconds

Developed by CRCAIH, this interactive training provides basic understanding of the various types of research data

6. Review of IRB policies and procedures. In step II, IRB members should also become familiar with their IRB policies and procedures. This exercise provides an opportunity for IRB members to understand how their IRB policies fit with federal research regulations and recognize any tribally specific regulations that may affect research.

Step III. In step 3, IRB members should review and discuss questions that may have come up during the trainings provided in step II. In this final step, IRB members should conduct a practice IRB review, using tools included in the CRCAIH Tribal IRB toolkit.

1. Review and Discussion

Duration: 30 minutes

Facilitated review of questions and topics from Step II.

2. Practice IRB Review

Duration: 1 hour

The IRB may use an existing research protocol submitted to the Tribe for the practice review. 'Research review checklists' and IRB Administration 'review process tools' included in the CRCAIH Tribal IRB Toolkit should be used.

Step IV. Partnerships: It is recommended that new tribal IRB members connect with other established tribal, community or academic IRBs to learn from their experience. It may be beneficial to visit and attend IRB meetings of other established IRBs.