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: 90 minutes
   www.hrsa.gov/publichealth/clinical/HumanSubjects/
   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. **"No Meaningful Apology for American Indian Unethical Research Abuses" Felicia Schanche Hodge, Ethics & Behavior 2012, 22:6, 431-444**
   Duration: self-paced
   Facilitated discussion of article which outlines the history of unethical medical and research activities involving American Indians since colonization.

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. Through this exercise, participants will gain in-depth knowledge of human subjects' research protections.

1. Human Subjects Research Training Certification
Duration: self-paced

National Institutes of Health (NIH) Protecting Human Research Participants (PHRP) Tutorial (FREE)	**or**	**CITI Program 'Human Subjects Research' course (FEE BASED)**
• 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.		• 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.

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. Using an interactive format, participants can learn and test their knowledge in this topic area. (See electronic version of toolkit)

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. (See electronic version of toolkit)

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 (See electronic version of toolkit)

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.