

Tohono O'odham Nation – Institutional Review Board (IRB)

DISTRICT CHAIR'S PRESENTATION

NOVEMBER 9, 2022

Board Members



Beth Michel
Chairwoman



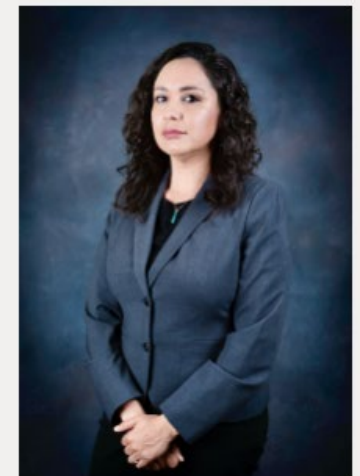
Naomi Tom
Vice Chairwoman



Lisa S. Palacios
Secretary



Susan Warmack
Elder Member



Allison Ramirez
Member

Title 17 – Health and Safety

Chapter 8 – Research Code

- ▶ The “Research Code” was enacted and codified as 17 Tohono O’odham Code Chapter 8 by Resolution No. 13-165 effective May 23, 2013
- ▶ October 2017, the first person was appointed to the Board
- ▶ May of 2021, 3 additional members were appointed with the 5th board position being filled in August of 2021
 - ▶ First Official IRB Meeting took place in May 2021

TON IRB Mission Statement

- ▶ *The mission of the Tohono O'odham Institutional Review Board (IRB) is to approve and oversee all research and systematic collection of data on the Tohono O'odham Nation and its members. The TONIRB assesses and evaluates the risks and benefits of proposed research to ensure that risks are minimized and are justified by the potential benefits of the research to the Tohono O'odham Nation and its members. The IRB is committed to respecting and protecting the Tohono O'odham Nation's values and sovereignty through culturally competent and customized research.*

“Research”

- ▶ The use of systematic methods to gather and analyze information for the purpose of proving or disproving a hypothesis, evaluating concepts or practices or otherwise adding to knowledge and insight in a particular discipline or field of knowledge or to demonstrate or investigate theories, techniques or practices.

“Research” includes but not limited to the following:

- 1) Basic and clinical research
- 2) Behavioral studies
- 3) Anthropological studies
- 4) Community based participatory research
- 5) Practice based research
- 6) Cultural or historical research
- 7) Feasibility and other studies designed to develop, test and evaluate basic data in all phases of environmental and public health. Changes in development, testing, or evaluation must be pre-approved by the Tohono O'odham Nation IRB
- 8) Research on plants, animals, water, land, air, or weather

Noteworthy

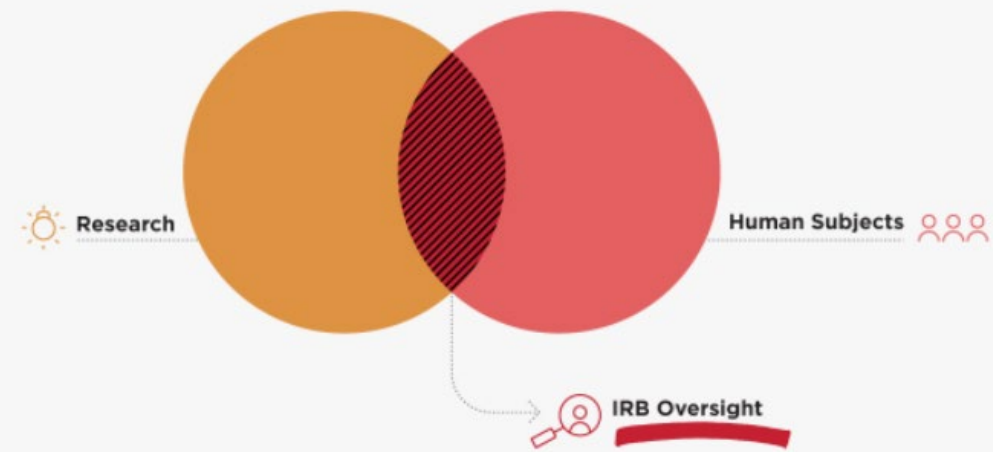
- ▶ This Chapter shall apply to all research conducted within the Nation, whether involving human subjects or not, and all research regarding materials wherever located as to which the Nation has a claim of intellectual, cultural, or other ownership.

Why is this Important to keep in mind?

Research (Mainstream Institutions)

- ▶ Generally associated with Universities
 - ▶ Professors – publication, public presentations
 - ▶ Graduate students – Thesis or Dissertation, public presentations
- ▶ There are two types of research
 - ▶ Research that does not need to be reviewed and approved – non-human subjects research
 - ▶ Research that must be reviewed and approved – human subjects research
 - ▶ Institutional Review Boards (IRB)

Our Purpose



When IRB approval is needed (Mainstream Institutions)

- ▶ Needed when research involves “Human Subjects”
- ▶ Collaborative Institutional Training – CITI Program
www.citiprogram.org
- ▶ Example of Trainings Provided:
 - ▶ Conflict of Interest
 - ▶ Humanities Responsible Conduct or Research
 - ▶ Native American Research
 - ▶ Social and Behavioral Responsible Conduct of Research

**The Trusted Standard in
Research, Ethics, Compliance,
and Safety Training**

When & Why did American Indian Nations start regulating research?

- ▶ Differing Worldview – Indigenous Ethics differ from mainstream/western ethics
 - ▶ University IRB's protect the Institution first
- ▶ What has changed since Havasupai Case?
 - ▶ Universities
 - ▶ Informed Consent
 - ▶ ABOR Tribal Consultation Policy - #1-118
 - ▶ American Indian Communities (Federally Recognized Tribes)
 - ▶ Tribes Asserting their inherent Sovereignty by instituting Tribal Research Law/Policies



Appointment. IRB members from the following fields shall be nominated by the Nation's chairperson and appointed by Legislative Council:

- 1) An individual with sufficient education and experience in the Nation's culture and traditions...
 - ▶ Lisa Palacios (21-116)
- 2) An individual with sufficient education and experience in health care...
 - ▶ Beth Michel (21-143)
- 3) An individual with sufficient education and experience in academics...
 - ▶ Naomi Tom (17-519)
- 4) An individual with sufficient education and experience in the field of elder care...
 - ▶ Susan Warmack (21-405)
- 5) A Nation's member over the age of eighteen.
 - ▶ Allison Ramirez (21-142)

How to apply for a research permit:

- ▶ Step 1: Prior to applying for a permit please review the Tohono O'odham Nation Research Code **Title 17 – Health and Safety, Chapter 8 – Research Code**
- ▶ Step 2: Complete a research proposal and submit to IRB@tonation-nsn.gov

It is vital that prior to reaching out to the IRB both the TON Research Code and Proposal Outline be thoroughly reviewed by the research team.

Report a research project or researcher(s):

If you are concerned about a research project or the conduct of a researcher please email the IRB at IRB@tonation-nsn.gov with a description of the activity or incident. If possible, please include location, date and time, and names of individuals involved.

TON IRB is a Resource

- ▶ We strive to be a resource to the TON Departments, Districts and Communities
- ▶ When reviewing a proposal, we will always look to see if it has District and/or Community support
 - ▶ If a researcher is claiming support from a District and/or Community, we will verify