

NIH Tribal Advisory Committee Meeting, Bethesda,
Maryland, September 14-15, 2017



NAVAJO NATION HUMAN RESEARCH REVIEW BOARD (IRB)

BEVERLY BECENTI-PIGMAN, CHAIRPERSON
DAVID BEGAY, PH.D., MEMBER

Research Policies and Procedures of the Navajo Nation Human Research Review Board (NNHRRB)



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NAVAJO NATION HUMAN RESEARCH

REVIEW BOARD MEMBERS

*(Navajo Nation IRB Federal Wide Assurance (FWA) # IRB00000641, I.H.S. #8) Expires 6/21/2021
For Protection of Human Subjects for Institutions. DHHS*

Beverly Becenti-Pigman, Chairperson

Dr. Raymond Reid, MD

Rebecca Izzo, MPH

Ursula Knoki-Wilson, MSN, MPH

Dr. David Begay, Ph.D.

Dr. Mark C. Bauer, Ph.D.

Wallace McGilbert

Dr. Calvin White, Ph.D.

Staff Member – Mike Winney, IRB Coordinator

MISSION STATEMENT

The mission of the Navajo Nation Research Program is to support research that promotes and enhances the interests and the visions of the Navajo people; to encourage a mutual and beneficial partnership between the Navajo people and Researchers; and to create an interface where difference cultures, lifestyles, disciplines, and ideologies can come together in a way that improves, promotes, and strengthens the health of the Navajo people.

History & Development of the Navajo Nation Human Research Review Board

- Navajo people possessed indigenous knowledge & science for years
- Most researchers are non-Indians

NNHRRB ASSETS / STRENGTHS

- ▣ NNHRRB meetings are held monthly and on a consistent basis. Dedicated group of skilled committee members.
- ▣ NNHRRB has National and International reputation as one of the strong tribal IRBs.
- ▣ Has established relationship with academic institutions such as Johns Hopkins, U of A, UNM, U of Utah, ASU, NAU, Diné College, NTU, etc.
- ▣ Hold bi-annual NNIRB Research Conference in Window Rock in order to share research findings with all.

Enabling Legislative

The Navajo Nation Human Research Review Board was developed in 1996 to guarantee ethical research for the Dine' People.

Purpose: The purpose of this Code shall be to set forth the conditions under which investigators, physicians, researcher and other may perform health and health related research activities within the territorial jurisdiction of the Navajo Nation;

Policy: It is the policy for the Navajo Nation to ensure that all persons within the territorial jurisdiction of the Navajo Nation are free from unreasonably harmful, intrusive ill-conceived or otherwise offensive research and investigation procedures.

- Navajo Nation Council 13.N.N.C. § 3253 Health and Welfare
- Chapter 25. Navajo Nation Human Research Code (section 3251 – 3271)
 1. October 25, 1995, CO-106-95
 2. April 16, 2002, CAP-16-02 (Revised)
- National I.H.S. IRB Navajo Nation Human Research Review Board (and Navajo Area I.H.S. IRB)
 1. Certification #IRB00000641

BELMONT REPORT

Ethical Principles and Guidelines for Research Involving Human Subjects



15 NNHRRB Members

- ▣ 3 persons appointed by the Navajo Area Health Board
- ▣ 3 persons appointed by the Office of the Navajo Nation President
- ▣ 3 persons appointed by the Navajo Nation Council Health and Social Services Committee
- ▣ 3 persons appointed by the Navajo Nation Council Education Committee
- ▣ 3 persons appointed by the Navajo Area Indian Health Services Director





TABLE H.1 Twelve-Phase Navajo Nation Human Research Review Board Review and Approval Processes

Phase	NN research protocol	Description of processes
Phase I	Community partnership	PI formalizes partnerships with NN chapters, boards, health and community organizations, securing resolutions supporting the study.
Phase II	Tribal program partnership	PI partners with tribal programs, providing them with a benefits analysis of the study, and secures a support letter—for example, from the program manager of the NN Division of Health.
Phase III	Screening of research application	PI submits NNHRRB application to NN Division of Health staff for review. Application is placed on NNHRRB agenda for the next meeting. The NNHRRB has a 2-week review period.

Phase IV	NNHRRB meeting and presentation	PI gives a 10-minute summary of study. After completion of inquiry, the NNHRRB meets in executive session to (1) approve, (2) request amendments, or (3) disapprove. If amendments are requested, PI can resubmit proposal for the next meeting.
Phase V	Study implementation	Within 30 days of research approval, PI will receive a 1-year, annually renewable, research permit. Quarterly and annual progress reports are required. NNHRRB vetting is requested prior to national and international presentations. This stipulation is in effect for 1 year after end of study.
Phase VI	Data analysis & preliminary findings	Upon completion of data collection, PI conducts preliminary data analysis and presents findings to NNHRRB.
Phase VII	Data work session	PI schedules a work session with partnering tribal programs, staff of the NN Division of Health, and others. A modified research report presented back to NNHRRB will include unique interpretations offered by NN partners and staff.

Phase VIII	Final report & submission for dissemination plan	PI compiles a final comprehensive report and submits all research products (materials, videos, photographs, and the like). Final report also includes a dissemination plan containing dates, times, and sites for NNHRRB approval.
Phase IX	Transfer of data to NN	PI and NNHRRB determine the NN program that will receive the data. PI then submits data to that program and trains program staff.
Phase X	Manuscript publications (optional)	PI as first author will submit a completed manuscript in an approved, publishable format. Upon its publication, PI submits three copies to the NN Division of Health.
Phase XI	Community feedback & presentations	PI will present research results to chapters, schools, health boards and facilities, tribal programs, and so forth, discussing the research findings and implications for practice.
Phase XII	Final transfer of data	All data are given to the NN Data Resource Center.

Data Sharing & Ownership

The Navajo Nation situation with data sharing and ownership of data

The Navajo Nation Research Code as major document for research and data ownership

Some underlying challenges ahead

Navajo Nation Human Research Review Board

Promote “*Expert Indians instead of Indian Experts*”

Quote from NNHRRB Chair, Ms. Beverly Pigman, (June 27, 2006)



Beverly Becenti-Pigman – Board Chair; Dr. Raymond Reid, MD, MPH; Rebecca Izzo-Manymules, MPH, PhD (c); Ursula Knoki-Wilson, MSN, MPH; Dr. David Begay, PhD; Dr. Mark Bauer, PhD; Wallace McGilbert; Dr. Calvin White PhD.