

Ya'at'eeh and Welcome



NAVAJO NATION HUMAN RESEARCH REVIEW BOARD PRESENTATION

HISTORY OF Navajo Nation Human Research Review Board

- 1979 Navajo Area Indian Health Service (NAIHS) Institutional Review Board (IRB) established;
- 1992-1993 Navajo Area Indian Health Service (NAIHS)/Navajo Nation Institutional Review Board established and operated;
- 10/1995: Navajo Nation Council enacted the Navajo Health Code (CO-106-95);
- 01/1996: Navajo Nation Health Research Review Board (NNHRRB) started reviewing proposals.

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

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.

“Indigenous people and researchers: building collaborative partnerships and the importance of responsibilities, ethics, and values of research on the Navajo Nation”

NAVAJO NATION HUMAN RESEARCH REVIEW BOARD MEMBERS:

- Dr. Rebecca Izzo-Manymules, Chairperson, NNC-HEHSC
- Dr. Sonya Shin, MD – IHS, *Medicine*
- Dr. Chirstopher Jentoft - *IHS*
- Dr. Paula Mora – *IHS*
- Dr. David Begay, Ph.D. – NNC-*HEHSC*
- Dr. Nanaabah Garrison – *OPVP*
- Del Yazzie, M.S.. - *OPVP*
- Dr. Paul Charlton – *IHS*
- Dr. Calvin White, Ph.D. – NNC-*HEHSC*

Board Composition Term of Appointments shall be Three (3) Years.

The Navajo Nation Human Research Review Board shall be composed of Fifteen (11) individuals, selected as follows:

- (3) persons appointed by the I.H.S. Navajo Area Director;
- (3) persons appointed by the Office of the President;
- (3) persons appointed by the Health and Human Services Committee;
- (3) persons appointed by the Navajo Area India Health Services Director;
- (3) persons appointed by the Health, Education, Human Services Committee;

Navajo Nation Governing Body

Office of Navajo Nation President and Vice-President

- Dr. Buu Nygren, President
- Richelle Montoya, Vice-President

Navajo Nation Council

- Crystalyne Curley, Speaker, 25th Navajo Nation Council

Health, Education and Human Services Committee

- Vince James, Committee Chairperson

Navajo Area Indian Health Services

- Dr. DuYane Begay, Director

Policy and Procedures

- Navajo Department of Health Plan of Operation
- Navajo Research Program Objectives
- Navajo Nation Human Research Review Board By-Laws
- Navajo Nation Human Research Review Board Plan of Operation is the Navajo Nation Research Code (enabling legislation)

Regulations and References

- The Navajo Nation Human Review Code (13 N.N.C.) Chapter 25
- CFR Title 45, Public Welfare, Part 46 Protection of Human Subjects
- National Research Act (P.L. 93-348)
- Civil Rights 1045
- Constitutions Law 255(5)
- Health 905
- Indians 32 (4.1)
- Westlaw Topic Nos. 78, 92, 198,H, 209
- C.J.S. Civil Rights §23
- C.J.S. constitutional Law §§1131 to 1138, 1253, 1263 to 1268
- C.J.S. Right to Die §2



**NAVAJO DIVISION OF HEALTH
Navajo Human Research Review Board
IRB Research Protocol Application**

GUIDELINES

1. The proposal must include **all** of the **necessary documents listed below in the order as listed in the Table of Contents before** it will be accepted for review:
 - 1a. Cover sheet of the IRB Research Protocol Application (NNHRRB-01)
 - 1b. Abstract
 - 1c. Part 1: Community Involvement
 - 1d. Part 2: Benefits to the Navajo Nation
 - 1e. Part 3: Research Project Description
 - 1f. Part 4: Informed Consent Form
 - 1g. Part 5: Certification by the Principal Investigator
 - 1h. Part 6: Attachments
 - Curriculum Vitae of Principal Investigator and Co-Principal Investigators.
 - Approving Resolutions from Agency Councils of the Navajo Nation.
 - Support Letters from CEO's of NAIHS Service Units and Navajo Nation Program Directors.
 - Copies of other approved IRB Letter(s).
 - Certificate of Confidentiality (if necessary).
 - OMB Clearance Document (if necessary).
 - A copy of the written letter to the Navajo Nation Historical Preservation Office (if applicable), and
 - Budget
2. Twelve (12) copies of the research proposal/evaluation must be submitted to the Navajo IRB Office **two months prior to the anticipated date of presentation**. The post office address and express package delivery address is:

**Attn: NAVAJO IRB Coordinator
Navajo Division of Health
P.O. Box 1390
Window Rock, Arizona 86515**
3. All research proposals/evaluation must be submitted in pre-punched 3-hole 8 1/2 x 11 white bonded paper clipped by large binder clips. Each proposal must follow a table of contents as outlined on this page. **Each page shall be numbered.**

Research Studies on Navajo Nation by Groups:

- Environmental;
- Medicine & Health;
- Behavioral & Mental Health;
- Education;
- Student Research

Some examples of approved studies on Navajo Nation:

- Diabetes (Type II, Prevention Programs, Obesity, Nutrition, Education, Youth Diabetes);
- Diseases (Respiratory, Cardiovascular Risk, Pneumococca, Celiac)
- Uranium (cancer, water, plants, animals, radon, Mining, Mine workers, unregulated drinking water, Health Impact);
- Cancer (Mining, Breast, Colorectal, Lungs, preventions, screenings, awareness, intervention);
- Navajo Language, Cultural (Understand Navajo Language, Cultural, People, Barriers & Support of Navajo Principals, Cultural Beliefs & Ritual Influence;
- Curriculum (Navajo full immersion, Indian Head Start Literacy, Listening to each other development, National Indian Education Study, Navajo Teacher Training Program, Impact of No Child Left Behind Act on NM and AZ Public Schools on Reservation, Indian Education in NM);
- Nutrition (Farming, Diabetes, Food for life, Cooking to Live, Edible School, Garden Program, Health & Horticulture Wellness, WIC, Food Distribution on Indian Reservation, Farm to Table Study);
- Environmental Health (Well Water, Investigation of Well Water, Environmental Health Project, Variable and changes);
- Efficacy (Efficacy Trial among Apache and Navajo Indian Infant of Haemonphilus Influenza Type B, Efficacy of Pneumococcal Conjugate Vaccine, Nasopharyngeal Carriage of Streptococcus pneumonia, Safety and Efficacy of Pentavalent (G1,G2, G3,G4,and P1) Human-Bovine Reasserting Rotavirus Vaccine, Double Blind, Controlled study of the Efficacy Immunogenicity, Safety, and Tolerability and Effectiveness of a Pneumococcal Conjugate Vaccine)

Contact Information

NNHRRB Website:

www.ndoh.org

Scroll down to NDOH Resources Link,
Navajo Nation Human Research Review Board.

You can download:

- NNHRRB application;
- Principal Investigator Guidelines;
- Reports Guidelines;
- Sample of Consent Form
- Meeting dates;
- upcoming meeting, conferences;

**Thank you for your time and have a
great day!**

Navajo Nation Human Research Review Board