

**Research Policies, Processes
and Protocol
Of
The Navajo Nation Human
Research Review Board
(NNHRRB)**

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Tribal research policies, processes and protocols are derived from the ethical principles and protections of law inherent in the rights and spirit of indigenous nations (UN, 2007). The Navajo Nation has exercised full sovereign rights and authority by developing research policies and protocols to protect all Navajo Nation residing human participants involved in research. The Navajo Nation Human Research Review Board's (NNHRRB) main responsibility is to review, approve, request modifications and/or disapprove human research involving Navajo people within the jurisdiction of the Navajo Nation.

History and Development of the Navajo Nation Human Research Review Board

Internationally and within the United States, Indigenous peoples have been subject to questionable intentions, processes and outcomes of western academic research. Historically, some research in Indian Country has been exploitive and unethical (Crazy Bull, 1997), has produced inaccurate and negative representations (Duran, 1996; Waldram, 2004), has denied Native people self-definition (Deloria, 1991) and has furthered the colonizing mission (Smith, 1999). Health research about Navajo people has been published as early as 1862 and like most research involving American Indians tribes and other indigenous peoples, the researchers were outsiders; non-Navajo. Even when culturally sensitive and high-quality research has been conducted on the Nation, it has seldom found its way back to the tribe in ways that help promote better services or healthy policies*

* For an example of how research creates academic careers versus Navajo benefits, see Jones, 2002 .

In 1974, Congress passed the National Research Act that created the Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1979 the "Belmont Report", the cornerstone of federal regulations regarding research, was published in the Federal Register (McGuire Dunn & Chadwick 2004). In response to the Belmont Report, the Indian Health Service (IHS) took action within the Navajo region and established an IRB committee to comply with the new federal 45 CFR part 46 DHHS regulations. However, it wasn't until 1992-93 that the IHS operationalized the NAIHS Human Research Review Board (HRRB). This board was comprised of IHS medical professionals, staff, Navajo representatives and community members. It was Navajo community members who recognized the need to transfer research review and approval power from NAIHS to the Navajo Nation, a federally recognized tribal government. In 1995 the Navajo Nation Council adopted a resolution CO-106-95, approving the Navajo Nation Health Research Code and created the Navajo Nation Human Research Review Board (NNHRRB). In January of 1996 the NNHRRB began reviewing research proposals on the Navajo nation.

After the Navajo Nation took control of the IRB, the board experienced an increase volume and a widening of the range of research proposals, manuscripts and abstracts regarding living human subjects submitted to the Board. Based on this upsurge of activity, the tribal government recognized the need to amend the Research Code to include all research conducted on tribal lands that involved any human life not just research involving IHS facilities. In 2002 the Navajo Nation Council amended the Research Code by resolution CAP-16-02 to expand

the authority of the NNHRRB to all review and approval all research that may involve humans. An explicit aim of the second Navajo research legislation was to ensure that research conducted within the Navajo Nation is beneficial to the tribe, community-based and consistent with Navajo Nation values, priorities and concerns.

Research Protocol Application Process

Any person proposing to conduct research on the Navajo Nation must submit a completed research protocol application to the HRRB Coordinator* The research Principal Investigator (PI) is responsible to submit materials at least two months prior to an in-person presentation to the Board.

In addition to the standard research protocol, the PI must submit at least two *approving resolutions* from *agency councils/Chapters* of the Navajo Nation or IHS Service Unit Health Boards; support letters from CEO's of NAIHS Service Units and Navajo Nation Program Directors that may be involved with the research; approved Letter(s) from any Navajo Nation office or agency involved with the research; Certificate of Confidentiality (if necessary); a copy of a letter to the Navajo Nation Historical Preservation Office (if applicable); and a detailed budget.

Navajo Nation Standards of Approval

The Navajo Nation standards of approval require explanation beyond the typical research protections. The following Navajo Nation standards must be

* Navajo IRB Coordinator, Navajo Division of Health, Window Rock Blvd., Admin, Bldg. #2, P.O. Box 1390, Window Rock, Arizona 86515

explained in detail and are required to move to the next phase of review processes.

Community Involvement: Researchers need to describe in detail how local chapters, relative Tribal programs, and community members will be active participants in the research.

Benefits to the Navajo Nation: Researchers need to describe in detail how the study will improve the health status of the Navajo People? The Navajo Nation as a collective whole?

Navajo Nation Authority: According to Research Code section 14, the researcher agrees to the civil jurisdiction of the NN with respect to all research to be undertaken and agrees to submit any publications arising from such research for HRRB approval.

Research Project Description: Researchers need to describe the rationale, aims, objectives, targeted participants, methods, study design, data gathering, data analysis and plans for reporting results. Any instrument that may be used is required to be attached to the application for review.

Informed Consent Form: Researchers must attach the informed consent procedure and form for review. Researchers are required to list their own institutions IRB office plus the NN HRRB office as contacts for questions and complaints and must contact the HRRB office to report all adverse events.

Certification by the Principal Investigator (PI)-Researchers need to certify their role and responsibilities as Principle Investigator to adhere to all standards set by

tribal law, policies, protocols and processes when doing research in the jurisdiction of the Navajo Nation.

The Navajo Nation research coordinator and Board members are available for technical assistance and guidance (as resources allow) through the application processes and beyond. Upon receipt of a complete research application, the research project is scheduled for presentation and review at a monthly HRRB meeting. Once approval is obtained, the PI or senior staff provides written and/or in person updates on the project at quarterly HRRB meetings. Once the research is completed, the PI and senior staff provides findings to the appropriate Navajo offices and programs. It is the intention of the HRRB that the greatest possible good is provided to Navajo Nation citizens before, during and after completion of the research.

Summary

The Navajo Nation Tribal Council has taken steps to protect and preserve Navajo people from harm in research by authorizing the NNHRRB to provide oversight and monitoring of all research conducted within the borders of the Navajo Nation. Since the operationalizing of the NNHRRB, a community member, and an enrolled member of the Navajo Nation has chaired and has guided the board through the review and approval processes.

The NNHRRB use a twelve-phase review and approval process for all research protocols involving human subjects. (See table 1)

The first three phases of the NN research process requires researchers to verify community involvement and tribal participation in the research and/or approval

process. In stage IV, research decisions are made and the subsequent 3 stages provide input and support for researchers to ensure the accuracy and relevancy their work to the target population and in many cases, to their respective professions. The final 4 dissemination stages guarantee that the Nation, through the most relevant offices and programs, will be adequately apprised of the research outcomes and findings. The final stage ensures that the Navajo Nation will take possession of its own data.

This process may seem arduous to some who have not previously worked with the Navajo Nation. Those who have may attest that these stages are intended to provide the maximum benefit to the Navajo Nation, the researchers and to the process and outcomes of applied science more generally. The HRRB welcomes culturally competent and high quality research partners in the process to promote wellness and improve the health of Navajo, Native and all peoples of the world.

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Table 1: Twelve Phase Navajo Nation Human Research Review Board Review and Approval Processes

Phase	NN Research Protocol	Description of Processes
Phase I	Community Partnership Phase	*PI needs to attain formalize partnerships by attaining resolutions supporting the study. For example, Navajo Nation Chapters, relative boards, health facilities, tribal offices, community organizations, etc...
Phase II	Tribal Program Partnership Phase	PI partners with one or two tribal program, providing the program with benefits from the preliminary and final analysis of the study, and attains a support letter. For example, program manager and the division director of the Division of Health or Education.
Phase III	Screening of Research Application Phase	PI submits NNHRRB application to NN Division of Health staff to review the contents for completion. When the application is deemed complete, it will be placed on the NNHRRB agenda for the next meeting. The NNHRRB shall have two-week review period.
Phase IV	NNHRRB Meeting and Presentation Phase	PI will be allotted ten minutes to provide a summary of proposed study. After NNHRRB has completed its inquiry, the board will exit in executive session for one of three decisions. Approval/Request for Amendments/Disapproval (if amendments are requested, the PI can readjust proposal and present at the next meeting.
Phase V	Study Implementation Phase	PI given verbal approval will receive a research permit (annual permit) one month after. PI can proceed once the permit is in place and must comply with all the standards and conditions outlined. Quarterly and annual progress reports are required; abstracts for presentations need NNHRRB approval, and the NNHRRB request all presentations be presented locally prior to the request for national/international presentations. This stipulation is in effect up to one year after end of study.
Phase VI	Data Analysis & Preliminary Findings Phase	PI shall conduct data analysis and present any preliminary findings to NNHRRB.
Phase VII	Data Work Session Phase	PI will then schedule a work session with partnering tribal programs and other interested individuals including assigned staff of the NN Division Of Health. The modified/amended data report presented back to NNHRRB will include the unique interpretations offered by NN partners and staff.
Phase VIII	Final Report & Submission for Dissemination Plan Phase	PI must be present and compile a final comprehensive report and submits all research products (materials, videos, photographs, etc.). Final report also includes a dissemination plan containing dates, times and sites for NNHRRB approval.
Phase IX	Transfer of Data to NN Phase	PI and NNHRRB determine the name of the NN Program that will receive the data, the PI then submits data to that program.
Phase X	Manuscript Publications Phase (Optional)	PI as the first author will submit a completed manuscript in an approved publishable format. Upon publication the PI is requested to submit three copies to the NN Division of Health, one copy filed, one copy to partnering NN program and one for the NN Data resource Center.
Phase XI	Community Feedback & Presentations Phase	PI utilizing the dissemination plan shall provide presentations to the relevant chapters, schools, health boards, health facilities, tribal divisions and tribal programs, etc., regarding the data findings to include all officials and programs that provided initial support and approval.
Phase XII	Final Transfer of Data	All Data given to the Navajo Nation or the NNHRRB shall be given to the NN Data Resource Center.