



**NAVAJO NATION DEPARTMENT OF HEALTH
Navajo Human Research Review Board (NNHRRB)
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 Research Protocol Application
 - 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 Navajo Nation Agency Councils and/or Chapters and/or School Boards as appropriate.
 - Letters of Acknowledgement from CEO's of Navajo Area Indian Health Service Units; Navajo Nation 638 Hospitals; and Navajo Nation Program Directors as appropriate.
 - Copies of other approved Institution Review Board (IRB) Letter(s) as appropriate.
 - 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. Ten (10) copies of the research proposal/evaluation must be submitted to the Navajo Nation Human Research Review Board (NNHRRB) Office **one months prior to the anticipated date of presentation.** One digital copy of the proposal can be email to the following address: mrwinney@navajo-nsn.gov. The post office address and express package delivery address is:

**Attn: NNHRRB Coordinator
Navajo Department of Health
Window Rock Blvd., Admin. Bld. #2
P.O. Box 1390
Window Rock, Arizona 86515**

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3. All research proposals must be submitted with a table of contents as outlined on this page. Each page shall be numbered.
4. For particularly sensitive projects/ subject matter or if experimental drugs/ devices are to be used in the project, the proposal may be referred to an outside reviewer before the Navajo Nation Human Research Review Board reviews it.
5. The approval of the study is for research conducted within the territorial jurisdiction of the Navajo Nation. Additional approval shall be required from the San Juan Southern Paiute tribe and the Hopi Tribe.
6. A Navajo NNHRRB meeting schedule will be sent with the NNHRRB application.

PRINCIPAL INVESTIGATOR ROLE

The Principal Investigator must provide written responses to all of the following questions on the NNHRRB application. If an item does not apply to your particular proposal, provide a statement as to the reason(s).

1. A one-page **abstract** written in a simple clear language describing your proposed research or evaluation may be submitted to the Navajo Nation Human Research Review Board Office by email prior to the full application submission. The email address is mrwinney@navajo-nsn.gov.
2. A **curriculum vitae** or **resume** for the principal investigator and co-principal investigators must be submitted as documentation to support the qualifications of the project staff to successfully conduct the proposed research.
3. An **Agency Council Supporting Resolution** within the agency of the research site must be obtained before the NNHRRB review process can proceed. Or a single Chapter resolution can be submitted only if the research is conducted within the boundaries of the said Chapter. You may call the Navajo Division of Community Development at (928) 871-6442/7182 to obtain a listing of meetings scheduled for the Agency Council across the Navajo Nation.
4. A **support letter** from the CEO of the facilities where the research will take place must be obtained and included in your research proposal before the NNHRRB review process can proceed.
 - If your research is going to be conducted at an IHS facility, a support letter from the CEO and a Health board resolution from the service unit must be obtained before the NNHRRB review process can proceed.

- If your research is going to be conducted in a 638 hospital facility, a letter from the CEO and Board resolution is required before the NNHRRB review process can proceed.
 - If your research is going to be conducted at a school, a school board resolution from the school board must be obtained before NNHRRB review process can proceed.
5. A copy of the **approval letter** from other Institutional Review Boards that have approved the study must be attached to your NNHRRB application.
 6. The Navajo Nation Human Research Review Board requests that the principal investigator(s) apply for the **Certificate of Confidentiality** from the Federal Agency to ensure maximum protection for their study participants regarding their privacy.
 7. If any investigator is a federal employee or is conducting research under a contract or cooperative agreement and 10 or more people will be surveyed and/ or given a questionnaire, **clearance** from the Office of Management and Budget (OMB) is required for research survey activities if necessary.
 8. A copy of a written **statement** to the Navajo Area IHS Director and the Navajo Area Office, Privacy Act Coordinator attesting to the understanding of and willingness by the Principal Investigator to abide by the provisions of the Privacy Act must be attached. The NAIHS Area Director's address is:

Address: Navajo Area IHS
P.O. Box 9020
Window Rock, Arizona 86515

Phone: (928) 871-5811
 9. A copy of a written statement to the CEO of 638 Hospital on the Navajo Nation attesting to the understanding of and willingness by the Principal Investigator to abide by the provisions of the Privacy Act must be attached. The contact telephone numbers for CEO for 638 Hospitals are listed below:
 - **Fort Defiance Indian Hospital Board, P.O. Box 649, Ft. Defiance, AZ 86504, Tel: 928-729-8000;**
 - **Sage Memorial Hospital, P.O. Box 457, Ganado, AZ 86505, Tel: 928-755-4500**
 - **Tuba City Regional Health Care Corp., P.O. Box 600, Tuba City AZ 86045, Tel: 866-976-5941;**
 - **Utah Navajo Health System, P.O. Box 130, Montezuma Creek, UT 84534, Tel: 435-651-3766**
 - **Winslow Indian Health Care Center, 500 N. Indiana Ave., Winslow, AZ 86047, Tel: 928-289-4646**
 10. A copy of the **budget** for your research project must be attached to the NNHRRB application.

11. If your research involves collection of historic information, use of ethnographic methods to collect data (focus groups), interviewed audio or video recordings, etc., you must contact the Navajo Nation Historic Preservation Office to secure a research permit.

Address: Navajo Historic Preservation Department
P. O. Box 4950
Window Rock, AZ 86515
Phone: (928) 871-7198/7153, Fax: (928) 871-7886
Website: www.hpd.navajo-nsn.gov

12. The Principal Investigator shall ensure that all contents of the NNHRRB application are submitted prior to requesting placement on the agenda.



NAVAJO DEPARTMENT OF HEALTH
Navajo Nation Human Research Program
Research Protocol Application
(THIS COVER SHEET MUST BE SUBMITTED WITH YOUR PROTOCOL)

Date: _____

Protocol Title: _____

Name of Principal Investigator: _____

Title/ Affiliation of the PI: _____

Name(s) of the Co-Principal Investigators: _____

Address: _____

City _____ State: _____ Zip Code: _____

Phone: _____

Fax: _____

E-mail: _____

Official Navajo IRB Use ONLY

Application Received: ____ / ____ / ____

1st qtr: ____ / ____ / ____

NNHRRB Approval Date: ____ / ____ / ____

2nd qtr: ____ / ____ / ____

Proposal ID#: NNR-____ - ____

3rd qtr: ____ / ____ / ____

4th qtr: ____ / ____ / ____



NAVAJO DEPARTMENT OF HEALTH
Navajo Nation Human Research Program
IRB Research Protocol Application

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PART ONE: COMMUNITY INVOLVEMENT

1. Indicate all the locations where your project will be conducted.
2. Describe how the community members have been involved in the planning of your research project.
3. Describe how the community members will be involved in the implementation of your research/ project.
4. Describe how you plan to provide findings of the study to health care providers, community agencies, schools, chapters, or other interested persons.
5. Briefly explain how you plan to provide technical assistance to the community (writing grants, conducting in-service training sessions, developing educational materials, assisting with the annual community research conference and/ or donation of equipment).

PART TWO: BENEFITS TO THE NAVAJO NATION

6. Explain specifically how the results of your study will be used to improve the health status of the Navajo People.
7. Has this research been conducted elsewhere? If so, explain what the results were.
8. Has the study been conducted on the Navajo reservation? If so, explain what the results were.
9. Has this study been coordinated with similar studies currently being conducted? If so, explain what plans will be made to ensure that necessary coordination occurs and duplication is eliminated.

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PART THREE: RESEARCH PROJECT DESCRIPTION

10. Describe the background and rationale for your research or evaluation project.
11. State the aims, objectives, and/or hypothesis of your proposed research or evaluation project.
12. Describe the targeted participants who will be recruited for your project.
13. Explain the procedures to be used for the participant recruitment, the selection criteria, and the exclusion criteria.
14. Explain the nature and procedures, if any, to be used for incentives for participation.
15. Describe the methods and the procedures for the study design, sampling, data gathering, data analysis, and plans for reporting the study results.
16. Describe the type and content of instrument (s) to be used for data collection. Copies of all instrument(s) to be used must be attached to your IRB application.

PART FOUR: INFORMED CONSENT FORM

17. A copy of the Informed Consent Form must be attached to your IRB application that fully describes procedures to be used for Informed Consent to protect study participants from injury or harm or breach of confidentiality.
 - a. Disclose the purpose of the research;
 - b. State the expected duration of the subject's participation;
 - c. Describe the procedures to be followed, including the collection and testing of specimen, any reasonably foreseeable risks or discomforts to the participants;
 - a. Describe the collection of any specimens (blood/tissue/hair/bodily fluids) What test(s) you will do;
 - b. How long you will keep the specimens;
 - c. How you will dispose of the specimens collected;
 - d. How you will maintain anonymity of the specimen collected, and;
 - e. Any other data that will be linked to each specimen collected in your research.

- d. Name any benefits from the research to the participants or others;
- e. Describe the extent to which confidentiality of records identifying the participant will be protected;
- f. Identify an individual to contact for answers to questions about the research and research participant's rights. The contact person for the Navajo Research Office is **Dr. Rebecca Izzo-Manymules, Board Chair, Navajo IRB Office. Navajo Department of Health, P. O. Box 1390, Window Rock, AZ 86515. Telephone number is (928) 871-6929. Fax number is (928) 871-6255.**
- g. Identify a person to contact in the event of a research related injury to the participant, and;
- h. Reiterate that participation in the research/evaluation is voluntary, and shall not interfere with services available to the rest of the population.
- i. Explain any potential physical risks, psychological risks or discomforts to participants that may be associated with or that may result from participation in your research project.

PART FIVE: CERTIFICATION

I, _____, certify that I am the Principal Investigator or Co-Principal Investigator, of this proposed study or evaluation and that the statements made in this application are accurate and complete.

I understand that all data collected as a result of this research study/evaluation is property of the Navajo Nation.

If I receive NNHRRB approval for this project, I agree to inform the Navajo Nation Institutional Review Board office in writing of any adverse events immediately as they occur.

If I receive NNHRRB approval for this project, I agree to submit in writing any proposed procedural changes as amendments. I will be available in person to present the modifications.

I agree not to proceed in the research until the problems have been resolved or the Navajo Nation Human Research Review Board has reviewed and approved the changes.

I agree to comply with all the requirements of the NNHRRB regarding the conduct of the approved research.

I agree to submit four Quarterly Reports and one Annual Report on research activity progress.

If the results of the research are to be used for an a presentation at a conference, I agree to submit a copy of the abstract and/or a power point presentation prior to submitting my abstract to the conference sponsors for approval. I agree to provide a presentation to the NNHRRB prior to presenting at a national or international conference.

If I receive approval for this project and my study will extend beyond the annual approval period, I understand that I will have to submit a written request for continuation **thirty (30) days prior to the expiration of the annual permit.**

I also agree to submit a final copy of a proposed manuscript for review and approval by the NNHRRB prior to publication. I will disclose the name of the journal/publication; name of the editor; address and telephone number and the anticipated date of the publication.

Principal Investigator: _____ **Date:** _____