NAVAJO DEPARTMENT 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. Ten (10) copies of the research proposal/evaluation must be submitted to the Navajo IRB Office **one months prior to the anticipated date of presentation**. The post office address and express package delivery address is:

Attn: NAVAJO IRB Coordinator
Navajo Department of Health
P.O. Box 1390
Window Rock, Arizona 86515

3. All research proposals/evaluation must be submitted in a 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.

4. For particularly sensitive projects/ subject matter or if experimental drugs/ devices are to be used in the project, the proposal will be referred to an outside reviewer before the Navajo Nation Human Research Review Board reviews it.

5. The approval of the study is only for members of the Navajo Nation. Additional approval shall be required from the San Juan Southern Paiute tribe and the Hopi Tribe.

6. A Navajo IRB meeting schedule will be sent with the Navajo IRB application.

PRINCIPAL INVESTIGATOR ROLE

The Principal Investigator must provide written responses to all of the following questions on the IRB 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 must be submitted to the Navajo Institutional Review Board Office by email. The address is mrwinney@navajo-nsn.gov. A copy may also be submitted by fax at (928) 871-6255 before proceeding with the Navajo IRB application.

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 IRB review process can proceed. You may call the Navajo Division of Community Development at (928) 871-6442 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 IRB 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 IRB review process can proceed.

    - If your research is going to be conducted at a school, a support letter from the school principal/superintendent and a school board resolution from the school board must be obtained before IRB review process can proceed.

5. A copy of the **approval letter** from other Institutional Review Boards that have approved the study or evaluation must be attached to your IRB application.

6. The Navajo Nation Human Research Review Board requests that the principal investigator(s) apply for the **Certificate of Confidentiality** from the Indian Health Service 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. Please contact Christina Rouleau, Coordinator for **OMB** clearance process for the Indian Health Service in Rockville, MD, at telephone number (301) 443-5938 for information on clearance procedures. The fax number is (301) 443-2316.

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 the **budget** for your research project must be attached to the IRB application.

10. 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) 871-7880/7147, Fax: (928) 871-7886
    Website: www.hpd.navajo.org

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

NAVAJO DEPARTMENT OF HEALTH
Navajo Nation Human Research Program
IRB 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: ____ / ____/ ____ Progress Report Received:

NNHRRB Approval Date: ____ /____/____ 1st qtr: ____/____/____

Proposal ID#: NNR-_____ - _____ 2nd qtr: ____/____/____

IHS IRB Action Letter: ____/____/____ 3rd qtr: ____/____/____

Continuation Request: ____/____/____ 4th qtr: ____/____/____

Research Final Report: ____/____/____ Annual Report: ____/____/____

NNHRRB-01
10/28/02

TABLE OF CONTENTS

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/evaluation project.

3. Describe how the community members will be involved in the implementation of your research/evaluation project.

4. Describe how you plan to provide findings of the study/evaluation 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.

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;

d. Describe the collection of any specimens (blood/tissue/hair/bodily fluids)

    a. 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.

e. Name any benefits from the research to the participants or others;

f. Describe the extent to which confidentiality of records identifying the participant will be protected;

g. Identify an individual to contact for answers to questions about the research and research participant's rights. The contact person for the Navajo IRB Office is **Dr. Sonya Shin, MD, Board Pro-Temp Chair, Navajo IRB Office. Navajo Department of Health, PO. Box 1390, Window Rock, AZ 86515. Telephone number is (928) 871-6929. Fax number is (928) 871-6255.**

h. Identify a person to contact in the event of a research related injury to the participant, and;

i. Reiterate that participation in the research/evaluation is voluntary, and shall not interfere with services available to the rest of the population.

j. 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 there is no expedited review of the study.

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

If I receive Navajo IRB 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 Navajo IRB 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 Navajo IRB regarding the conduct of the approved research.

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

If the results of the research are to be used for an oral presentation at a conference, I agree to submit a copy of the abstract and a power point presentation prior to submitting my abstract to the conference sponsors for approval. I agree to provide a presentation to the Navajo Nation 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 **sixty (60) 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 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**: _____

NNHRRB-02; 10/28/02