NAVAJO NATION HUMAN RESEARCH REVIEW BOARD
Procedural Guidelines for Principal Investigators

PRE-APPLICATION ACTIVITIES

The Navajo Nation Human Research Review Board (NNHRRB) is authorized to use a twelve-phase review and approval process for all research protocols involving human subjects.

The twelve phases are:

Phase I:	Community Partnership
Phase II:	Tribal Program Partnership
Phase III:	Screening of Research Application
Phase IV:	NNHRRB Meeting Presentation
Phase V:	Study Implementation
Phase VI:	Data Findings
Phase VII:	Data Work Session
Phase VIII:	Final Report and Dissemination Plan
Phase IX:	Transfer of Data
Phase X:	Manuscript Publication
Phase XI:	Community Feedback/Presentation
Phase XII:	Transfer of Data to the Navajo Data Resource Center

LETTER OF INTENT

Any person interested in conducting human subject research shall inform the Navajo Nation Human Research Review Board of his/her intent by submitting a one page typewritten Letter of Intent to conduct research on the Navajo Nation by sending the letter to the following address:

Navajo Nation Human Research Review Board
Navajo Department of Health
P. O. Box 1390
Window Rock, Arizona 86515
Telephone Number: (928) 871-6929
Fax Number: (928) 871-6255

Upon receipt of The Letter of Intent by the Navajo Department of Health, the Navajo Nation shall be placed on notice that an individual desires to submit a Navajo Nation Human Research Review Board application. Upon receipt of the Letter of Intent, the staff assigned to the Navajo Nation Human Research Review Board shall immediately send out by electronic mail the NNNHRRB Research Application and hard copies by regular mail serve the following attachments:

1. Navajo Nation Human Research Code
2. Navajo Nation Privacy and Access to Information Act
3. Schedule of NNHRRB Meetings and Deadline for Submission of Materials

The Letter of Intent shall initiate a pending file within the record keeping system established in the Navajo Division of Health. The individual submitting the Letter of Intent shall be designated and referred to as the Principal Investigator or PI. The Principal Investigator is responsible for the overall implementation of the study.

ABSTRACT

The PI shall also submit a one or two page abstract with the following information:

1. The name of the proposed study,
2. A general description of the study population,
3. The geographical area where data will be collected,
4. The number of the subjects to be recruited for the study,
5. The gender of the subjects to be recruited for the study,
6. The proposed benefits to the subjects,
7. The proposed benefits to the Navajo Nation,
8. The proposed personal benefits to the Principal Investigator.
9. The proposed time period for the study to complete the twelve-phase process.

Upon receipt of the abstract, the Navajo Department of Health staff shall electronically send a copy of the Letter of Intent and Abstract to the Program Manager of the Navajo Historic Preservation Department of the Navajo Division of Natural Resources. The PI will be referred to the following address to obtain a permit, if necessary:

Navajo Historic Preservation Department
P. O. Box 4950
Window Rock, Arizona 86515
Telephone Number: (928) 871-7198/7153 Fax: (928) 871-7886

TECHNICAL ASSISTANCE

The assigned staff of the Navajo Department of Health shall provide telephone or office visit consultation to Principal Investigators in completing the NNHRRB Application.

Upon completion of the NNHRRB Application, one original and Ten (10) copies shall be submitted to the Navajo Department of Health where it will be reviewed by assigned staff. There are Nine (9) NNHRRB members and one staff reviewer. The original application is filed with the pending file and will not receive an assigned number until it has been approved by the NNHRRB.

If it is deemed complete, then it will be scheduled for the next regularly scheduled NNHRRB meeting. A copy of the proposed agenda shall be sent to the Principal Investigator confirming his presentation.

DESCRIPTION OF PHASES OF THE NNHRRB REVIEW AND APPROVAL PROCESS

The following section will describe the activities conducted during each phase of the twelve (12) phase review and approval process of the NNHRRB.

Phase I is known as the Community Partnership phase.
Depending upon where the Principal Investigator intends to conduct his study, the Principal Investigator will meet with the local community Navajo Nation chapters, school administrators, school boards, health facilities administrators, health advisory boards to obtain approving resolutions supporting the study.

Phase II is known as the Tribal Program Partnership phase.
This phase requires the Principal Investigator to engage one or two program administrators and the Division Director to obtain a letter of support for the study. The PI informs the administrators that the program shall receive the benefits of the preliminary and final analysis of the data collected. The Final Report containing the data shall be provided to the tribal program.

Phase III is the Screening of Research Application.
This phase includes the staff assigned by the Navajo Department of Health to review the contents of the NNHRRB Application submitted by the Principal Investigator. The staff shall notify the PI in writing by electronic mail the status of the application. Incomplete applications shall be placed in the pending status until all of the items required in the NNHRRB Application have been submitted. When an application is deemed complete, it will be placed on the agenda of the next regularly scheduled NNHRRB meeting. The NNHRRB shall have two-week review period prior to the meeting.

A copy of the agenda shall be sent to the PI by electronic mail. At the request of the PI, an agenda can be faxed. The agenda shall follow the format given below:

a. Continuation Request
b. Proposed Amendments to Protocols
c. Returning Presentations
d. Adverse Events
e. New Presentations
f. Manuscripts
g. Conference Abstracts

Phase IV is the NNHRRB Meeting Presentation.
All meetings are held in a selected location. All meetings of the NNHRRB begin at 9:00 a.m. and conclude at 5:00 p.m. The Board has working lunch business meetings and will temporarily adjourn to conduct any board business at that time. All presenters shall be excused. The Board will return to its regular meeting after l:00 p.m. to continue with its agenda.

Each Principal Investigator shall be allotted ten minutes to provide a summary of the highlights of the proposed study. Questions shall be posed by the NNHRRB and when it has completed its inquiry, the Board shall enter an executive session wherein the NNHRRB will deliberate and reach a decision. The Board will exit the executive session and return to the regular session of the meeting. The Principal Investigator shall return to the meeting and given the decision.

If the Board needs further documentation, materials and determines that the study shall need to be sent to an expert for further consultation, the Principal Investigator shall be informed to return to the next regularly scheduled meeting to receive the decision from both the consultant and the Board. This is called a "returning presentation". During the interim, the Principal Investigator shall be required to submit any other materials that the NNHRRB has requested.

Phase V is the Study Implementation.
Once a Principal Investigator has been given verbal approval, the PI must wait for one month to receive his/her Research Permit. The Permit is valid for one year and will expire on the date given in the letter of approval. The staff assigned by the Navajo Department of Health are responsible for composing the contents of the letter of approval with standard conditions and sending it to the Principal Investigator by fax and hard copy. The PI is expected to adhere to his proposed timeline provided in the study. The PI is required to reference the assigned research

number for all inquires whether by phone or letter. The PI can proceed with his study once he receives the Research Permit. The PI is required to adhere and comply with all of the standard conditions outlined in the Research Permit. Additional Specific Conditions may also be included in the Research Permit. Progress reports are submitted quarterly with one Annual Report per study year until all of the data has been collected.

Phase V is completed when the PI has finished his data collection activities as described in his/her timeline.

During this phase, the NNHRRB will receive proposed amendments and act upon them with the PI present.

If the study needs to continue beyond the approved time period, the PI shall submit a written letter sixty days in advance of the expiration by requesting for a continuation of his study. The Board will act upon this request with the PI present.

The PI may submit an abstract to NNHRRB for approval to present at a conference on his/her approved study. The NNHRRB recommends that conference abstracts be submitted only after one year of study has elapsed and that the same information has been presented locally prior to the request for a national or international presentation.

Phase VI is the Data Analysis and Preliminary Findings Phase.
The PI shall conduct data analysis and present any preliminary findings to the NNHRRB.
During this phase, the Principal Investigator shall analyze the data and develop the preliminary findings into a presentation and provide the same to the NNHRRB during its regularly scheduled meeting.

Phase VII is the Data Work Session.
This data set is presented to the NNHRRB and a work session is scheduled with the partnering tribal program and other interested individuals including assigned staff of the Navajo Department of Health. The PI then reports back to the NNHRRB about the comments and results of the work session. The data report can then be amended or modified to include the unique interpretations offered by the program staff.

Phase VIII is the Final Report and Submission of the Dissemination Plan.
The Principal Investigator compiles a comprehensive report known as the Final Report and submits all of the products (materials, videos, photographs, etc.) to the NNHRRB. A Dissemination Plan containing dates, times and sites of where the Principal Investigator shall provide final feedback regarding the results/outcome of the study will be submitted to the NNHRRB. The Board will approve the Final Report and Dissemination Plan with the PI present.

Phase IX is known as the Transfer of Data to the Navajo Nation.
The PI and the NNHRRB determine the position and name of the Navajo Nation Program that will receive the data. The PI then submits the data to the program.

Phase X is known as the Manuscript Publication.
This phase is optional. If the PI determines that he/she will develop the data into a proposed manuscript for publication, the PI as the first author will submit a completed manuscript in an approved publishable format. The PI/Author shall submit one original and sixteen copies of their proposed manuscript to the following address:

Navajo Nation Human Research Review Board
Navajo Department of Health
P. O. Box 1390
Window Rock, AZ 86515

The assigned staff shall distribute the manuscripts to the NNHRRB with a cover sheet for comments and vote. The Cover Vote/Comment Sheet shall be returned to the assigned staff and tallied for voting purposes. All comments shall be forwarded to the PI to include in his revision of the manuscript. Upon revised manuscript submittal, the Board shall render a final vote. A vote of five (5) approvals not including the chair shall determine a quorum vote and a letter of approval shall be sent to the PI/author. A period of one month is given to the Board members to review proposed manuscripts. Upon approval by the Board, the PI/Author shall receive an approval letter with conditions.

Upon publication, the PI is requested to submit three copies of the publication to the Navajo Department of Health. One copy is filed, another is given to the partnering program and the other is reserved for the Navajo Nation Data Resource Center.

Phase XI: Community Feedback and Presentation.
Utilizing the Dissemination Plan, the PI shall provide presentations to the chapters, schools, health boards, health facilities, tribal divisions and tribal programs regarding the data findings. Findings shall be presented to all officials and programs that provided initial support and approval.

Phase XII: Transfer of Data to the Navajo Nation Data Resource Center.
Any data given to the Navajo Nation or the NNHRRB shall be given to the Navajo Nation Data Resource Center.