Meeting Minutes
Institutional Review Board, Dinè College

Friday, 10/14/2022, 9:00 a.m.

1. In attendance
    - IRB members: C. Ami, M. Bauer, R. Benally, H. Cody, S. Hakim, S. Russ
2. Approval of minutes from 8/19/2022 meeting and 9/16/2022 meeting (attached)
    - 8/19/2022: Motion to approve: S. Hakim. Seconded by C. Ami; Approved unanimously
    - 9/16/2022: Motion to approve: C. Ami, Seconded by S. Hakim; Approved unanimously
3. Old Business
    - Reports: No concluding reports
    - CITI training certificates needed from R. Benally, T. Bennett, F. Morgan, J. Tutt
4. New Business:
    - Seek approval of first batch of revised Forms: IRB forms, available at this link
        i. Flowchart and SoftDocs: (Input sought; S. Russ):
            - Suggestions: Include a separate trajectory for animal models
            - Question whether extra form needed for DC students
        ii. IRB Request for Review
            - Section III:; Clarify where stored and who is in charge
            - Section IV: Eliminate detailed section in Inclusion criteria and change to a simply text box. Add example for screening question
            - Section V. Do we need special ethnographic approval? We could defer to NAU, but timeline is a concern. NN Historic Preservation Department. Do we want to handle this in-house at student level? Faculty already have to go through NN IRB, and it may be too much for students. To learn how to research, this will be an impediment. We will not add a requirement, but will handle in house.
        iii. Exempt guidelines:
            - Examination of typical exempt categories
            - Concern that NNRRB does not have an exempt category; anything involving Navajo people must be approved, even classroom materials. More discussion needed.
        iv. Continuation forms: Not addressed.
        v. Report Submission Form: Not addressed
    - Request continued time for development of the following:
        i. Supplementary Forms
        ii. Biosciences forms: To be prepared for subsequent meeting.
5. Other: Next Meeting: 10/28/2022 at 9:00 a.m..
6. Adjournment: C Ami moved to adjourn. Seconded by M. Bauer. Adjourned at 10:08 a.m.

Respectfully submitted by S. Russ, Chair

Diné College

INSTITUTIONAL REVIEW BOARD (IRB)
Proposal for Sociocultural Research
(revised October 2022)

Instructions: To comply with federal regulations and conform with Dinè College IRB guidelines, any research involving collection of data from human subjects must be approved by the IRB at Dinè College. Please take the following steps:

1. Determine whether you are seeking Exempt Status, Expedited Review, or Full Review (link to information).
2. Prepare the following materials
    a. Information needed to submit your proposal
    b. Any required supplementary forms
    c. Summary of Research Plan
    d. Informed Consent Documents
    e. Research Instruments, including any questionnaires, surveys, interview materials, etc.
    f. CITI training certificates for each member of the research team
3. Submit all forms at the link (TBD)

I. GENERAL INFORMATION

A. Project Title:

B. Brief Description: Write 1 or 2 sentences describing your project.

C. Principal Investigator (PI):

The principal investigator is:

☐ Dinè College Student. If student, name faculty mentor:

☐ Dinè College Faculty*[1]. Department: Program

☐ Other. If other, please describe role:

D. Timing: Proposed Start Date: _____ End date: _____

E. Location of Data Collection:
Physical Location (Complete if in-person data are to be collected, or write N/A):

Virtual Source (Use if data will be collected online (e.g., mTurk, Facebook, Email, etc.), or write N/A):

[1] All research in which a Faculty/Staff member is the PI must be submitted for review and approval by the Navajo Nation Human Research Review Board (NNHRRB) after DC IRB approval is received.

F. CONTACT INFORMATION

Principal Investigator (PI)

Name: _____ Institution: _____

Institution Location: _____

Email: _____ Phone: _____

CITI training certificate expiration date[2]: _____

DC Faculty Mentor (if student PI) or Co-Investigator

Name: _____ Institution: _____

Role: ____ Faculty Mentor ____ Co-investigator ____ Other (*Describe:* _____)

Email: _____ Phone: _____

CITI training certificate expiration date[2]: _____

Research Assistants or Collaborators

Name: _____ CITI training certificate expiration date[2]: _____

Name: _____ CITI training certificate expiration date[2]: _____

Name: _____ CITI training certificate expiration date[2]: _____

Name: _____ CITI training certificate expiration date[2]: _____

Name: _____ CITI training certificate expiration date[2]: _____

Name: _____ CITI training certificate expiration date[2]: _____

II. FUNDING INFORMATION

Does this protocol receive external funding? ____ No ____ Yes *If yes, please complete the following:*

A. Source of Funding _____

B. Project Title (if different from above): _____

C. Principal Investigator (if different from above): _____

D. Type of Application: ____ Grant ____ Subcontract ____ Contract ____ Fellowship

E. Date of Funding Submission: _____

F. Potential conflict of interest: Describe any potential conflict of interest based on funding, such as a situation in which the funding agency has a vested interest in a particular outcome. If the funding agency has no vested interest, please state this directly.

[2] Please attach CITI training certificates for each member of the research team

III. COOPERATIVE RESEARCH

Cooperative research projects are those that involve more than one institution and can be designed to be both multi-site and multi-protocol in nature. Each participating institution is responsible for safeguarding the rights and welfare of human subjects and for complying with all regulations. Diné College maintains the right to review all cooperative research projects that are associated with Diné College faculty, staff, or students.

A. Is this a cooperative research project involving collaboration with a partner from another institution?

____ No ____ Yes *If yes, please complete the following:*

Name of Institution: _____

B. Will data be collected at the cooperating institution? ____ No ____ Yes

C. Will data be stored at the cooperating institution? ____ No ____ Yes

where stord
Nurse

D. Name of the person responsible for securing data at the cooperating institution:

If you answered yes to B or C, IRB processes at the cooperating institution must be completed:

E. Date of IRB Review at cooperating institution: _____ Protocol Number: _____

IRB Response: _____

IV. PARTICIPANT INFORMATION

A. Types of Subjects/Patients (check all that apply).

___ Adults (over 18)

___ Fetus in Utero/non-viable fetus/abortions*

___ People under the age of 18 (Infants, Children, or Adolescents)*

___ Pregnant Women*

___ Special populations (e.g., prisoners, mentally disabled)* Specify: _____

*Complete the "Special Populations" form if your participants include the asterisk groups.

B. Use of Dinè College (DC) students as participants.

Note the following: (a) An instructor may not personally recruit students for his/her own research from classes they teach. (b) If course credit is offered as compensation, an alternative opportunity must be available.

a) Does your research involve DC students as participants? ____ No ____ Yes

b) Will DC students be recruited in classes? ____ No ____ Yes

c) If yes, who will present the opportunity to students? _____

d) Will students be compensated with course points or credit? ____ No ____ Yes

e) If yes, what alternate activity be offered to earn the same points or credit?

C. Number of Participants: It is important to establish the optimal number of participants in your study so that the IRB can assess the extent of the impact if unforeseen harm occurs.

Minimum: _____ participants Maximum: _____ participants

D. Approximate Time Commitment for each participant:

Number of sessions: _____ Minutes per session: _____ Total minutes: _____

E. Compensation to subjects/patients: ___ Yes ___ No

If yes, in what form will compensation be given?

___ Gift card or certificate *Amount:* _____

___ Cash *Amount:* _____

___ Goods. *Please describe:* _____ *Value:* _____

___ Services *Please describe:* _____ *Value:* _____

___ Other *Please describe:* _____ *Value:* _____

F. Inclusion criteria: Most studies have a particular target population, such as people with a particular job, or people with a particular ethnic or racial background, or gender, or health condition. Describe your target population in terms of all relevant parameters (e.g., ethnic/racial stipulations, gender stipulations, parent or marital status, health status or health condition, etc.).

G. Exclusion criteria: On what criteria will you exclude individuals from your research? For example, is it reasonable to exclude people who are not fluent in a particular language, or people who are older than a particular age, or people who are at risk of depression or anxiety, or people with any other situations making them vulnerable?

H. Recruitment and Screening: How will you recruit your participants? How will you screen your potential participants to ensure that they meet your criteria for inclusion in the study before allowing them to participate? For example, will they answer questions, provide evidence, etc.?

V. RISKS AND BENEFITS

In order to respect rights of participants, the benefits of the research must exceed the risks to participants.

A. Describe the benefits of this research (may include benefits to the individual, to society, or to science):

B. Describe any potential psychological or physical risks of this research, even if minimal:

C. In the opinion of the research team, what is the level of psychological or physical risk?

_____ Minimal ____ Moderate ____ Serious

D. Describe any potential risks involving Navajo traditional beliefs (if your research involved Dinè people:

E. In the opinion of the research team, what is the level of spiritual risk?

_____ Minimal ____ Moderate ____ Serious

F. What steps will be taken to ensure that participants suffer no negative effects? (e.g., *debriefing, mental health services, ceremonies, post-study assessment, etc.)*

VII. PRIVACY AND CONFIDENTIALITY

A. Will any identifying information be collected from participants? ____ Yes ____ No

B. If not, would it be possible to determine who participated in the study based on information gathered for the study? ____ Yes ____ No

C. If you answered Yes to either of the preceding questions, please complete the following:

A. Where will data be stored?

B. How long will data be stored in that location?

C. Who will be responsible for securing and destroying the data?

D. How will identifiable information about the participants be kept separate from data provided for the study?

V. CHECKLIST

A complete proposal includes all of the following. Any missing materials will delay review of your proposal.

_____ Proposal for Sociocultural Research

_____ Supplemental Materials if required

_____ CITI training certificates for all members of the research team

_____ Informed Consent documents for each group

_____ All surveys, questionnaires, or materials to be used in the research

_____ Brief Research Protocol (approximately one page) including

- Rationale for research based in existing scientific literature
- Research question/s and/or hypotheses
- Method including
    - data collection procedures
    - timeline
    - data analysis plan,
- Dissemination (including intention for publication and sharing back with the community)

VI. SIGNATURE OF PRINCIPAL INVESTIGATOR

As the principal investigator of the proposed study, I attest that all of the information provided is complete and accurate to the best of my ability.

Name of Principal Investigator: _____

Signature:

Date:

EXEMPT STATUS

(adapted from University of Pittsburgh for the purpose of discussion)

Final Revisions to the Common Rule were effective starting on January 21, 2019. After this time, older versions of exempt guidance/forms are no longer valid. Always ensure that you are using the most current guidance and exempt forms available in the PittPRO library and via the links at the bottom of this page.

Introduction to Exempt Review

The Code of Federal Regulations identifies several different categories of minimal risk research as being exempt from Federal Policy for the Protection of Human Research Subjects. This does not mean that they are exempt from IRB review.

- The IRB does not "approve" an exempt study but instead makes a determination that the project meets at least one of the federal exempt categories criteria.
- Faculty mentors are responsible for oversight of student projects and should ensure that studies are completed and closed before the student leaves the University.
- No annual continuing review is required and no expiration date will be listed on your approval letter.
- It is very important that you close your project when completed or if you leave the University.

IRB determination that a study is either Not Research or Does Not Involve Human Subjects

The federal regulations include a very specific definition of what constitutes “research” and of what is meant by a “human subject”. Note that all studies involving human specimens require IRB review.

- **Human subject**: A living individual about whom an investigator (whether professional or student) conducting research:
    - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
    - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Although the federal regulations do not require official IRB review of studies that do not involve human subjects research, investigators may be required to obtain documentation that their project either is not research and/or does not involve human subjects (e.g., as may be required by a student’s doctoral dissertation committee, a funding agency, or a journal editor). If a study likely does not meet the definition of human subject research or otherwise likely does not require review, [what procedure should be in place?]. The IRB will not provide a formal written determination after the project has been initiated.

Activities deemed not to be research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Exempt Categories

The IRB has developed guidance documents and application forms for the most commonly requested exemptions as noted below. You will be required to [procedure to be inserted]

1. Educational Strategies, Curricula, or Classroom Management Methods. Link to description.
2. Tests, Surveys, Interviews, or Observations of Public Behavior. See description at this link.
3. Research Involving Benign Behavioral Interventions: See description at this link.
4. Secondary Research with Data and/or Specimens: See definitions at this link.
5. Research and Demonstration Projects Conducted or Supported by a Federal Department or Agency . Link to description
6. Determination that Research does not involve human subjects or is not research: Link to information

Important Definitions

- **Anonymous:** No one can identify the subject at any time.
- **Recorded Anonymously:** Recorded data are not linked to the identity of the individual subjects in any way. If there are linkage codes, data is not anonymous.
- **Coded information:** Identifiers are recorded, but data are labeled with a code without identifiers. Linkage information is kept in a separate, secure location.
- **Sensitive information**: Information that has the potential to damage participants' reputation, employability, financial standing, educational advancement, place them at risk for criminal or civil liability, etc.).
- **Intervention:** Both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction:** Communication or interpersonal contact between investigator and subject.

- **Private information:** Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- **Identifiable private information**: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **Identifiable biospecimen:** A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.