**Institutional Review Board for Research with Human Subjects (IRB)**

**Submission Form** (revised 01-08-19)

**Instructions**: In order to comply with federal regulations as well as to conform with guidelines of the College's Institutional Review Board (IRB), the principal investigator is required to complete all of the following items contained in the Submission Form and the IRB Protocol. Upon completion of all information, the principal investigator must submit the original Submission Form and one copy of the IRB Protocol, including all consent forms and research instruments (questionnaires, interviews, etc.) to the Institutional Grants and Sponsored Projects Office (IGO). Incomplete forms may delay review by the IRB. For further information, refer to the **Policy Manual for Research with Human Subjects and the Procedure Manual for Research with Human Subjects**.

**I. General Information**

1. Project Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

New\_\_\_\_\_ Continuation/Renewal\_\_\_\_\_ Revision\_\_\_\_\_

Proposed Start Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Proposed Duration of Research\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Performance Site(s)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Principal Investigator\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Student \_\_\_\_\_ Faculty \_\_\_\_\_ Staff \_\_\_\_\_
\**Please note that all research in which a Faculty/Staff member is the Principal Investigator is also subject to review and approval by the Navajo Nation Human Research Review Board (NNHRRB)*

College/Center \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Home Mailing Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
City\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ State\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Zip\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Home Phone Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Office Phone Number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Co-Investigator(s) *Please Note: For Student PIs, Co-Investigators include instructor(s), mentor(s), and/or advisor(s):*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator's Signature**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**\_\_\_\_\_\_\_

**II. Funding Information**

If this protocol is part of an application to an outside agency, please provide:

1. Source of Funding \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Project Title (if different from above)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Principal Investigator (if different from above)\_\_\_\_\_\_\_\_\_\_
4. Type of Application:
5. Grant\_\_\_\_\_ Subcontract\_\_\_\_\_ Contract\_\_\_\_\_ Fellowship\_\_\_\_\_\_
6. Date of Submission \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**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. If this proposal has been submitted to another Institutional Review Board please provide:

Name of Institution \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Date of Review \_\_\_\_\_\_\_\_\_\_\_ Contact Person \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
IRB Recommendation \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**IV. Subject/Patient Information**

1. Types of Subjects/Patients (check all that apply)
Fetus in Utero/non-viable fetues/abortuses
Newborns/Infants
Children (aged 2-12)
Adolescents (aged 13-18)
Adults (over 18)
Pregnant Women
Special populations (e.g., prisoners, mentally disabled)
Specify \_\_\_\_\_\_\_\_\_\_\_\_
2. Other (Check all that apply)
Use of investigational drugs or devices
Information to be collected may require special sensitivity
(e.g. substance abuse, sexual behavior)
3. Number of Subjects/Patients \_\_\_\_\_\_\_\_\_\_
4. Approximate time commitment for each subject/patient \_\_\_\_\_\_\_\_\_\_\_
5. Compensation to subjects/patients : Yes\_\_\_\_\_ No\_\_\_\_\_
6. Form (e.g. cash, meals) \_\_\_\_\_ Amount\_\_\_\_\_

**V. Continuation or Renewals**

1. Attach a copy of the original IRB protocol
2. Indicate all proposed changes in the IRB protocol affecting subjects
3. Progress Report
* Indicate the number of subjects entered in the study, including their group status, whether they are active or completed, the number of subjects still pending, and the time frame of subject participation.
* Indicate adverse or unexpected reactions or side effects that have occurred or are expected. If none, state none.
* Summarize the results of the investigation to date (in terms of subjects entered, in process, completed, and pending).
* Attach consent form(s) to be used and indicate if any changes have been made.

**VI. Protecting Human Participants Training**

* “Human Subjects Research Training” is completed within the last 3 years. To access the training, click on the link below, click “Register,” and choose NAU (Northern Arizona University) when asked for your affiliation (NAU has agreed to partner with Diné College to offer this training).

<https://about.citiprogram.org/en/course/human-subjects-research-2/>

Yes \_\_\_\_ No \_\_\_\_\_

Date of Completion: \_\_\_\_\_\_\_

Certificate demonstrating completion is included in proposal: Yes \_\_\_\_ No \_\_\_\_\_