

DINÈ COLLEGE

THE HIGHER EDUCATION INSTITUTION OF THE NAVAJO NATION SINCE 1968

Institutional Review Board

Form F. Identifying Non-Human-Subjects-Research and Exempt Research

Human subjects research that is classified as “exempt” means that the research qualifies as no risk or minimal risk to subjects and is exempt from most of the requirements of the Federal Policy for the Protection of Human Subjects.

Protocol #: _____ Principal Investigator: _____

STEP 1. DETERMINE WHETHER YOUR PROJECT IS HUMAN SUBJECTS RESEARCH.

1. Does the project meet the definition of “research”?

Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” See 45 CFR 164.501.

___ Yes ___ No

2. Does the project meet the definition of a “human subject”?

“Human Subjects” data includes information collected from or about living individuals, either through interaction or intervention, or use of identifiable private information or identifiable biospecimens.

___ Yes ___ No

3. Does your project involve student researchers from Dinè College?

___ Yes ___ No

If no to either Question 1 or Question 2, then your research is not human subjects research according to federal policy. However, the Dinè College IRB also considers protections of students researchers or research assistants. If DC students are involved in the research, then recommendations for their protection may be made even for research that is not considered to be Human Subjects Research.

If your research is not Human Subjects Research, you may stop here, complete the New Proposal form, and submit your application.

STEP 2. DETERMINE WHETHER YOUR PROJECT INVOLVES NO MORE THAN MINIMAL RISK.

See more [information about minimal risk at this link](#).

1. Physical Harm

Physical harm represents adverse physical reactions to an experience related to the study. Check any of the following that apply to your study.

- The probability of physical harm is *not greater* than would be encountered in daily life.
- The magnitude or severity of potential physical harm is *not greater* than what would be encountered in daily life.

2. Psychological Harm

Psychological harm can range from short-term mild effects (e.g., momentary stress or indecision) to more enduring effects (e.g., worsening of depression).

- The probability of psychological harm that may be experienced is *not greater than* the probability that such harm would be encountered in daily life?
- The potential for acute psychological harm, such as momentary discomfort or distress, is *not greater than* what would be encountered in daily life.
- The potential for enduring psychological harm, such as exacerbating an existing mental health condition or causing reductions in self-esteem, is *not greater than* what would be encountered in daily life.

3. Informational Harm:

Informational harm includes any potential harm to an individual's reputation, financial or employment status, interpersonal relationships, or other aspects of an individual's life that could be impacted by exposure of the data collected or by the recruitment process.

- This project *does not involve* collection of identifiable data.
- The risk that the data collected from participants could place a participant at risk of arrest, exposure, or financial, interpersonal, or employment difficulties is *not greater than what* would be encountered in daily life.
- The risk that the recruitment process would place a participant at risk of arrest or exposure or financial, interpersonal, or employment difficulties is *not greater than* levels likely to be encountered in daily life.

If you checked all of the boxes above, please continue to Step 3.

If one or more of the boxes is unchecked, your research has greater than minimal risk and is not eligible for exempt status.

STEP 3. DETERMINE WHETHER YOUR PROJECT FALLS INTO ONE OF THE SIX FEDERALLY DESIGNATED EXAMPLE CATEGORIES BELOW.

- Exempt Category 1 - [Educational Practices](#)
- Exempt Category 2 - [Educational Tests, Interviews, Surveys, Observation of Public Behavior](#)
- Exempt Category 3 - [Benign Behavioral Interventions with Adults](#)
- Exempt Category 4 - [Secondary Uses of Identifiable Private Information or Identifiable Biospecimens](#)
- Exempt Category 5 - [Public Service Projects](#)
- Exempt Category 6 - [Taste and Food Quality Evaluation and Consumer Acceptance Studies](#)

If your research falls into one of the exempt categories and if you checked all the boxes in Step 2, your research may qualify for exempt status. Please append this form to your proposal and check the appropriate box on the proposal form.

DEFINING EXEMPT CATEGORIES

1. Exempt Category 1 - Educational Practices

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as a) research on regular and special education instructional strategies; or b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (45 CFR 46 104 (d)(1))

- This category does not apply to surveys, interviews, questionnaires, or focus groups which are covered under exempt category 2.
- The study cannot adversely impact the students' opportunity to learn required curriculum.

Examples:

- A study comparing two curricula being implemented at a school with observation and analysis of class evaluations.
- A study about professional development workshops.
- A study evaluating the effectiveness of a commonly accepted math curriculum.
- A study involving a cooking class in a grocery store.

2. Exempt Category 2 - Educational Tests, Interviews, Surveys, Observation of Public Behavior

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, if at least one of the following is met:

- information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects;
- any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or
- information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and if the IRB conducts a limited review for provisions for protecting privacy and maintaining confidentiality (45 CFR 46 104 (d)(2))

Exceptions:

- This category does not apply to interviews or surveys with minors.
- This category only applies to observation of public behavior involving children if the study team does not participate in the activities being observed.
- Observations must be of public behavior in a public setting (i.e., park, intersection, parking lot, lobby, etc.)

Examples:

- a. observational study of a pedestrian street crossing where the researcher takes notes of age, gender, clothing of pedestrians.
- b. A focus group involving college students and their STEM experiences.
- c. An online anonymous survey studying various types of social media use.

3. Exempt Category 3 - Benign Behavioral Interventions with Adults

Research involving benign behavioral interventions in conjunction with the collection of information through verbal or written responses or audiovisual recordings if at least one of the following criteria

is met: (a) information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects; (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or (c) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and if the IRB conducts a limited review for provisions for protecting privacy and maintaining confidentiality. (45 CFR 46 104 (d)(3))

Exceptions:

- This category does not include minors.
- Benign behavioral interventions must be brief in duration, harmless, painless and not physically invasive and there is no reason to think the interventions will be offensive or embarrassing.
- Interventions should not have a last significant adverse impact on the participants.
- Research involving deception is allowed if the participant is prospectively informed, and agrees to, that they will be unaware of, or misled regarding the nature or purpose of the research.

Examples include:

- A random assignment of participants to take a test under various noise conditions.
- A study involving randomly assigning participants to various experimental conditions where they decide how to allocate cash between themselves and others.

4. Exempt Category 4 - Secondary Uses of Identifiable Private Information or Identifiable Biospecimens

Secondary research for which consent is not required if at least one of the following criteria is met: (a) The sources are publicly available; or (b) the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects and the investigator does not contact or re-identify the subjects; or (c) the research is collected by or on behalf of the federal government using government generated or collected information obtained for non-research activities. (45 CFR 46 104 (d)(4))

- a. Many projects involving the secondary use of data/specimens do not meet the definition of a "human subject"
- b. This category does not apply to data protected under HIPAA due to UC's hybrid entity status
- c. This category covers re-using identifiable data collected for some other primary purpose or initial activity, or in other words the data must not be collected for the purpose of the specific proposed study.
- d. If access to the data is "limited" or "restricted" then the data set is not likely publicly available.
- e. This category covers data analysis from online repositories where users may pay a "user fee" or needs to register to access the data.

Examples include:

- A study involving secondary research of audio archives in a public library
- An analysis of biospecimens from an IRB-approved biorepository.
- A study involving review of national census data that contains zip codes.

5. Exempt Category 5 - Public Service Projects

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine the following: (a) public benefit or service programs; or (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs. (45 CFR 46 104 (d)(5))

- a. This category is limited to programs designated by a federal department head, such as the Secretary of Health and Human Services.
- b. The federal entity conducting or sponsoring the research must publish a list of projects that are covered under this exemption on a publicly available website prior to commencing the research involving human subjects.

Examples include:

- The US Department of Social Security Administration is charged by Congress with providing periodic reports about the effectiveness of access to benefits under the program and SSA contracts with a researcher to collect data for the report.

6. Exempt Category 6 - Taste and Food Quality Evaluation and Consumer Acceptance Studies

Taste and food quality evaluation and consumer acceptance studies, if: (a) wholesome foods without additives are consumed; or (b) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. (45 CFR 46 104 (d)(6))

Examples include:

- A study involving consumer acceptance of various brands of frozen meals.
- A study involving a taste-testing of fruit varieties that do not contain additives to determine consumer preference.
- A study involving taste-testing of various pork products that have been given feed with a chemical additive, if the researcher can document the additive was at or below the levels approved by the USDA.