

# DINÉ COLLEGE

THE HIGHER EDUCATION INSTITUTION OF THE NAVAJO NATION SINCE 1968

## Institutional Review Board

### Supplement B. Prisoners

Prisoners are considered to be a vulnerable research population because they are in a restrictive environment with limited opportunity for free choice, earning money, communicating with outsiders, or obtaining medical care. For this reason, they may only participate in certain categories of research, and have special protections to ensure that their participation is informed and voluntary.

**Project Name:** \_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_

**DC-IRB Protocol number:** \_\_\_\_\_ **Date of IRB Approval:** \_\_\_\_\_

1. Does this project meet criteria for minimal risk research?

[Read about minimal risk research at this link.](#)

Yes                      No            If no, please describe.

2. Into which category of the following allowable categories does your research fit?

- a. Study of the possible causes, effect, and processes of incarceration and of criminal behavior.
- b. Study of prisons as institutional structures or of prisoners as incarcerated persons
- c. Research on conditions particularly affecting prisoners as a class, such as vaccine trials that might be more prevalent in prison than elsewhere
- d. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

3. Describe specific steps to be taken to ensure that prisoners are not unduly coerced to participate.

4. Describe specific steps taken to ensure that prisoners will be fully informed about their rights as research subjects and that these rights will be available to them in the research setting.

Signature of principal investigator:

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### **Additional Information**

When an IRB is reviewing a protocol in which a prisoner is a subject, the IRB must make seven additional findings under 45 CFR 46.305 as listed below.

- a. A. The research under review represents one of the categories of research permissible under Section 46.306(a)(2).
- b. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.
- c. The risks involved in research are commensurate with risks that would be accepted by non-prisoner volunteers.
- d. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
- e. The information is presented in language that is understandable to the subject population.
- f. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.
- g. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.