



**Institutional Review Board
Vulnerable Populations: Prisoners**

Research Proposal Title: _____

Principal Investigator: _____

Campus: _____ **Department:** _____

Phone: _____ **Email Address:** _____

Please read [45 CFR 46, Subpart C](#) of the Department of Health and Human Services' website regarding the involvement of prisoners in research studies.

"Prisoner" is defined as any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals: (a) sentenced to an institution under a criminal or civil statute; (b) detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution or (c) detained pending arraignment, trial or sentencing.

Note: Probation and parole are usually not considered incarceration.

Section 1: Select the category that best represents the research and provide the rationale for that choice:

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The research is a study of the possible causes, effects and processes of incarceration and of criminal behavior.

- Justify why your research meets this category:

- Explain why the research is no more than minimal risk:

- Explain why the research represents no more than inconvenience to the subjects:

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The research is a study of prisons as institutional structures or of prisoners as incarcerated persons.

- Justify why your research meets this category:

- Explain why the research is no more than minimal risk:

- Explain why the research represents no more than inconvenience to the subjects:

The study represents research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults).

- Justify why your research meets this category:

- Explain the condition(s) that will be studied and provide the rationale:

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The study represents research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

- Justify why your research meets this category:

- Explain the research practices used in this study and how they are intended to improve the health and well-being of the subjects:

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The study is epidemiologic research to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease, where prisoners are not a particular focus of the research.

- Justify one of the following:

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The study is epidemiological research to describe the prevalence or incidence of a disease by identifying all cases:

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The study is epidemiologic research to study potential risk factor associations for a disease that your research meets this category:

- Justify that prisoners are not a particular focus of the research:

- Explain why the research is no more than minimal risk:

- Explain why the research represents no more than inconvenience to the subjects:

Section 2: How do each of the following required conditions apply to the research?

- A. Are there 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, that are 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 prisoner is impaired?

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No

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Yes - Justify that the possible advantages are NOT of such a magnitude that the prisoner's ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prisoner is impaired.

Explain the possible advantages that can be expected for prisoner subjects:

- B. Are the risks involved in the research commensurate with the risks that would be accepted by non-prisoner subjects?

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No

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Yes

If yes, describe the foreseeable risks for prisoner subjects.

Justify that the risks involved in the research are commensurate with the risks that would be accepted by non-prisoner subjects:

- C. Are the procedures for the selection of subjects within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners?

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No

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Yes

Explain how prisoners will be selected for participation in this research study:

If the prisoners are not the targeted population, explain the importance of continuing to intervene, interact or collect identifiable private information during a participant's incarceration.

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Not applicable, prisoners are the target population.

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Explanation:

Will the control subjects be selected randomly from the group of available prisoners who meet the characteristics needed for the research project?

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No

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Yes

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Not Applicable

Explain why the procedures for the selection of subjects within the prison will be fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners:

- D. Explain how you will insure that the information to be presented in the consent process will be in a language that is understandable to the subject population:

- E. Explain what steps will be taken to insure that parole boards will not take into account a prisoner's participation in the research when making decisions regarding parole:

- F. Explain what steps will be taken to insure that each prisoner will be clearly informed in advance that participation in the research will have no effect on his/her parole:

G. Will there be a need for follow-up examination or additional care of subjects after the research procedures have been concluded taking into account the varying lengths of individual prisoners' sentences?

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No

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Yes

If "Yes," please explain what follow up provisions have been made?

If "Yes", please explain how you will communicate this to the prisoner subjects:

Principal Investigator Signature: _____ **Date:** _____

Email forms and supporting documentation to: irb@tccd.edu.