**IRB Protocol #**_____
**Funded Grant #**_____
**Contract #** _____

**Office of Research Compliance**
**Phone: (817) 272-3723**
**Fax: (817) 272-1111**

THE UNIVERSITY OF TEXAS AT ARLINGTON

# IRB Form # 2C
## Application for Research Including Prisoners as Research Subjects

Principal Investigator: _____

Protocol Title: _____

This form should be submitted in conjunction with IRB Form #1 when prisoners are used as human subjects in a research protocol.
The following questions will assist the IRB in determining that the research fulfills all the requirements of the federal regulations at 45 CFR 46.305(a) for the inclusion of prisoners as research subjects. If additional space is required, use a separate sheet. Special risk/benefit determinations must be discussed and documented by the IRB in order for prisoners to be included as research subjects.

1. Are there any possible advantages accruing to the prisoner subject 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 risk of the research against the value of having such advantages in the limited choice environment of the prison is impaired.

Yes ☐ No ☐ N/A ☐ (e.g., Chart Reviews)

If Yes, please explain:

_____

_____

_____

2. Are the risks involved in the research commensurate with the risks that would be accepted by non-prisoner volunteers? Yes ☐ No ☐

If No, please explain:

_____

_____

3. Are the procedures for the selection of subjects within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities of prisoners? Yes ☐ No ☐ (Note: Unless the PI provides justification to the IRB in writing for following some other procedure, control subjects must be selected randomly from the group of available prisoner subjects who meet the inclusion criteria needed for the research project).

If No, explain the procedures:

_____

_____

_____

_____

_____

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4. Is the information regarding the research presented in language understandable to the subject population? Yes ☐ No ☐ N/A ☐ (e.g., chart reviews)

If Yes, explain how it will be presented:

5. State how you will assure that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole.

Is each prisoner clearly informed in advance that participation in the research will have no effect on his or her parole? Yes ☐ No ☐ N/A ☐
Is this stated in the consent form? Yes ☐ No ☐ N/A ☐

6. When the research requires follow-up beyond the period of incarceration, have the provisions been made for locating the individual? Yes ☐ No ☐ N/A ☐
Are participants informed of how follow-up will take place, if such is required?
Yes ☐ No ☐

So that the IRB will be provided with sufficient information to make the required determinations under 45 CFR 46.305(a)(7), discuss the following:

a) What are the potential complications that may result from participation in the research?

b) What is the possible duration of such complications?

c) What are the types of examinations and care that would typically be needed for such complications?

d) Describe the provisions for such examinations and care to subjects after their participation in the research has ended.

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7. Please designate the category that you feel describes the involvement of prisoners in this research activity.

☐ (A) A study of the possible causes, effects, and processes of incarceration, and criminal behavior provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

☐ (B) A study of prisons as institutional structures or of prisoners as incarcerated persons provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

☐ (C) Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary (DHHS) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice in the Federal Register, of his/her intent to approve such research.

☐ (D) Research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well being of the subjects. In cases in which the research requires assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups that may not benefit from the research, the study may continue only after the Secretary (DHHS) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice in the Federal Register, of his/her intent to approve such research. (Does the proposed treatment benefit at least as many individuals as the last available standard therapy and that number is greater than any other eligible treatment)

The inclusion of prisoners as research subjects must be approved at a convened meeting by a majority vote of a quorum of the IRB that includes the Prisoner Advocate/Representative. In accordance with appropriate regulations, the research may also have to be reviewed and approved by Federal authorities and **inclusion of prisoners as research subjects may not commence until all approvals are complete.**

Principal Investigator Date

_____ _____