**Form IRBF022**

**RESEARCH with PRISONERS: ADDITIONAL INFORMATION**

This attachment covers the **Subpart C of 45 CF$ 46 – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (§46.301-§46.306).** The requirements under Subpart C are in addition to those imposed under other suparts. For instance, if the subject is a minor and pregnant, then the requirements listed here would be in addition to Subparts B and D.

1. **GENERAL INFORMATION**
	1. **Protocol Title:**
	2. **Protocol ID:**
	3. **Today’s Date:**
	4. **Primary Investigator (PI) Information:**

[ ] Faculty/Staff [ ] Graduate [ ] Undergraduate [ ] Other

|  |  |
| --- | --- |
| Name |       |
| MTSU Email |      mtsu.edu |

* 1. **Faculty/Senior Investigator Information** (Skip if same as PI)

|  |  |
| --- | --- |
| Name |       |
| MTSU Email |      @mtsu.edu |

\*The application documents MUST be emailed to irb\_submissions@mtsu.edu by the faculty investigator. Suggested subject line to the email is “Protocol Addendum”

DO NOT CONVERT THIS APPLICATION TO PDF – There are embedded XML features

**Definitions:**

"Prisoner" refers to any individual involuntarily confined or detained in a penal institution. The term is intended to encompass:

* Individuals sentenced to such an institution under a criminal or civil statute;
* Individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution; or
* Individuals detained pending arraignment, trial, or sentencing.
* The research study may qualify for an expedited review ONLY if the proposed research is determined to be no more than minimal risk

**Note: Probation and parole are usually NOT considered as incarceration.**

1. **RESEARCH CLASSIFICATION**

The proposed study to involve prisoners must fall within one of the following criteria (**§46.306**):

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

Explain why the research is no more than minimal risk to the participants.

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

Explain why the research is no more than minimal risk and represents no more than inconvenience to the participants.

[ ]  **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).

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

[ ]  **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**.

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

1. **MANDATORY REQUIREMENTS**

**How does each of the following required conditions apply to the research?**

* 1. 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? **[ ]  No [ ]  Yes**

Explain the possible advantages that can be expected for prisoner participants.

* 1. Are the risks involved in the research commensurate with the risks that would be accepted by non-prisoner volunteers? **[ ]  No [ ]  Yes**

Explain the possible risks that can be reasonably expected for prisoner participants.

* 1. Are the procedures for the selection of participants within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners? **[ ]  No [ ]  Yes**

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

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

* 1. Will the control subjects be selected randomly from the group of available prisoners who meet the characteristics needed for the research project? **[ ]  No [ ]  Yes**
	2. Will the information be presented in a language that is understandable to the participant population? **[ ]  No [ ]  Yes**
	3. Does adequate assurance exist that parole boards will not take into account a prisoner's participation in the research when making decisions regarding parole; and, will each prisoner be clearly informed in advance that participation in the research will have no effect on his/her parole?

**[ ]  No [ ]  Yes**

If “Yes,” explain what assurances are there and how they will be communicated to the prisoner-participants.

* 1. Where the IRB finds there may be a need for follow-up exam or care of participants after the end of their participation, taking into account the varying lengths of individual prisoners' sentences, are there adequate provisions made to do so and for informing participants of this fact?

**[ ]  No [ ]  Yes**

If “Yes,” please explain what provisions will be made for follow-up and how you will communicate this to the prisoner-participants

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| **The IRB Committee must review the recommendations from both the Expert and Community Review Panels (IRB USE ONLY)** |
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1. **DECLARATION**

I, **,** certify that:

1. this project is carried ot by me or and under my direct supervision
2. I have read this application thoroughly and I am fully aware of the activities to be performed under this protocol involving minors

PI Signature \_\_\_\_

Date \_\_\_\_

(Enter your name and TODAY’s date in the space provided)