RESEARCH PROTOCOLS INVOLVING PRISONERS AS PARTICIPANTS IN RESEARCH

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Introduction

The inclusion of prisoners as subjects in research requires that the investigator comply with the additional protections provided in 45 CFR 46, subpart C. The following questions must be answered in order for the PHSC to review the research.

Note: "Prisoner" is defined by HHS regulations at 45 CFR part 46.303(c) as "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, and individuals detained pending arraignment, trial, or sentencing." In practice this definition includes persons under house arrest or otherwise restricted by criminal proceedings.

Minimal risk for prisoners is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.*

*Note the definition for minimal risk for prisoners differs from that found elsewhere in the regulations.

Research projects involving use of committed persons in medical, cosmetic, or pharmaceutical experiments shall not be permitted. Moreover, certain types of research with prisoners approvable under the federal regulations may not be allowed under Texas state law.

1. Listed below are the permissible categories of research that may include prisoners. Indicate the category (ies) that best describes this research proposal (please check all applicable choices).

The research involves solely:

☐ The study of the possible causes, effects, or processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants.

☐ The 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 participants.

☐ Research on conditions particularly affecting prisoners as a class of people (for example, 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). [HHS funded or

conducted research in this category may proceed only after the Secretary (through OHRP) has consulted with the appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research. For research that is not HHS funded or conducted, the need to convene an expert panel will be determined on a protocol per protocol basis.]

☐ Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. [In cases in which the study protocol design is such that it is required to assign prisoners to control groups which may not benefit from the research, HHS funding of conducted research may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published, in the Federal Register, of the intents to approve such research. For research that is not HHS funded or conducted, the need to convene an expert panel will be determined on a protocol-by- protocol basis.]

2a. Describe the correctional facility(ies) where the research will be carried out. Include the name, type of facility and indicate if it is a local, state, or federal facility.

2b. Describe the criteria, if any, used in selecting this correctional facility(s).

3. Describe the procedures for the selection of participants. The selection of subjects within the prison should be fair to all prisoners and not expose either participants or those who decline participation to stigmatization, harassment, prejudice, or retaliatory treatment. In addition, the procedures for assignment to various groups within the research should also be designed to be fair (e.g., experimental, control groups).

4. Describe the possible advantages for prisoners if they participate. Advantages may not be of such magnitude that they will unduly influence the prisoner's ability to weigh the risks of the research against the value of such advantages.

5. Discuss the risks to the prisoners involved in the research and compare them (similarities and differences) to the risks that would be likely to be deemed minimal or reasonable by non-prisoner volunteers.

6. How will the investigator ensure that there is no arbitrary influence or intervention by prison authorities regarding the selection, assignment, and withdrawal of prisoners over the course of the study?

7. Describe the provisions made to ensure that the parole boards will not have access to information pertaining to the prisoners' participation in the research. If the parole board will have access, verify that the parole board will not use such information when considering the prisoner's parole.

8. Based upon the research design and the type of research intervention, do you anticipate the need for follow-up examinations or care for participants after the end of their research participation (e.g., psychological counseling)?

   If yes, describe the provisions for follow-up examinations or care of participants after their participation in the research has ended. Include detailed information about the follow-up exams or care, including how often, how long they will be available, and under what conditions (taking into account the varying lengths of individual prisoners' sentences).

9. Describe what plans are in place for prisoners who are released, transferred, or moved from the primary research site during their research participation and before the completion of the full research study. For Example, would there be any attempt to follow-up with these individuals and continue to collect information or data?