APPENDIX D

# RESEARCH INVOLVING PRISONERS (45 CFR 46, SUBPART D)

This form should be completed to justify the inclusion of prisoner populations. All research involving prisoners, regardless of funding, will be reviewed by the DU IRB prisoner advocate.

**NOTE: Research which falls under the purview of the Colorado Department of Corrections (DoC) may be subject to additional requirements of the DoC regardless of funding. As part of the IRB process for obtaining approval, the investigator will be required to provide documentation of DoC approval.**

**For research conducted or supported by DHHS to involve prisoners, two additional actions must occur. Plan for additional time, post-IRB approval, before scheduling research activity as the IRB must apply for OHRP certification:**

* **The institution engaged in the research must certify to the Secretary (through OHRP) that the IRB designated under its assurance of compliance has reviewed and approved the research under 45 CFR 46.305; and**
* **The Secretary (through OHRP) must determine that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2). Prisoners cannot be included in DHHS supported research until the certification is completed.**

## 1. Prisoner Subjects

Identify Prisoner Subjects Proposed for Inclusion Under this Subpart:

Click here to enter text.

**45 CFR 46.305(a): Prisoners may be involved in research if ALL of the seven findings below are met. Please provide protocol-specific information to support each finding.**

## 2. Federal Criteria for Approval 45 CFR 46.305 (a)

When an IRB reviews a protocol which a prisoner is a subject, the IRB will approve the research only if it finds and documents that:

### 2.1.

The research falls within one of the regulatory criteria for approval addressed under 45 CFR 46.306(a)(2); that is the research is a study of: (select one or more of the following four categories)

[ ]  Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

[ ]  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;

[ ]  Research on conditions particularly affecting prisoners as a class (for example, 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 (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; OR (iii)

[ ]  Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary (of OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research.

### 2.2.

Describe in detail if any of the following statements CANNOT be fulfilled as part of the proposed research:

1. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, and quality of food, amenities and opportunity for earning in the prison, are not of such 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;

Click here to enter text.

1. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

Click here to enter text.

1. 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 s 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 research project;

Click here to enter text.

1. The information is presented in a language which is understandable to the subject population;

 Click here to enter text.

1. 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;

Click here to enter text.

1. Where the IRB finds there may be a need for follow-up examination or care of subjects 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 subjects of this fact,

**NOTE:** An IRB finding that follow-up examination or care of the prisoner-subjects may be needed after the end of their study participation will necessitate a change in the standard Compensation for Injury section of the informed consent document. The change will need to address the provision of long-term care for this subject population and must be obtain prior approval by legal counsel to the IRB.

Click here to enter text.