

APPENDIX D – RESEARCH INVOLVING PRISONERS 45 CFR 46, SUBPART D

Criteria must be met for Federally Funded research.

The PI should use this form as guidance to justify the inclusion of prisoner populations in non-federally funded studies.

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. The investigator may 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 will apply for OHRP certification:

- (1) 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
- (2) 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. Identify Prisoner Subjects Proposed for Inclusion Under this Subpart:

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.

The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2)

- Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents not more than minimal risk and no more than inconvenience to the subjects; (i)
- Study of prisons as institutional structures or of prisoners as incarcerated person, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects; (ii)
- 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 he 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 (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. (iv)

IRBNet #:

PI:

- Epidemiological studies whose sole purpose is one of the following:
 - To describe the prevalence or incidence of a disease by identifying all cases.
 - To study potential risk factor associations for disease.

The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and prisoners are not a particular focus of the research. (v)

Study specific description to support this finding is: (please list below)

An 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 earning in the prison, are not 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 prison is impaired;

Study specific description to support this finding is: