

Prisoners are not the targeted population.

Instructions

This review is in keeping with 45 CFR 46.306 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.306>) calling for a review by a prisoner advocate or representative of this study. You are evaluating this protocol because you have a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner, and/or the appropriate background and experience to serve as a prisoner representative. You must assess the appropriateness of the research for prisoners, whether the consent method is acceptable, determine the research category, and to identify any issues that might be of concern in implementing this study regarding human subjects.

If you are conducting a Continuation Review (CR), Modification Review (MR), or Unanticipated Problem/Adverse Event (UP/AE) review, indicate in the comments section under the "Finish" tab if there are any changes impacting the category or the conditions.

Section 1. Category of Research

- Category 1 (45 CFR 46.306(a)(2)(i)) - This research involves the study of possible causes, effects, processes of incarceration, and of criminal behavior.
- Category 2 (45 CFR 46.306(a)(2)(ii)) - This research involves the study of prisons as institutional structures, or of prisoners as incarcerated persons.
- Category 3 (45 CFR 46.306(a)(2)(iii)) - This research involves the study of conditions particularly affecting prisoners as a class.
- Category 4 (45 CFR 46.306(a)(2)(iv)) - This research involves the study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

Section 2. The IRB reviewer finds justification that six additional conditions are met.

- Advantages acquired through participation in the research, when compared to the prisoners' current situation, are not so great that they impair their ability to weigh risks.
- Risks are the same as those that would be accepted by non-prisoners.
- Procedures for selection are fair to all prisoners and are immune from intervention by prison authorities in prisons; control subjects are randomly selected.
- Parole boards cannot take into consideration a prisoner's participation in research. Informed consent states that participation will not impact parole.
- For studies that require follow-up, provisions are made including consideration for the length of individual sentences; informed consent must reflect provisions for follow-up.
- Information about the study is presented in a language understandable to prisoners.

Section 3. Only complete if applicable: Epidemiologic Research Involving Prisoners

This waiver applies to epidemiologic research on prisoners that presents no more than minimal risk and no more than inconvenience to the prisoner-subjects. *(Note: Reviewer should still complete Section 2 of this form)*

Check the box below if the reviewer finds that this research meets the listed criteria.

- The PI has requested a waiver for meeting the category conditions under Section 1 of this form.
- This research involves epidemiologic research intended to describe the prevalence/incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease; and
- Prisoners are not the sole focus of the research.