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Reviewer Checklist - Research Involving Prisoners

The research is NOT conducted or supported by DHHS.

The institution responsible for the conduct of the research has certified to the Secretary of HHS (through OHRP) that the Institutional Review Board has reviewed the research and made seven findings as required by the regulations. OHRP sent a letter to the institution authorizing the involvement of prisoners in the proposed research (only if OHRP determined that the research involves one of the permissible categories).

Clear

PERMISSIBLE CATEGORIES OF PRISONER RESEARCH

The IRB may approve studies involving prisoners only if the research falls into one of the following categories.

Select one:

Category 1: The research proposes to study the possible causes, effects, and processes of incarceration, and of criminal behavior. The study presents no more than minimal risk and no more than inconvenience to the participants. 45 CFR 46.306(a)(2)(i)

Category 2: The research proposes to study prisons as institutional structures or to study prisoners as incarcerated persons. The study presents no more than minimal risk and no more than inconvenience to the subjects. 45 CFR 46.306(a)(2)(ii)

Category 3: The research proposes to study the conditions particularly affecting prisoners as a class (e.g., 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).

If the research is conducted or supported by DHHS, the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics and the Secretary has published notice, in the Federal Register, of his/her intent to approve such research. *Research proposals in this category that are not conducted or supported by HHS do not require a Secretarial consultation.* 45 CFR 46.306(a)(2)(iii)

Category 4: The research proposes to study the practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participants.

If the research is conducted or supported by DHHS and the research requires the assignment of prisoners to control groups that may not benefit from the research, the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics and the Secretary has published notice, in the Federal Register, of his intent to approve such research. *Research proposals in this category that are not conducted or supported by HHS do not require a Secretarial consultation.* 45 CFR 46.306(a)(2)(iv)

Category 5: Epidemiologic studies when the research proposes to study the prevalence or incidence of a disease by identifying all cases or to study the potential risk factor associations for disease. The study presents no more than minimal risk, no more than an inconvenience to the participants and prisoners cannot be the particular focus of the study. Federal Register, Vol. 68, No. 119, pp. 36929-36931, Friday, June 20, 2003

Clear

APPROVAL CRITERIA FOR RESEARCH INVOLVING PRISONERS

In order to approve research involving prisoners, the IRB must determine that the following seven (7) requirements are satisfied.

Yes

No 1. The research falls into one of the allowable categories of prisoner research (see above).

Clear

Yes 2. Advantages to the prisoner as a result of participation are not coercive.

N/A if study is a retrospective chart review.

No

- When compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, any possible advantages should not be of such magnitude that his/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.

N/A

Clear

Yes

No 3. The risks involved in this research are commensurate with risks that would be accepted by non-prisoner volunteers.

Clear

Yes

4. Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

No

N/A if study is a retrospective record view.

N/A

- *If the study proposes the use of a control group, control participants are selected randomly from the group of eligible prisoners, unless the investigator provides the IRB with sufficient justification in writing for following some other selection procedure.*

Clear

- Yes
 No
 N/A

5. Information is presented in language which is understandable to the participant population.
N/A if study is a retrospective record view.

Clear

- Yes
 No
 N/A

6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole. Each prisoner is clearly informed in advance (through the proposed consent process) that participation in the research will have no effect on his/her parole.
N/A if study is a retrospective record review.

Clear

- Yes
 No
 N/A

7. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths or individual prisoners' sentences, and for informing participants of this fact.
N/A if study is a retrospective record review.

Clear

Specific Concerns: If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolutions to Concerns: Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

REMINDER: *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

Determination: Is the proposed use of prisoners approvable?

- Yes.
 Yes, if the above stipulation is met.
 No.

Clear

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