Requirements for Research that Involves Prisoners as Participants

Overview

Federal regulations (45 CFR §46, Subpart C) impose special requirements for research involving prisoners as participants. DF/HCC does not target prisoners for involvement in research, and DF/HCC policy requires investigators and IRB members to take extra steps to protect the rights and welfare of these individuals. Prisoners are considered a vulnerable population because their lack of physical liberty may affect their ability to make a truly voluntary and noncoerced decision to participate in research. Furthermore, practical challenges may exist with respect to adequately maintaining the confidentiality of prisoners' participation and data, arranging for prisoners to travel to the clinic for study visits, and ensuring that prisoners are able to comply with study procedures between visits.

Therefore, prisoners may not participate in research unless the IRB has specifically granted approval for the inclusion of these individuals. If a current participant becomes incarcerated or detained, all research activities involving the participant must cease until IRB approval is provided. Furthermore, if the research is supported by DHHS, review and approval from DHHS is required before prisoners may participate in the research.

Who is a "Prisoner?"

Federal Regulations define a "prisoner" 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.

Study Team Responsibilities

Before a prisoner may participate in any research activities, the study team must submit an Amendment to the IRB. The Amendment must include the following:

- **Amendment Form:** The Form should state that approval of prisoner participation is requested, whether the prisoner is a current participant or proposed to be a new participant, how the rights and welfare of the prisoner will be safeguarded, and how study participation will be accommodated logistically.
- **Letter of Cooperation from the Penal Facility:** Because the penal facility is responsible for the care of the prisoner, it must participate to some degree in the implementation of the study, such as by facilitating transportation to the study clinic and making study treatments available to the participant. Therefore, the study team must obtain a letter from penal facility authorities stating that preliminary approval is granted for the prisoner's participation.
- **Consent**: The study team must submit a separate Consent Form for the enrollment of prisoners. The Consent should state that participation in the research will have no effect on their sentence or parole, and that they will not receive any advantages - such as better living conditions or amenities - than would otherwise be available to them in the normal prison environment. The Consent should also address privacy concerns, given that prison staff will be involved in or made aware of their participation. Finally, the Consent should state whether follow-up examination or

care will be needed, taking into account that the participant may or may not be a prisoner at that time.

- **Protocol**: The protocol should be revised if any changes are needed to accommodate prisoners as participants. Study teams should consider, for instance, where and when study procedures will take place, how confidentiality will be maintained, and how the study team and prisoner will communicate.

After the study team submits the Amendment, they must wait to obtain written IRB approval, and if required, DHHS approval (facilitated by OHRS), before prisoners may participate in research activities.

All protocol submissions involving incarcerated participants require review by the full IRB. None may be reviewed on an expedited basis and none may be determined exempt research.

What if a Current Participant Becomes Incarcerated?

If the study team becomes aware that a current participant becomes incarcerated after enrollment, then all interactions, interventions, and collection of identifiable information must cease immediately.

If compliance with the prisoner-participant requirements will not be sought, then the study team should remove the participant from the research and recommend standard of care, if applicable.

If the participant and the study team would like participation to continue, then the study team must submit an Amendment to OHRS, discussed above. While the Amendment is pending review and approval, the participant may not engage in any further research activities.

Exception: The study team may submit a Major Deviation/Violation/Exception Form to OHRS if the PI determines that it is in the best interests of the individual to continue their participation in the research while incarcerated. The IRB may then approve their participation while the research is brought into compliance with the additional prisoner requirements.

Note: If the incarceration is temporary, such that no research interactions, interventions, or obtaining of identifiable information will occur during the incarceration, and the incarceration will not otherwise impact the research, then the study team is not required to submit an Amendment or notify OHRS.

IRB Review of Research Involving Prisoners

When research involving prisoners is reviewed by the IRB, at least one IRB member at the meeting must be a prisoner or prisoner representative. The prisoner representative will have a close working knowledge, understanding, and appreciation of prison conditions from the perspective of the prisoner. This IRB member will conduct their review with a focus on the unique protections required for research involving prisoners.

In addition to the approval criteria applicable to all human participant research, the IRB will only approve research involving prisoners if it meets the following seven criteria:

1. The research under review represents one of the permissible categories of research involving prisoners under federal regulations (45 CFR 46.306(a)(2)). Normally, the DF/HCC IRB will only consider research that falls into the following category:
    - Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participants. In cases where those studies require the assignment of prisoners, in a manner consistent with protocols approved by the IRB, to control groups that may not benefit from the

research,[1] the study may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of the intent to approve such research.

2. Any advantages that prisoners will obtain as a result of participating in the research, when compared to general living conditions within the prison, are not so great as to impair the prisoner's ability to weigh the risks and benefits of participation and freely choose whether to participate.
3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers (usually demonstrated by enrolling non-prisoner subjects from the community, as well).
4. Procedures for selecting participants within the prison are fair, and free from arbitrary manipulation by prison authorities or other prisoners.
5. The information presented during recruitment and consent procedures is in a language, and level of complexity, understandable to the participant population.
6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and prisoners are clearly informed in advance that participation in the research will have no effect on their parole.
7. If 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 of individual prisoners' sentences, and for informing participants of this fact.

DHHS Authorization

For research supported by the DHHS, review and approval from DHHS is required before prisoners may participate in the research. If the IRB approves the research involving prisoners as participants, it will require DHHS approval as an activation requirement. OHRS will submit the required documentation to DHHS, and will notify the study team when it receives a letter from DHHS approving or disapproving the research.

After the Prisoner-Participant is Enrolled

The study team must report to OHRS when an incarcerated participant is no longer incarcerated and/or when they are removed from the study. This should be submitted using the Major Deviation/Violation/Exception Form.

Please contact OHRS for further information relating to the inclusion of prisoners in research.

[1] "Control groups which may not benefit from research" include a control group receiving standard of care that the prisoner would otherwise receive, services as usual, or a placebo.