Research with Prisoners

Steps:

1) IRB must include a prisoner/prisoner rep. IRB member in the review process as a reviewer.
2) IRB must find that the research falls into one of the 4 categories and make 6 additional findings
3) IRB submits Certification Letter to DHHS Secretary (see OHRP website for what to include).
4) OHRP will review and send back an Authorization Letter.
5) The PI can begin research.
6) Amendments & continuation need to be reviewed by the prisoner/prisoner rep IRB member.

7 Findings That Must Be Met: (see steps 4-8 under unexpected)

1) Pick a category: the research under review represents one of the categories of research permissible (*see below*) under 45 CFR 46.306(a)(2). **#1 or #4** likely chosen for participant who unexpectedly becomes a prisoner.

2) Any 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 earnings 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.

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

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. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.

5) The information is presented in language which is 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 each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole

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 of individual prisoners' sentences, and for informing participants of this fact.

Note: If participant unexpectedly becomes a prisoner, the IRB might note N/A for some of the findings

4 Categories and a Waiver: (Pick One)

(1) Study of the possible causes, effects, & processes of incarceration or criminal behavior, provided that the study is no more than minimal risk and no more than inconvenience to the participants;
(2) 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 participants;
(3) Research on conditions particularly affecting prisoners as a class (e.g., hepatitis, alcoholism, drug addiction, sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts (penology, medicine, and ethics) and published notice in the Federal Register of his/her intent to approve such research;

(4) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. 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 has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research; or
(5) The HHS Secretarial Waiver for certain epidemiological research conducted or supported by HHS: The research must have sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease. All requirements of subpart C apply. The institution still must review the research under subpart C and certify to OHRP and receive OHRP authorization prior to initiating any research involving prisoners.

The Definition of Minimal Risk for Prisoners:
The probability and magnitude of **physical or psychological harm** that is normally encountered in the daily lives, or in the routine medical, **dental,** or psychological examination of **healthy persons.**
Note: the prisoner/ prisoner rep must concur that it is minimal risk.

Expedited:
OHRP recommends that if possible, all research involving prisoners receive full-board review. If reviewing via expedited review, the prisoner or prisoner representative must be one of the reviewers (unless it is a retrospective chart review or research that does not involve interactions with prisoners).

What to Do When a Participant Unexpectedly Becomes a Prisoner

3 Options:

1) Retain participant and have IRB review the research for subpart C (If it is DHHS funded/supported or if you are applying the FWA & subpart C to all research).
2) Withdraw participant from the study.
3) Stop all research activities with the participant and then resume activities after the participant has concluded his/her prisoner status.

Steps:

7) PI must notify the IRB immediately. UP report
8) PI must immediately stop all research activities with the participant who became a prisoner and stop obtaining identifiable info. Exception: If it is in the participant's best interest and safety to continue in research. If IRB Chair concurs, then part. continues while Subpart C is reviewed.
9) PI gets prison's permission and submits an amendment to the IRB.
10) IRB must include a voting prisoner/prisoner rep. IRB member in review process as a reviewer.
11) IRB must find that the research falls into one of the 4 categories and make 6 additional findings (some may need to be recorded as *N/A* to OHRP for part. who unexpected became a prisoner)
12) IRB submits Certification Letter to DHHS Secretary (see OHRP website for what to include).
13) OHRP will review and send back an Authorization Letter. The PI can, at this point, resume research with the participant who became a prisoner.
14) Amendments and continuations need to be reviewed by the prisoner/prisoner rep IRB member.

Excellent Go-To Website Resources:
OHRP: Prisoner Research FAQs, Guidance document, Prisoner Research Certification document
AAHRPP Prisoner Research Tip Sheet 18
45 CFR 46, subpart C 46.301-.306