OHRP Prisoner Frequently Asked Questions

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Question 1: Are there additional regulatory considerations for research involving prisoners?

Answer: Yes. In addition to the requirements of subpart A, subpart C of the HHS regulations at 45 CFR part 46 identifies more requirements for research involving prisoners. In summary, the major additional considerations are:

- the exemptions that generally apply to certain types of research involving human subjects do not apply to research involving prisoners (45 CFR 46.101, footnote 1);
- in order to approve research involving prisoners, the IRB must find that the proposed research falls into one of the permissible categories of research, and make six other findings;
- the institution must certify to OHRP that an IRB has reviewed the proposal and made seven required findings, and receive OHRP authorization prior to initiating any research involving prisoners; (45 CFR 46.305(c))
- the IRB must include a prisoner or prisoner representative, (45 CFR 46.304(b)) and meet a membership requirement concerning the number of IRB members not associated with a prison involved in the research; (45 CFR 46.304(a))and
- Secretarial waiver of informed consent in certain emergency research is not applicable to research involving prisoners (61 FR 51531, October 2, 1996)

Question 2: How do the regulations define "prisoner"?

Answer: The regulations define "prisoner" as follows:

> "Prisoner" means 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 (45 CFR 46.303(c)).

Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.

Common examples of the application of the regulatory definition of prisoner are as follows:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.
- Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness,

or who have been civilly committed to nonpenal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.

- Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.
- Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Institutions may consult with OHRP when questions arise about research involving these populations.

Question 3: When is an institution "engaged" in research involving prisoners?

Answer: In general, an institution is considered engaged in a particular human subjects research proposal involving prisoners when its employees or agents, for the purposes of the research proposal, obtain: (1) data about the prisoner subjects through intervention or interaction with them; or (2) identifiable private information about the prisoner subjects.

Some examples of activities that would make an institution engaged in human subjects research involving prisoners are: (1) seeking the informed consent of prisoners to be subjects in research; (2) using, studying or analyzing, for research purposes, identifiable private information about prisoners, or identifiable specimens obtained from prisoners; and (3) surveying prisoners for a research study.

In addition, institutions generally become engaged in research involving prisoners if they are the primary awardee of HHS funds to conduct such research, even where all activities involving prisoner subjects are carried out by agents or employees of another institution.

Question 4: Do the exemptions apply to research involving prisoners?

Answer: No. None of the exemption categories in the HHS regulations for research involving human subjects at 45 CFR 46.101(b) apply to research involving prisoners (45 CFR 46.101(i), Footnote 1).

Question 5: What are the categories for permissible research involving prisoners?

Answer: Research involving prisoners is permissible only if the research involves one or more of four permissible categories, or if the research meets the criteria described in an HHS Secretarial waiver that applies to certain epidemiological research (68 FR 36929, June 20, 2003):

- The first two categories are (i) the study of the possible causes, effects, and processes of incarceration, and of criminal behavior, and (ii) the study of prisons as institutional structures or of prisoners as incarcerated persons. Research in these two categories is permissible only if the study

presents no more than minimal risk, and no more than inconvenience to the subjects (45 CFR 46.306(a)(2)).

- The third category (iii) is research on conditions particularly affecting prisoners as a class; the regulations list as examples 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 addition, and sexual assaults. Research in this category 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 his or her intent to approve the research (45 CFR 46.306(a)(2)).
- The fourth category (iv) is research on practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In this category, if the IRB-approved proposal is a study in which some prisoners will be assigned to a control group and these prisoners may not benefit from their participation in research, such research 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 his or her intent to approve the research (45 CFR 46.306(a)(2)). OHRP interprets control groups which may not benefit from research to include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo.
- The HHS Secretarial waiver for certain epidemiological research conducted or supported by HHS functions as a fifth category of permissible research. The criteria for this category are that the research must have as its 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. The institution still must review the research under subpart C and certify to OHRP that an appropriately constituted IRB has reviewed the proposal and made all other required findings under HHS regulations at 45 CFR 46.305(a) and receive OHRP authorization prior to initiating any research involving prisoners. All of the other requirements of subpart C apply to research in this category.

You may wish to view the following related question and answer:

Does research involving prisoners not conducted or supported by HHS require Secretarial consultation?

Question 6: Does research involving prisoners not conducted or supported by HHS require Secretarial consultation?

Answer: No. Research proposals in category (iii) or (iv) that are not conducted or supported by HHS do not require a Secretarial consultation, nor do they require certification to OHRP.

Question 7: What are the certification requirements for research involving prisoners?

Answer: For any HHS-conducted or -supported research involving prisoners, the institution(s) engaged in the research must certify to the Secretary (through OHRP) that the IRB reviewed the research and made seven findings as required by the regulations (45 CFR 46.305(c) and 46.306(a)(1)). The certification request must be forwarded to OHRP. OHRP then will determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2), and if so which one. Following its review of the certification, OHRP will send the institution a letter authorizing the involvement of prisoners in the proposed research, if OHRP determines that the research involves one of the permissible categories.

OHRP (on behalf of the Secretary of HHS) will consult with appropriate experts with respect to certain research that falls under paragraphs (iii) and (iv) of 45 CFR 46.306(a)(2). When applicable, OHRP (on behalf of the Secretary of HHS) also will publish a notice of intent to approve such research in the Federal Register. Research involving prisoners may proceed only after receipt of the OHRP authorization letter.

If OHRP determines that the proposed research does not involve one of the permissible categories, it will state in the letter to the institution that such research involving prisoners cannot proceed.

You may wish to view the following related questions and answers:

What materials and information should be sent to OHRP for certification of research involving prisoners?

What happens if an IRB chooses the wrong category of research involving prisoners in its certification to OHRP?

Does research involving prisoners not conducted or supported by HHS require certification?

If a study involving prisoners previously authorized by OHRP is amended, does the institution need to recertify?

If multiple institutions are engaged in the same research study involving prisoners, do all institutions need to certify to OHRP?

Question 8: What materials and information should be sent to OHRP for certification of research involving prisoners?

Answer: The institution's certification must indicate that the IRB reviewed the research under subpart C and made the seven findings as required by the regulations (45 CFR 46.305(a)).

Under its authority at 45 CFR 46.115(b), OHRP also requires the responsible institution to submit a copy of the research proposal so OHRP can determine

whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2), and if so, which one. The term "research proposal" includes:·

- the IRB-approved protocol;any relevant HHS grant application or proposal;
- any IRB application forms required by the IRB;
- and any other information requested or required by the IRB to be considered during initial IRB review.

OHRP also encourages the institution to include the following information in its prisoner research certification letter to facilitate processing:

- the OHRP Federalwide Assurance (FWA) number;
- the IRB registration number for the designated IRB; and
- the date(s) of IRB meeting(s) in which the protocol was considered, including a brief chronology that encompasses:
    - the date of initial IRB review; and
    - the date of subpart C review, if not done at the time of initial IRB review.

Question #9: What happens if an IRB chooses the wrong category of research involving prisoners in its certification to OHRP?

Answer: If OHRP's review of the certification materials leads to the conclusion that the IRB incorrectly applied the categories of permissible research to the research protocol under consideration, OHRP has the authority to re-categorize the study to the appropriate category. OHRP will inform the institution of this action by letter. If the research does not fit any of the permissible categories of research, OHRP will inform the institution that the research cannot involve prisoners.

Question 10: Does research involving prisoners not conducted or supported by HHS require certification?

Answer: No. If research is not HHS-conducted or -supported, the institution does not need to submit any certification to OHRP, regardless of whether the institution has chosen to extend the applicability of its FWA and subpart C to all research.

Question 11: If a study involving prisoners previously authorized by OHRP is amended, does the institution need to recertify?

Answer: Usually not. OHRP should be notified only if there is a fundamental change in the research that alters the applicability of the approved category under 45 CFR 46.306.

Question 12: If multiple institutions are engaged in the same research study involving prisoners, do all institutions need to certify to OHRP?

Answer: Each institution engaged in a multicenter research study involving prisoners must certify to OHRP in accordance with the requirements of HHS regulations at 45 CFR 46.305(c) and 46.306(a)(1), unless (a) an institution relied upon the review

of an IRB operated by another institution engaged in the research; and (b) that IRB or the other institution certified to OHRP on behalf of both institutions.

Question 13: What conditions must be met for an IRB to approve research involving prisoners?

Answer: Along with the requirements of subpart A, an IRB must make the following seven additional findings required by the regulations in order to review and approve research involving prisoners:

1. The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2);
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 receiving such advantages in the limited-choice prison environment is impaired;
3. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides the IRB with written justification for following some other procedures, control subjects must be selected randomly from the group of available prisoners that meet the characteristics needed for that particular research proposal;
5. The information is presented in language that is understandable to the subject 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; and
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 (45 CFR 46.305(a)).

OHRP notes that in order to make some of these seven findings and meet the requirements of subpart A of 45 CFR part 46, the IRB must be familiar with the specific conditions in the local prison(s) or jail site(s) that are pertinent to subject protections, before approving the proposal for the local site (45 CFR 46.107(a)).

Question 14: What are the IRB composition requirements for review of research involving prisoners?

Answer: In addition to satisfying the requirements of 45 CFR 46.107, when an IRB reviews a proposal involving prisoners as subjects, the composition of the IRB must satisfy the following regulatory requirements at 45 CFR 46.304(a) and (b):·

- A majority of the IRB (exclusive of prisoner members) shall have no

association with the prison(s) involved, apart from their membership on the IRB.
- At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research proposal is reviewed by more than one IRB, only one IRB need satisfy this requirement.

The IRB must meet these composition requirements for all types of review by the convened IRB, including initial review, continuing review, and review of amendments.

OHRP recommends that a prisoner representative have a close working knowledge and understanding and appreciation of prison conditions from the prisoner's perspective.

You may wish to view the following related question and answer:

How should institutions list prisoner or prisoner representative members on their IRB registration roster?

Question 15: How should institutions list prisoner or prisoner representative members on their IRB registration roster?

Answer: Institutions registering IRBs with members who are prisoners or prisoner representatives should follow the instructions on the OHRP website for registering IRBs. If the IRB frequently reviews research involving prisoner research, the IRB registration should identify each IRB member who is a prisoner or prisoner representative simply by inserting a note in the Comment section for that member. If the IRB infrequently reviews prisoner research, OHRP suggests the following alternatives when submitting an IRB registration:

- Register two IRBs, annotating the name of the IRB with the prisoner representative, for example “Prisoner Research.” This roster would only be invoked and used to determine quorum when the IRB is reviewing a study covered by subpart C of 45 CFR part 46. The assurance should list both IRBs; or
- Register one IRB with the prisoner representative and add a "Comment" to the IRB roster identifying the voting member who is the prisoner representative and stipulating that the prisoner representative will only count towards quorum when he or she is in attendance and reviewing studies covered by subpart C.

Question 16: Can research involving prisoners be approved under expedited review?

Answer: Yes. However, because of the vulnerability of prisoners, OHRP recommends that all research involving prisoners be reviewed by the convened IRB. If the research is reviewed under the expedited review procedure, OHRP recommends that the IRB member(s) reviewing the research include a prisoner or prisoner

representative. OHRP's website includes guidance on the use of expedited review procedures and the list of expedited review categories.

Question 17: How do the regulations define "minimal risk" for research involving prisoners?

Answer: For research involving prisoners, the regulations at subpart C of 45 CFR part 46 define "minimal risk" as follows:

> Minimal risk is 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 (45 CFR 46.303(d)).

The wording of the subpart C definition differs in several ways from the definition of "minimal risk" in subpart A of 45 CFR part 46, which applies generally to research involving human subjects. The differences are:

- The subpart C definition refers to "physical or psychological harm" rather than "harm or discomfort" as in subpart A.
- The subpart C definition compares the probability and magnitude of harm in the research to the probability and magnitude of those harms normally encountered in daily life, or in "routine medical, dental, or psychological examinations," rather than in daily life or "routine physical or psychological examinations or tests" as in subpart A.
- The subpart C definition identifies "healthy persons" as the comparison group against which the risks of the research should be measured, rather than leaving the comparison group unspecified, as in subpart A. OHRP interprets the term "healthy persons" in this definition as referring to healthy persons who are not prisoners.

Question 18: Can informed consent be waived or altered in research involving prisoners?

Answer: Yes. So long as the appropriately constituted IRB reviews the research and makes the appropriate findings regarding the waiver or alteration of informed consent requirements, research involving prisoners may be approved with a waiver or alteration of informed consent. However, even if informed consent is waived or altered, subpart C of 45 CFR part 46 still requires that the subjects be clearly informed in advance that participation in the research will have no effect on their parole, if such notification is relevant. (45 CFR 46.305(a)(6)).

Note that prisoners cannot be involved in emergency research where the requirement for informed consent has been waived by the Secretary under the authority of 45 CFR 46.101(i).

Question 19: What happens if a human subject becomes a prisoner during the course of a research study?

Answer: If a human subject involved in ongoing research becomes a prisoner during the course of the study, and the relevant research proposal was not reviewed and approved by the IRB in accordance with the requirements for research involving

prisoners under subpart C of 45 CFR part 46, the investigator must promptly notify the IRB. All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must be suspended immediately, except as noted below. Upon receipt of the investigator's report that a previously enrolled research subject has become a prisoner, if the investigator wishes to have the prisoner subject continue to participate in the research, the IRB must promptly re-review the proposal in accordance with the requirements of subpart C, and the institution(s) engaged in the research involving the prisoner subject must send a certification to OHRP and wait for a letter of authorization in reply. Otherwise, the prisoner subject must stop participating in the research, except as noted below.

OHRP allows one important exception to the requirement that all research interactions or interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must cease until the regulatory requirements for research involving prisoners are met. In special circumstances in which the investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the subject may continue to participate in the research until the requirements of subpart C are satisfied. The investigator must promptly notify the IRB of this occurrence, so that the IRB can re-review the study. Note that in these circumstances, some of the findings required by 45 CFR 46.305(a) may not be applicable; for example, the finding required under 45 CFR 46.305(a)(4) regarding the selection of subjects within the prison may not be applicable, if the subject was recruited outside of an incarcerated context. The IRB should document findings of non-applicability accordingly.

Question 20: Can subpart C be applied to research in anticipation of some subjects being or becoming prisoners?

Answer: Yes. If investigators anticipate that some of the subjects in a planned research study population are likely to be prisoners or become prisoners during the course of the study (for example, subjects in substance abuse treatment studies) the IRB may review the research prospectively for prisoner involvement in accordance with the requirements of subpart C of 45 CFR part 46. When an IRB reviews a research proposal in which the subjects are not prisoners, but in anticipation of the likelihood that some of the subjects will become prisoners during the course of the research, some of the seven findings required by 45 CFR 46.305(a) may not be applicable. As examples, if subjects are not recruited from within a prison, the finding under 45 CFR 46.305(a)(4) would not be applicable; and, if there is no particular parole board involved yet, the finding under 45 CFR 46.305(a)(6) would not be applicable. The IRB should document these findings accordingly, and must certify the research to OHRP. The IRB must wait for OHRP to authorize the research study prior to initiating any interaction or intervention with, or obtaining identifiable private information about, prisoners.

IRBs should use their discretion in deciding whether to apply the additional

requirements of subpart C to research in anticipation of some subjects being or becoming prisoners. In some cases, the involvement of subjects who may be prisoners or become prisoners can be anticipated in ways that make the additional protections of subpart C meaningful. In other cases there may be insufficient information available at that time to make the seven findings required by 45 CFR 46.305(a) (for example, the IRB may not know the specific penal institutions where subjects will be prisoners and therefore will lack important information about the local research context), and the IRB may have to wait until more specific information becomes available. In these instances, the IRB would need to conduct the subpart C review after research subject(s) have become incarcerated.