RESEARCH INVOLVING PRISONERS

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DEFINITIONS AND EXAMPLES

The DUHS IRB reviews and approves research involving prisoners in compliance with 45 CFR 46 Subpart C and other applicable regulations and laws. The provisions of Subpart C apply whenever the research targets prisoners as subjects, or whenever a human subject becomes a prisoner after a research study has commenced. In the case of an adolescent detained in a juvenile detention facility, the provisions of Subpart C apply, and if the adolescent is a minor as defined by NC state law, the provisions of Subpart D apply.

A *prisoner* is defined as a person who is 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.

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 non-penal 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.

All prisoners are regarded as being vulnerable to coercion or undue influence and therefore need additional safeguards to protect their rights and welfare as research participants. These additional safeguards are described below.

IRB REVIEW

When reviewing research involving a prisoner, the IRB must satisfy all general requirements of 45 CFR 46 and, as applicable, 21 CFR 50 and 56 and other FDA regulations and guidance, plus the following:

- 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 shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

The IRB must meet the special composition requirements noted above for all types of review of protocols involving prisoners, including initial review, continuing review, review of protocol amendments, and review of reports of unanticipated problems involving risks to subjects or others.

In addition, the IRB notes that:

- None of the exemption categories in DHHS regulations for research involving human subjects at 45 CFR 46.101(b) apply to research involving prisoners (45 CFR 46.101(i), Footnote 1).
- Prisoners cannot be involved in planned emergency research (OHRP [OPRR] Report 97-01) where the requirement for informed consent has been waived by the Secretary of DHHS under the authority of 45 CFR 46.101(i).
- For a planned emergency research study that is subject to both FDA and DHHS regulations, the study may not involve prisoners as subjects (61 Fed. Reg. 51531).

The IRB will review research involving prisoners and approve such research only if it finds that each of the following seven (7) conditions is met and documents the protocol-specific findings supporting that conclusion for each condition:

1) The research under review represents one of the categories of research permissible under §46.306(a)(2)
    a. Study of (i) the possible causes, effects, and processes of incarceration, and of criminal behavior, and (ii) prisons as

institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk (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 who are not prisoners) and no more than inconvenience to the subjects;

b. Research on conditions particularly affecting prisoners as a class (for example, 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 addiction and sexual assaults) provided that the study may proceed only after the HHS Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his or her intent to approve such research; or
c. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which the study requires the assignment of prisoners to a control group that may not benefit from the research, the study may proceed only after the HHS Secretary (through OHRP) has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research. Control groups which may not benefit from research include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo.
d. The DHHS Secretarial waiver for certain epidemiological research conducted or supported by DHHS (68 FR 36929, June 20, 2003) that presents no more than minimal risk and no more than inconvenience to the prisoner-subjects. Such 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.

[Note that if any of the above research is to be conducted or supported by DHHS, it may involve prisoners as subjects only if:

- the DUHS Institutional Official or his/her designee has certified* to the Secretary of DHHS (through OHRP) that the IRB has approved the research under §46.305, and
- in the judgment of the Secretary (through OHRP), the proposed research involves solely one of the above categories of research permissible under §46.306(a)(2).

[Note that research proposals in category b. or c. that are not conducted or supported by DHHS do not require a Secretarial consultation, nor do they require certification to OHRP.]

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 subjects 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 with justification in writing for following some other procedures, control subjects 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 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.

In order to both conclude that the above 7 conditions are met and satisfy the requirements of 45 CFR 46 Subpart A, the IRB must be familiar with the specific conditions in the local prison(s) or jail site(s) where the research will be conducted before approving the research for implementation at the site(s).

*Certification by the Institutional Official (or his designee) for research conducted or supported by DHHS will indicate that the IRB reviewed the research under Subpart C and made the seven (7) findings as required by the regulations. The certification request will include:

- the OHRP Federal-wide 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.

Appended to the certification will be:

- the IRB-approved protocol and any relevant DHHS 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 the initial IRB review.

In the event of a change in the study, OHRP will be notified if there is a change in the research that alters the applicability of the approved category under 45 CFR 46.306.

The IRB notes that OHRP guidance titled “Prisoner Research - FAQs” includes the following: “Can research involving prisoners be approved under expedited review? 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.

EXPEDITED REVIEW OF RESEARCH INVOLVING PRISONERS

In cases where a greater-than-minimal risk study involving prisoners qualifies for expedited annual review under categories 8a, 8b, or 8c, the study may be reviewed by the expedited process only if an IRB prisoner representative participates in the expedited review. This review may occur within the IRB’s review software, iRIS, or via email with the prisoner representative’s full access to the study record in iRIS. In the case of the latter, the prisoner representative may return his/her written review via email to the IRB office for uploading into the study record in iRIS. This review should become part of the iRIS study record before the assigned Primary Reviewer completes his/her expedited review and approval is issued.

In cases where the study is minimal risk, annual review must still occur with participation by the prisoner representative via the process outlined in the above paragraph.

Likewise, review by the prisoner representative as described above must be utilized for any amendments that qualify for expedited review where the study is approved for prisoners as study participants.

ADDITIONAL CONSIDERATIONS:
IF A RESEARCH SUBJECT BECOMES A PRISONER

If a human subject involved in ongoing research becomes a prisoner during the course of the study, and the research proposal was not reviewed and approved by the IRB for prisoner participation (in accordance with 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 notice of authorization in reply. Otherwise, the prisoner subject must stop participating in the research, except as noted below.

- If the incarcerated subject cannot be terminated for health or safety reasons, as asserted by the investigator, 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.

- Soliciting information from the parents or spouse, rather than the incarcerated subject, for information about the subject's behavior and attitudes would constitute "obtaining identifiable private information about" the incarcerated subject, and would invoke subpart C.

- During detention, the subject does not have to be formally withdrawn; as long as there is no interaction/intervention/obtaining with the subject while incarcerated - see above- subpart C is not invoked. Therefore, there is no need to withdraw and re-enroll. If the investigator can wait until the person is no longer incarcerated, subpart C is never an issue.

- Data that had been acquired prior to incarceration may continue to be analyzed.

Important considerations for the inclusion of prisoners in research include the following:

- Will the prisoner have access to necessary follow-up care?
- Will the prisoner have the ability to contact the study team or IRB during the course of the study without penalty or cost to himself/herself?
- Has the inclusion of the prisoner met the review requirements of the federal or state prison in which he/she is confined?
- If compensation is offered to study participants, is there wording in the consent form that compensation to the prisoner will be at the discretion and direction of prison authorities?
- Does the consent form make it clear that participation will have no effect on parole?

For research funded by the Department of Defense, see the policy titled “Research Supported by a Department of Defense (DOD) Component” and the section titled “Research Involving Vulnerable Populations”.

WAIVER OF THE CONSENT PROCESS

Informed consent can be waived or altered in research involving prisoners. As 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)).

ENGAGEMENT IN RESEARCH INVOLVING PRISONERS

In general, an institution is considered engaged in a particular human 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.

AMENDING AN ACTIVE PROTOCOL APPROVED FOR THE INCLUSION OF PRISONERS

If a study involving prisoners previously authorized by OHRP is amended, DUHS does not have to recertify with DHHS. However, if there is a fundamental change in the research that alters the applicability of the approved category under 45 CFR 46.306, OHRP should be notified.

RESEARCH IN ANTICIPATION OF SOME SUBJECTS BEING OR BECOMING PRISONERS

If an investigator anticipates 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. For example, 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. The IRB will use its 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.

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