Research Involving Prisoners

SOP 124
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Purpose and Scope

If research involves prisoners, subpart C of 45 C.F.R. part 46 will be followed. The incarceration could affect the Prisoners' ability to make a truly voluntary decision on whether to participate as subjects in research. To protect prisoners' rights and welfare, the Investigator and the IRB should take extra measures to meet the ethical and regulatory requirements on research involving prisoners.

This SOP outlines the procedures for reviewing and reporting research involving incarcerated participants.

Procedures

Review Procedures

Presence of a Prisoner or Prisoner Representative

A prisoner or prisoner representative must be present as a voting member when the convened IRB reviews research involving prisoners, including initial review, continuing review, review of protocol modifications, and review of unanticipated problems.

Full-Board Review

1. The categories of exempt studies are not applicable to research involving prisoners.[1]
2. Expedited review procedures will not be used in reviewing such research.[2]
3. A convened IRB will review research involving prisoners.

When a Human Subject Becomes a Prisoner During the Course of a Study

If a subject involved in ongoing research becomes a prisoner during the course of the study, and the study was not reviewed and approved by the IRB in accordance with subpart C of 45 C.F.R. part 46:

1. the Investigator must promptly notify the IRB;
2. 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; and

[1] See 45 C.F.R. §§ 46.305(a)(1), 46.306(a)(2).
[2] See Guidance on Expedited Review Procedures, OHRP (Aug. 11, 2003), http://www.hhs.gov/ohrp/policy/exprev.html.

3. upon receipt of the Investigator's notification that a previously enrolled subject has become a prisoner, if the Investigator wishes to have the subject continue to participate in the research, the IRB must promptly re-review the proposal in accordance with subpart C, and the institution engaged in the research must certify to OHRP and wait for a letter of authorization in reply (see the section below for certification requirements). The prisoner subject must cease participating in the research before the receipt of the authorization letters, except as noted below.[3]

Exception: If the Investigator asserts that it is in the best interest of the subject to remain in the 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 C.F.R. § 46.305(a) may not be applicable: for example, the finding required under 45 C.F.R. § 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.

Reporting Procedures

Certification Requirement if Research Supported by HHS

For HHS-conducted or –supported research involving prisoners, two actions must occur before the research may proceed:

1. The institution engaged in the research must certify to the OHRP that the IRB has reviewed and found that the seven requirements under 45 C.F.R. § 46.305(a) (see below) have been met; and
2. After reviewing the certification provided by the institution and consulting with appropriate experts, OHRP approves the research and send the institution a letter authorizing the involvement of prisoners in the research.[4]

The Human Studies Program Director is responsible for certifying to OHRP the duties of the IRB have been fulfilled.

Required Findings Under Section 46.305(a)

The required seven findings under 45 C.F.R. § 46.305(a) are as follows[5]:

1. The research under review represents one of the categories of research permissible under 45 C.F.R. § 46.306(a)(2);
2. When compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, any possible advantages accruing to the prisoner through his or her participation in the research are not of such a magnitude that his or her ability is impaired in weighing the risks of the research against the value of such advantages in the limited choice environment of the prison;
3. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
4. Procedures of selecting subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal Investigator justifies some other procedures in writing to the IRB, control subjects must be selected

[3] Prisoner Research, Frequently Asked Questions, HHS, Question 19, http://www.hhs.gov/ohrp/policy/prisonerfaqsmar2011.pdf (last visited May 28, 2014) [hereinafter Prisoner Research – FAQ].
[4] Id. at Question 7.
[5] 45 C.F.R. § 46.305(a).

randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. The information is presented in language 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. When the IRB finds that participants need follow-up examination or care after the end of their participation, the Investigator has adequately addressed such examination or care, taking into account the varying lengths of individual prisoners' sentences, and the Investigator will inform participants of this fact.

The Certification to HHS

In the certification sent to HHS, the HSP must[6]:

1. indicate that the IRB reviewed the research under subpart C and made the seven findings under 45 C.F.R. § 46.305(a); and
2. include a copy of the research proposal, where the research proposal includes:
   (a) the IRB-approved protocol; any relevant HHS grant application or proposal;
   (b) any IRB application form required by the IRB; and
   (c) any other information requested or required by the IRB during initial IRB review.

And the HSP should include:

1. the OHRP FWA number;
2. the IRB registration number of the designated IRB; and
3. the dates of IRB review.

If Research Not Supported by HHS

If an Investigator conducts research involving prisoners not supported by HHS, certification to HHS is not required but the rest of the policies and procedures regarding research involving prisoners still apply to the research.

Prisoners Who Are Minors

When a prisoner is also a minor, e.g., an adolescent detained in a juvenile detention facility as a prisoner, the additional protections regarding children in research in subpart D of 45 C.F.R. part 46 also apply.[7]

Federal Bureau of Prisons

The Federal Bureau of Prisons places additional restrictions on research that takes place within the Bureau of Prisons.[8] Investigators should review the regulations at 28 C.F.R. part 512 when considering

[6] Prisoner Research – FAQs, supra note 4 at Question 8.
[7] OHRP Guidance on the Involvement of Prisoners in Research, HHS, 7 (May 23, 2003), http://www.hhs.gov/ohrp/policy/prisoner.pdf.
[8] 28 C.F.R. §§ 512.10–512.19 (2013), available at http://www.gpo.gov/fdsys/pkg/CFR-2002-title28-vol2/pdf/CFR-2002-title28-vol2-part512.pdf.

such research.

Materials

- APP 04 New Research Protocol/ Proposal for Initial Approval – Non-Exempt
- WKSH 303 Non-Exempt Reviewer Worksheet
- WKSH 357 Quorum and Expertise
- GUIDE 629 Vulnerable Populations

References

- 45 CFR 46 (Subpart C)
- 45 CFR 46 (Subpart D)
- 28 CFR 512
- AAHRPP Element II.4.A.
- AAHRPP II.4.B.
- AAHRPP Element III.1.C.