Frequently Asked Questions
Prisoners in Research (Guidance from OHRP)

1. Does subpart C apply only where the research targets prisoners as subjects?

No, subpart C applies whenever any human subject in a research protocol becomes a prisoner at any time during the study.

2. What should an investigator do if a subject becomes a prisoner after enrollment in research?

The investigator should report this situation to the IRB immediately.

3. What should be done when a subject becomes a prisoner after enrollment in a study which was not reviewed and approved by the IRB in accordance with the requirements of subpart C?

When a previously enrolled research subject becomes a prisoner and the relevant research protocol was NOT reviewed and approved by the institutional review board (IRB) in accordance with the requirements of subpart C, the principal investigator should promptly notify the IRB of this event. All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must cease until the requirements of subpart C have been satisfied with respect to the relevant protocol.

NOTE: OHRP has allowed one important exception. In special circumstances in which the principal investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research until the requirements of subpart C are satisfied.

Upon receipt of notification that a previously enrolled research subject has become a prisoner, the IRB should promptly re-review the protocol in accordance with the requirements of subpart C if the principal investigator wishes to have the prisoner subject continue to participate in the research.

It is important that the IRB remind the principal investigator that, except in the special circumstances noted above, all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must cease until all of the requirements of subpart C have been satisfied with respect to the relevant protocol.

4. Is an adolescent (e.g., age 14) detained in a juvenile detention facility a prisoner?

Yes. In addition to subpart C, most likely subpart D (Protections for Children) would also apply.

5. Can research involving prisoners be expedited?

Yes, however, OHRP recommends that the convened IRB review research involving prisoners as human subjects.

6. Do the exemptions apply to research involving prisoners?

The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners. See 45 CFR 46.101(i), footnote 1.