



## SOP: Unexpected Incarceration

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### 1. PURPOSE

- 1.1. This procedure establishes the process to manage unexpected incarcerations of subjects.
- 1.2. This procedure begins when an IRB receives information that a subject in a study not approved for involvement of prisoners as subjects has been incarcerated.
- 1.3. This procedure ends when all actions have been taken to protect the rights and welfare of the subject prior to <Committee Review>.

### 2. POLICY

- 2.1. None

### 3. RESPONSIBILITY

- 3.1. An IRB chair or the convened IRB carries out these procedures.

### 4. PROCEDURE

- 4.1. Confirm that the subject meets the definition of a <Prisoner>.
  - 4.1.1. If not, take no further action.
- 4.2. Determine whether any research procedures need to take place while the subject is a <Prisoner>.
  - 4.2.1. If none, ensure that the investigator will not perform any research procedures until the subject is no longer a <Prisoner> and take no further action.
- 4.3. Determine whether it is feasible for the subject to remain in the research.
  - 4.3.1. If it is not feasible for the subject to remain in the research, have the investigator withdraw the subject, consider the risks associated with terminating participation in the research, and implement actions as needed to protect the subject's rights and welfare, such as alternative treatment or expanded access.
- 4.4. Determine whether it is in the subject's best interests to remain in the research.
  - 4.4.1. If it is not in the subject's best interest to remain in the research, have the investigator withdraw the subject, consider the risks associated with terminating participation in the research, and implement actions as needed to protect the subject's rights and welfare, such as alternative treatment or expanded access.
- 4.5. Keep the subject enrolled in the research.
- 4.6. Have the study scheduled for <Committee Review>.
  - 4.6.1. If the study is subject to DHS, HHS, or VA regulations:
    - 4.6.1.1. Ensure the IRB is constituted to review <Prisoner> research under 45 CFR §46 Subpart C.
    - 4.6.1.2. If some 45 CFR §46 Subpart C requirements are unmet, but it is in the best interests of the subject to stay in the study, keep the subject enrolled and inform OHRP of the decision and the justification.
- 4.7. If the research is subject to DHS or HHS regulations, notify OHRP within 30 days.
- 4.8. If the research is subject to DOD regulations, notify DOD within 30 days and obtain DOD's concurrence.

### 5. REFERENCES

- 5.1. DOD Instruction 3216.02 November 8, 2011
- 5.2. OHRP Guidance: Prisoner Research - FAQs