1. PURPOSE

1.1. This procedure establishes the process to manage unexpected incarcerations of Human 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 actions have been taken to protect the rights and welfare of the subject.

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 the study is subject to DHS, DHHS, or VA regulation. If not, take the following action.
   4.2.1. Determine whether any research procedures need to take place while the subject is a Prisoner.
      4.2.1.1. 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.
   4.2.2. Determine whether it is feasible for the subject to remain in the research.
      4.2.2.1. If it is not feasible for the subject to remain in the research, consider the risks associated with terminating participation in the research. When appropriate, have the investigator withdraw the subject. Implement actions as needed to protect the subject’s rights and welfare, such as alternative treatment or Expanded Access.
   4.2.3. Determine whether it is in the subject’s best interests to remain in the research.
      4.2.3.1. If it is not in the subject’s best interest to remain in the research, consider the risks associated with terminating participation in the research. When appropriate, have the investigator withdraw the subject. Implement actions as needed to protect the subject’s rights and welfare, such as alternative treatment or Expanded Access.
   4.2.4. If it is feasible for the subject to remain in the research and it is in the subject’s best interests to remain in the research:
      4.2.4.1. Keep the subject enrolled in the research
      4.2.4.2. Reference "IRB REGULATORY GUIDANCE: Unexpected Incarceration (HRP-309)", as needed.

4.3 If subject to DHS, DHHS, or VA regulation, take the following action:
   4.3.1 Cease all interactions and interventions (including obtaining identifiable private information) with the Prisoner, unless the PI asserts that it is in the best interest of
the Prisoner to remain in the study until the requirements of subpart C are satisfied and the IRB or IRB Chair confirms that assertion.

4.3.2 Ensure appropriate review under the 45 CFR Part 46, subpart C. Reference "IRB REGULATORY GUIDANCE: Unexpected Incarceration (HRP-309)"

5. REFERENCES

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