

SOP Number: SOP CW AHC 213	SOP Name: Unexpected Incarceration
Location: *Company-Wide Policies	Responsible Department: Research Services
Executive Owner: Executive Director of Research Services	Original Creation Date: 01/18/2022
Effective Date: 04/04/2022	Review Date: 04/04/2022

- I. **SCOPE:** This standard operating procedure (SOP) applies to the Institutional Review Board (IRB) staff members at AdventHealth.
- II. **PURPOSE:** This procedure establishes the process to manage unexpected incarcerations of subjects. 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. This procedure ends when all actions have been taken to protect the rights and welfare of the subject prior to Committee Review.
- III. **QUALIFIED PERSONNEL:** IRB staff members or IRB Executive Chair carry out these procedures or ensure they are carried out by other personnel.
- IV. **TRAINING:** Not applicable
- V. **SUPPLIES & EQUIPMENT:** Not applicable
- VI. **PROCESS/PROCEDURE:**
 - A. Confirm that the subject meets the definition of a Prisoner. If not, take no further action.
 - B. Determine whether any research procedures need to take place while the subject is a Prisoner. 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.
 - C. Determine whether it is feasible for the subject to remain in the research. 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.
 - D. Determine whether it is in the subject’s best interests to remain in the research. 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.
 - E. If feasible for the subject to remain in the research and in the subject’s best interests to remain in the research:
 1. Keep the subject enrolled in the research.
 2. Use HRP-309 CHECKLIST – Unexpected Incarceration.
- VII. **DEFINITION(S):** For capitalized terms not defined in this policy, refer to CW AHC 107
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Definitions in Human Research.

For capitalized designations not defined in this policy, refer to CW AHC 103 Designations in Research.

For abbreviations not defined in this policy, refer to CW AHC 102 Abbreviations in Research.

VIII. EXCEPTION(S): See CW AHC 101 Research Oversight

IX. REFERENCE(S):
DOD Instruction 3216.02 November 8, 2011
OHRP Guidance: Prisoner Research - FAQs

X. RELATED DOCUMENT(S) / ATTACHMENT(S):

- CW AHC 107 Definitions in Human Research
- CW AHC 103 Designations in Research
- CW AHC 102 Abbreviations in Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program
- CHECKLISTS are located on the AdventHealth Research Institute website
 - o HRP-309 CHECKLIST – Unexpected Incarceration