

Standard Operating Procedure (SOP)

SOP #: 401.113	HRP-113 Unexpected Incarceration
Executive Owner: Vice President Research Operations	Effective Date: 6/11/2018
	Review Date: 09/23/2019

Scope	This standard operating procedure (SOP) applies to the HRPP staff members at AdventHealth Orlando.
Purpose	<p>This procedure establishes the process to manage unexpected incarcerations of subjects.</p> <p>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>.</p>
Qualified Personnel	HRPP staff members and/or [IRB Executive Chair] carry out these procedures or ensure they are carried out by other personnel.
Training	Not applicable.
Supplies & Equipment	Not applicable.
Procedure	<ol style="list-style-type: none"> 1. Confirm that the subject meets the definition of a <Prisoner>. <ol style="list-style-type: none"> 1.1. If not, take no further action. 2. Determine whether any research procedures need to take place while the subject is a <Prisoner>. <ol style="list-style-type: none"> 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. 3. Determine whether it is feasible for the subject to remain in the research. <ol style="list-style-type: none"> 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. Determine whether it is in the subject's best interests to remain in the research. <ol style="list-style-type: none"> 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. 5. If feasible for the subject to remain in the research and in the subject's best interests to remain in the research:

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Definition(s)	5.1. Keep the subject enrolled in the research 5.2. Use “CHECKLIST: Unexpected Incarceration (HRP-309)”
Reference(s)	IRB: Institutional Review Board HRPP: Human Research Protection Program DOD Instruction 3216.02 November 8, 2011 OHRP Guidance: Prisoner Research - FAQs
Related Documents	Not applicable.
Keywords	IRB, institutional review board, IRB member