

Standard Operating Procedure (SOP)

SOP #: 401.114	HRP-114 Suspension and Termination by the Organization
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	This procedure establishes the process to institute a <Suspension of IRB Approval> or <Termination of IRB Approval> outside of a convened IRB meeting. This procedure begins when an authorized individual institutes a <Suspension of IRB Approval> or <Termination of IRB Approval>. This procedure ends when the authorized individual has notified the HRPP staff.
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. Notify the investigator of the <Suspension of IRB Approval> or <Termination of IRB Approval> and the reasons for the action. 2. Ask the investigator for a list of currently enrolled subjects and their level of involvement in the research (e.g., active intervention or long-term follow-up.) 3. Consider whether the rights and welfare of currently enrolled subjects may be adversely affected. If so, consider the following actions: <ol style="list-style-type: none"> 3.1. Transfer subjects to another investigator 3.2. Make arrangements for clinical care outside the research 3.3. Allow continuation of some research activities under the supervision of an independent monitor 3.4. Require follow-up of subjects 3.5. Require adverse events or outcomes to be reported to the IRB 3.6. Notify current subjects 3.7. Other actions 4. Notify the HRPP staff member handling the protocol of the action to place on the agenda of a convened IRB meeting.
Definition(s)	IRB: Institutional Review Board HRPP: Human Research Protection Program
Reference(s)	DOD Instruction 3216.02 November 8, 2011 OHRP Guidance: Prisoner Research - FAQs
Related Documents	Not applicable.
Keywords	IRB, institutional review board, IRB member