Standard Operating Procedure (SOP)

SOP #: 401.111	HRP-111 Post Review	
Executive Owner: Vice President Research Operations		Effective Date: 6/11/2018 Review Date: 9/19/2019

Scope	This standard operating procedure (SOP) applies to the HRPP staff members at AdventHealth Orlando.
Purpose	This procedure establishes the process to communicate the IRB findings and actions. This procedure beings when the IRB has completed a review and ends when the IRB has communicated its findings and actions.
Qualified Personnel	HRPP staff members carry out these procedures.
Training	Not applicable.
Supplies & Equipment	Not applicable.
Procedure	A. AdventHealth Orlando does not need to directly report to a regulatory agency, if the agency has been notified by alternate mechanisms. B. OHRP does not require organizations to report <Unanticipated Problems Involving Risks to Subjects or Others>, <Serious Noncompliance>, and <Continuing Noncompliance> when unrelated to the local context. C. Calculate the <End Approval Date> following "POLICY: End Approval Date (HRP-022)". D. Complete the applicable template notification (See Table 1 in REFERENCES) or when necessary draft a unique notification. E. Update any newly approved consent document with the approval and expiration dates. D. Within 10 days of a decision send the notification to: d. The investigator e. Study contacts f. The DOD component[1] when the research involving human subjects is DOD-supported and the notification involves any of the following: i. Significant changes to the research protocol are approved by the IRB, the results of the IRB continuing review ii. A change in the IRB used to review and approve the research to a different IRB iii. Communication from any Federal department or agency or national organization informing the <Organization> that any part of its HRPP is under investigation for cause

[1] Send to the Human Research Protections Officer (HRPO) of the DOD component, which is the individual who is delegated the responsibilities as defined in paragraph (a)(2) of section 252.235-7004 of Reference (n). There may be more than one HRPO in a DOD Component. Some DOD Components may use a different title for the person(s) with the defined responsibilities.

g. Sponsor, when the notification is

i. a disapproval of a request for a waiver of the consent process for planned emergency research that is FDA-regulated (21 CFR 50.24(e)).

ii. Information that has been publicly disclosed about the initiation of a study involving a waiver of the consent process for planned emergency research that is FDA-regulated (21 CFR 50.24(7), 56.109(g)).

iii. Information that has been publicly disclosed following completion of the study involving a waiver of the consent process for planned emergency research that is FDA-regulated (21 CFR 50.24(7), 56.109(g)).

h. Other individuals or organizations, when determined to be appropriate by the [HRPP Administrator], [IRB Executive Chair], or [Organizational Official]

E. Within 10 days of a decision, the following individuals or entities must receive notification from AdventHealth Orlando or the institution where the research is being conducted, when the notification involves an <Unanticipated Problems Involving Risks to Subjects or Others>, <Serious Noncompliance>, <Continuing Noncompliance>, <Suspension of IRB Approval>, or <Termination of IRB Approval>:

i. [Organizational Official]

ii. If sponsored: Sponsor or Contract Research Organization, when the research is sponsored

iii. If funded: Office responsible for oversight of the grant or contract

iv. Legal Counsel

v. Risk Management

vi. Site Management Organization or equivalent, when the research is reviewed on behalf of such an organization.

vii. Institutional contact, when the research is associated with an institution~~:~~

viii. For unauthorized use, loss, or disclosure of individually identifiable information: Privacy Officer

ix. For violations of information security requirements: Information Security Officer

x. For research subject to regulation when reporting is required by the agency (E.g., DOD, EPA, FDA, HHS, VA)

xi. For international or collaborative research involving collaboration with a local research ethics committee or equivalent: The local research ethics committee or equivalent

xii. Additional contacts, when required by any relevant agreement

xiii. Other individuals or organizations, when determined to be appropriate by the [HRPP Administrator], [IRB Executive Chair], or [Organizational Official]

F. Make any newly approved consent documents, scripts, or assent documents available to the submitter.

Update <Regulatory Review> findings as needed.

Definition(s)

IRB: Institutional Review Board

Reference(s)

Not applicable.

Related Documents

21 CFR §50.54

45 CFR §46.207 and §46.407

21 CFR 50.24(e) and 21 CFR 56.109(g)

DOD Instruction 3216.02 November 8, 2011

Table 145 CFR §46.207 and §46.407

Notification	Template
Acknowledgement	Acknowledgement (HRP-520)
Approve (with no continuing review date)	Approval Without Expiration (HRP-521)
Approve (with continuing review date)	Approval (HRP-522)
Close	Closure Acknowledgement (HRP-523)
Modifications Required (Conditionally Approve)	Modifications Required (HRP-524)
Modifications Required to Determine Human Research Not Engaged	Modifications Required to Determine Human Research Not Engaged (HRP-525)
Modifications Required to Determine Not Human Research	Modifications Required to Determine Not Human Research (HRP-526)
Defer	Deferral (HRP-527)
Disapprove	Disapproval (HRP-528)
Expired	Expiration of Approval (HRP-529)
Human Research Not Engaged	Human Research Not Engaged Determination (HRP-530)
Lift Suspension	Lifting of Suspension (HRP-531)
Not Human Research	Not Human Research Determination (HRP-532)
Suspend	Suspension (HRP-533)
Terminate	Termination (HRP-535)
Transfer of Research to Another IRB	Transfer Acknowledgement (HRP-536)
Information Item	Information Item Report (HRP-540)

Information Item determined to be: • <Continuing Noncompliance> • <Serious Noncompliance> • <Suspension of IRB Approval> • <Termination of IRB Approval> • <Unanticipated Problems Involving Risks to Subjects or Others>	External Report (HRP-541) Internal Report (HRP-542)
Waiver of HIPAA Authorization	HIPAA Waiver of Authorization (HRP-543)
Notification to OHRP of approval of waiver of consent for planned emergency research	OHRP Notification of Emergency Waiver (HRP-550)
Request for FDA or OHRP review of Not Otherwise Approval Research	Federal Notification of Not Otherwise Approvable Research (HRP-551)
Request for NSR determined to be SR	Significant Risk Device Determination (HRP-552)
Request for OHRP certification of prisoner research	OHRP Certification of Prisoner Research (HRP-553)
Pre-Review of Emergency Use: Criteria Met	Pre-Emergency Use Criteria Met (HRP-560)
Pre-Review of Emergency Use: Criteria Not Met	Pre-Emergency Use Criteria Not Met (HRP-561)
Post-Review of Emergency Use: Criteria Met	Emergency Use Criteria Met (HRP-562)
Post-Review of Emergency Use: Criteria Not Met	Emergency Use Criteria Not Met (HRP-563)

Keywords IRB, institutional review board, IRB member