AdventHealth Orlando

Policy

Policy#: 400.070	HRP-070 Investigator Obligations in Research	
Executive Owner: Vice President of Research Operations		**Effective Date:** 6/11/2018 **Review Date:** 6/11/2018

Scope

This policy applies to all Investigators conducting <Human Research> overseen by AdventHealth Orlando.

Purpose

This policy describes the obligations of all Investigators conducting <Human Research> overseen by AdventHealth Orlando's local Institutional Review Board (IRB). For research overseen by an IRB other than AdventHealth Orlando's local IRB, investigators will follow the requirements of that IRB.

Policy

A. Research will not commence until the IRB approval letter is provided as well as all other required approvals, such as <Institutional Clearance>, radiation safety approval, biosafety approval, and approvals of departments or divisions that require approval of the use of their resources.

   1. If there are any questions about conducting research involving human subjects, contact the IRB before commencing the study.

B. Comply with all requirements and determinations of the IRB.

C. Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

D. Ensure that research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.

   1. Investigators and research staff are required to complete initial training and continuing training at least every three years.

E. Personally conduct or supervise the research.

F. Conduct the research in accordance with the relevant current protocol approved by the IRB.

G. Protect the rights, safety, and welfare of subjects involved in the research.

H. Submit proposed modifications to the IRB prior to their implementation.

   1. Do not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.

I. Submit continuing reviews when requested by the IRB.

J. Submit a continuing review to close research (end the IRB's oversight) when:

   1. The protocol is permanently closed to enrollment
   2. All subjects have completed all protocol related interventions and interactions

3. For research subject to federal oversight other than FDA:
   a) No additional identifiable private information about the subjects is being obtained
   b) Analysis of private identifiable information is completed

K. If research approval expires, stop all research activities and immediately contact the IRB.

L. Promptly report to the IRB the information items listed in "POLICY: Prompt Reporting Requirements (HRP-071)."

M. Do not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")

N. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.

O. For studies regulated by a federal department or agency, follow the additional obligations, as applicable:

1. "INVESTIGATOR GUIDANCE: Additional DOD Obligations (HRP-810)"
2. "INVESTIGATOR GUIDANCE: Additional DOE Obligations (HRP-811)"
3. "INVESTIGATOR GUIDANCE: Additional DOJ Obligations (HRP-812)"
4. "INVESTIGATOR GUIDANCE: Additional EPA Obligations (HRP-813)"
5. "INVESTIGATOR GUIDANCE: Additional ED Obligations (HRP-814)"
6. "INVESTIGATOR GUIDANCE: Additional FDA Obligations (HRP-815)"

P. For studies where ICH-GCP compliance is required, follow additional the obligations in "INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816)."

Q. Unless the IRB affirmatively approved a protocol to include the following populations, such subjects may not be enrolled:

1. Adults unable to consent
2. Children
3. Neonates of uncertain viability
4. Nonviable neonates
5. Pregnant women
6. Prisoners
7. Individuals unable to speak English

R. When consent, permission, or assent are required by the IRB ensure that they are obtained and documented in accordance with the relevant current protocol as approved by the IRB.

S. Follow AdventHealth Orlando requirements to disclose financial interests in research.

1. Disclose financial interests on submission of an initial review.
2. Disclose changes to financial interests.

a) On submission of continuing review

b) Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest that would have required disclosure on initial review

T. Retain research records (including signed consent documents) for the greater of:

1. Seven years after completion of the research;
2. The retention period required by the sponsor;
3. The retention period required by local, state, or international law; or

a) HIPAA requires signed authorizations to be retained for six years from the date signed or the date when it last was in effect, whichever is later.

The retention period required by a site that is not part of AdventHealth Orlando.

U. Employ sound study design in accordance with the standards of a discipline and design studies in a manner that minimizes risks to subjects.

V. Update the IRB with any changes to study personnel.

W. Lead investigators of a multi-site study, will ensure there is a plan to manage information that is relevant to the protection of subjects, such as <Unanticipated Problems Involving Risks to Subjects or Others>, interim results, and protocol modifications, and submit that plan to the IRB.

X. For plans to conduct community-based participatory research, contact the IRB for information about:

1. Community-based participatory research design
2. Community advisory boards
3. Subject advocates
4. Partnerships with community-based organizations

Definition(s)

For <Angle Brackets> refer to Policy 400.001 HRP-001 Definitions
For [Square Brackets] refer to Policy 400.003 HRP-003 Designations

	Human Research: Any activity that is <Human Research as Defined by HHS> or <Human Research as Defined by FDA>. **Institutional Clearance:** Action required and provided by the Office of Sponsored Programs (OSP) in order to initiate a research project. **Unanticipated Problems Involving Risks to Subjects or Others:** Information that: a) Is unexpected (inconsistent with information previously reviewed by the IRB); and b) Indicates that subjects or others are at increased risk of harm because of the research study.
Reference(s)	Electronic Code of Federal Regulation (*e-CFR*™). (June 18, 2015). 21 CFR, §50, §56: IRB Review of Research. Retrieved from: Click here and here. Electronic Code of Federal Regulation (*e-CFR*™). (June 18, 2015). 45 CFR, §46: IRB Review of Research. Retrieved from: Click here.
Related Document(s)	Not Applicable
Keywords	HRP.070