AdventHealth Orlando

Policy

Policy#: 400.010	HRP-010 Human Research Protection Program	
Executive Owner: Vice President of Research Operations		Effective Date: 6/11/2018
		Review Date: 4/15/2019

Scope

This policy applies to all employees and agents of AdventHealth Orlando conducting human subjects' research.

1. The Human Research Protection Program (HRPP) applies to:
   a. All <Human Research> in which engages AdventHealth Orlando as defined by "WORKSHEET: Engagement (HRP-422)."
   b. All <Human Research> submitted to the Institutional Review Board (IRB) for review.
2. <Human Research> may not commence until IRB approves and <Institutional Clearance> is obtained. This includes exempt research.
3. Activities that are not <Human Research> do not require IRB review unless there is uncertainty whether the activity is <Human Research>.

   Activities that are not <Human Research> may require additional review and/or approval by the Office of Sponsored Programs (OSP) or components of the Office of Research Integrity (ORI).
4. Direct questions about whether an activity (such as classroom research, quality improvement, program evaluation, or surveillance activities) represents <Human Research> to the IRB. AdventHealth Orlando provides written determinations in response to written requests.
5. Direct questions about whether an organization is engaged in <Human Research> to the IRB. AdventHealth Orlando provides written determinations in response to written requests.

Purpose

This policy establishes AdventHealth Orlando's Human Research Protection Program (HRPP) and its commitment to protect the rights and welfare of human subjects.

Policy

A. Ethical Principles

1. AdventHealth Orlando follows the ethical principles described in the report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" also known as "The Belmont Report." (see Reference 1)
2. AdventHealth Orlando applies its ethical principles to all <Human Research> regardless of support or geographic location.

   Policies and procedures applied to research conducted domestically are applied to international research.
3. The following categories of individuals are expected to abide by these ethical requirements:
   a) Investigators (whether professional or student)
   b) <Research personnel>
   c) IRB members, IRB chairs, and IRB vice-chairs

d) HRPP personnel

e) The [Organizational Official]

f) Employees and agents

4. Clinical trials will be conducted in accordance with the ethical principles in Reference 1 that have their origin in the Declaration of Helsinki and are consistent with good clinical practice and the applicable regulatory requirements.

B. Legal Requirements

1. For <Human Research as Defined by HHS> conducted, supported, or otherwise subject to regulations by a federal department or agency who is a signatory of the Common Rule, AdventHealth Orlando applies 45 CFR §46 Subpart A and all other regulations of that agency relevant to the protection of human subjects.

   a) AdventHealth Orlando applies <Pre-2018 Requirements> to all <Human Research as Defined by HHS> initially approved, waived per 45 CFR §46.101(i), or determined exempt before January 21, 2019.

   b) AdventHealth Orlando applies <2018 Requirements> to all <Human Research as Defined by HHS> conducted or supported by a federal department that is a signatory to the 2018 Common Rule initially approved, waived per 45 CFR §46.101(i), or determined exempt after January 21, 2019.

   c) AdventHealth Orlando applies <Pre-2018 Requirements> to all <Human Research as Defined by HHS> conducted or supported by a federal department that is not a signatory to the 2018 Common Rule.

   d) AdventHealth Orlando applies <Hybrid Requirements> to all other <Human Research as Defined by HHS>.

   e) AdventHealth Orlando applies all subparts of 45 CFR §46 to <Human Research as Defined by HHS> conducted or supported by DHS, HHS, or VA.

   f) AdventHealth Orlando applies 10 USC 980, Department of Defense (DOD) Instruction 3216.02, OPNAVINST 5300.8B, and SECNAVINST 3900.39D to <Human Research as Defined by HHS> conducted or supported by DOD.

   g) AdventHealth Orlando applies DOE Order 443.1A and to use "Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with the Department of Energy (DOE) Requirements" to

<Human Research as Defined by HHS> conducted or supported by DOE.

h) AdventHealth Orlando applies 28 CFR §22 and 28 CFR §512 to <Human Research as Defined by HHS> conducted or supported by Department of Justice (DOJ).

i) AdventHealth Orlando applies 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98, 34 CFR §99, and 34 CFR §356 to <Human Research as Defined by HHS> conducted or supported by ED.

j) AdventHealth Orlando applies 40 CFR §26 and EPA Order 1000.17 Change A1 to <Human Research as Defined by HHS> conducted or supported by EPA, or where the results of the <Human Research> are to be submitted to EPA.

2. For <Human Research as Defined by FDA>, AdventHealth Orlando applies 21 CFR §50 and §56.

   For research involving a clinical trial of a drug or device, the AdventHealth Orlando commits to apply the "International Conference on Harmonisation – Good Clinical Practice E6." (ICH-GCP).

3. For research conducted in other countries, AdventHealth Orlando applies all policies and procedures applied to research conducted domestically, including:

   a) Confirming the qualifications of investigators for conducting the research.

   b) Conducting initial review, continuing review, and review of modifications to previously approved research.

   c) Post-approval monitoring.

   d) Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others.

   e) Consent process and other language issues.

   f) Ensuring all necessary approvals are met.

   g) Coordination and communication with local IRBs.

4. When the laws of a local jurisdiction encompass activities not included in the definition of <Human Research>, AdventHealth Orlando complies with those laws.

5. AdventHealth Orlando prohibits payments to professionals in exchange for referrals of potential subjects ("finder's fees.")

6. This IRB reviews payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") and does not allow them unless the possibility of coercion and undue influence is minimized.

C. Components of the HRPP

1. [Organizational Official]

   a) The [Organizational Official] is the leader of the HRPP.

   b) Subject to the legal obligations of AdventHealth Orlando, the [Organizational Official] is authorized to:

      i. Allocate HRPP resources.
      ii. Appoint and remove IRB members, IRB chairs, and IRB vice-chairs
      iii. Bind HRPP policies of AdventHealth Orlando.
      iv. Determine what IRBs the AdventHealth Orlando will rely upon
      v. Disapprove, suspend, or terminate <Human Research>.
      vi. Hire and fire <HRPP personnel>.
      vii. Limit or condition privileges to conduct <Human Research>.
      viii. Determine that information represents <Serious Noncompliance>, <Continuing Noncompliance>, an <Unanticipated Problem Involving Risks to Subjects or Others>, a <Suspension of IRB Approval>, or a <Termination of IRB Approval>.
      ix. Require or recommend personnel action against employees related to <Serious Noncompliance> or <Continuing Noncompliance>.
      x. Sign IRB authorization agreements.

   c) The [Organizational Official] is responsible to:

      i. Oversee the HRPP.
      ii. Ensure the independence of the review process.
      iii. Ensure that complaints and allegations regarding the HRPP are appropriately handled.
      iv. Ensure that the HRPP has sufficient resources, including IRBs, appropriate for the volume and types of <Human Research> reviewed, so that reviews are accomplished in a thorough and timely manner.
      v. Establish a culture of compliance with HRPP requirements.
      vi. Investigate and correct allegations and findings of undue influence on the <Human Research> review process.
      vii. Investigate and correct systemic problems related to the HRPP.
      viii. Periodically review HRPP policies and procedures.
      ix. Periodically review HRPP resources.
      x. Review and sign federal assurances (FWA) and addenda.

2. All employees and agents of AdventHealth Orlando:

a) All employees and agents of AdventHealth Orlando ultimately report to the [Organizational Official] for HRPP issues.

b) All employees and agents of AdventHealth Orlando are responsible to:

i. Be aware of this policy.
ii. Be aware of the definition of <Human Research>.
iii. Consult the IRB when there is uncertainty about whether an activity is <Human Research>.
iv. Not conduct <Human Research> without IRB approval and OSP institutional clearance.
v. Report allegations of undue influence related to the HRPP.
vi. Report <Allegations of Noncompliance> or findings of <Noncompliance>.

3. IRB members and <HRPP personnel>

a) IRB members, IRB chairs, IRB vice-chairs, and <HRPP personnel> are responsible to:

i. Follow HRPP policies and procedures.
ii. Undergo initial training, including training on specific federal agency requirements (e.g., DOD) when such research is reviewed.
iii. Participate in continuing education activities at least annually, including training on specific federal agency requirements (e.g., DOD) when such research is reviewed.
iv. Respond to contacts from participants or others
v. Ensure contacts from participants or others are reported to the IRB when required by the IRB's written procedures
vi. Ensure research submitted to an external IRB meets local requirements
vii. Ensure research approved by an external IRB has all local approvals before being conducted
viii. Make "BROCHURE: Should I Take Part in Research (HRP-900)" available to research staff to provide to subjects

b) IRB members and <HRPP personnel> ultimately report to the [Organizational Official] for HRPP issues.

4. IRB

a) AdventHealth Orlando may rely upon the IRB of another organization provided an Institutional Agreement for IRB review (IAIR) is in place and one of the following is true:

i. The IRB is part of an AAHRPP-accredited organization.
ii. All <Interventions> and <Interactions> occur at another organization.

iii. AdventHealth Orlando is engaged in <Human Research> solely because it receives funding directly from a federal department or agency.

b) The IRB has the authority:

i. To approve, require modifications to secure approval, and disapprove all <Human Research>.activities overseen and conducted by AdventHealth Orlando
ii. To suspend or terminate approval of <Human Research>.not being conducted in accordance with HRPP requirements or that had been associated with unexpected serious harm to participants
iii. To observe, or have a third party observe, the consent process and the conduct of the <Human Research>.
iv. Determine whether an activity is <Human Research>.
v. Determine whether AdventHealth Orlando is engaged in <Human Research>
vi. To decide whether financial interests <Related to the Research> and the management, if any, allow approval of the <Human Research>.

c) AdventHealth Orlando cannot approve <Human Research>.that the IRB has not approved.

d) The following individuals are authorized to suspend, terminate, or disapprove research that has been approved by the IRB:

i. [Organizational Official]
ii. [Research Compliance Senior Manager]
iii. [Vice President, Research Services]

5. External organizations that rely on AdventHealth Orlando's IRB can expect the AdventHealth Orlando's IRB to do the following and when AdventHealth Orlando relies on an external IRB AdventHealth Orlando expects the IRB to do the following:

a. Determine whether an activity is <Human Research>.
b. Determine whether <Human Research> engages the organization.
c. Determine which persons are considered engaged (agents) in the <Human Research>.
d. Assure all IRB members, IRB Chairs and Vice Chairs are trained in accordance with applicable IRB SOPs.
e. Evaluate scientific or scholarly validity of proposed research.
f. For clinical trials, assure ICH-GCP guidelines are met, including whether the available non-clinical and clinical information on an investigational product is adequate to support the clinical trial.
g. Identify any relevant local, state, or international requirements related to <Human Research>, and apply AAHRPP criteria to international research.

h. Make contact information for the IRB available to current and former subjects.
i. Explain to subjects how to contact someone independent of the investigator for questions, concerns, complaints, or subject rights, or to offer input.
j. Assure individuals with knowledge of community-based participatory research attend meetings where such research is reviewed.
k. Evaluate and manage <Unanticipated Problems Involving Risks to Subjects or Others>, <Noncompliance>, <Serious Noncompliance> and <Continuing Noncompliance>, including when necessary to conduct an audit.
l. Determine whether each allegation of noncompliance has a basis in fact and whether each incident of noncompliance is serious or continuing, including when necessary to conduct an audit.
m. Manage and when appropriate, collaborate with AdventHealth Orlando to manage <Unanticipated Problems Involving Risks to Subjects or Others>, <Noncompliance>, <Serious Noncompliance> and <Continuing Noncompliance>, <Suspension of IRB Approval> and <Termination of IRB Approval>.
n. Notify the FDA and collaborate with AdventHealth Orlando to notify regulatory agencies other than the FDA of any <Unanticipated Problems Involving Risks to Subjects or Others>, <Serious Noncompliance> and <Continuing Noncompliance>, <Suspension of IRB Approval> and <Termination of IRB Approval.
o. Conduct independent IRB review to manage organizational conflict of interest related to the research.
    i. The relying organization is responsible to identify organizational conflicts of interest.
p. Identify and manage financial conflicts of interest of investigators and research staff and upon request, review and incorporate the relying organization's management plan.
q. Evaluate and confirm test articles have appropriate regulatory approval (e.g., IND or IDE, meet exemption requirements)

    i. The relying organization is responsible to have and follow written policies and procedures to ensure that the handling of investigational or unlicensed test articles conforms to legal and regulatory requirements.

r. For emergency uses of test articles:
    i. Evaluate and permit emergency uses of a test articles and assure uses follow FDA requirements.
    ii. Assure that emergency uses of a test articles are not considered <Human Research as Defined by HHS> and prohibit use of data obtained from an emergency use for <Human Research as Defined by HHS>.

s. When research is DOD-regulated:
   i. Assure investigators and research staff are trained on DOD requirements, note the potential for additional training, and the possibility of DOD oversight of the educational program.
   ii. Assure that IRB members, IRB Chairs and Vice Chairs are trained in accordance with applicable IRB SOPs on DOD requirements.
   iii. Evaluate DOD research for scientific merit.
   iv. Determine that the investigator has permission to conduct research in that country by certification or local ethics review.
   v. Determine that the investigator will follow all local laws, regulations, customs, and practices.
   vi. Assure the IRB consent has the requirements of DOD Instruction 3216.02 when reviewing non-exempt classified DOD research.
   vii. Report serious or continuing noncompliance with DOD research to the DOD human research protection officer.

t. Assure all DOE requirements of 10 CFR 745 and DOE Order 443.1.B. are met.

u. For DOJ research:
   i. Assure all DOJ requirements of 28 CFR 22 and 512 are met.
   ii. Evaluate DOJ research to assure there is an adequate research design and it contributes to the advancement of knowledge about corrections.

v. Assure all ED requirements of 34 CFR 98, 99 and 356 are met.

w. Assure EPA requirements of 40 CFR 26 and EPA Order 1000.17 Change A1 are met, and to flag research that collects data intended to be submitted to EPA as subject to EPA regulations.

x. Provide equivalent protections for participants in non-funded research.

y. Ensuring concordance between any applicable grant in the IRB application, when required by regulators.

z. Assure that investigators and research staff are appropriately trained.

aa. For international research:

   i. Ensure appropriate expertise and knowledge of the country(ies) either through IRB members or consultants.
   ii. Ensure knowledge of local laws.
   iii. Ensure knowledge of cultural context.
   iv. Confirm the qualifications of the researchers and research staff for conducting research in that country.
   v. Conduct initial review, continuing review, and review of modifications to previously approved research.
   vi. Conduct post-approval monitoring.
   vii. Handle complaints, noncompliance, and unanticipated problems involving risk to participants or others.
   viii. Manage consent process and document and other language issues.
   ix. Coordinate and communication with local IRBs when appropriate.

bb. Should the relying organization terminate reliance on the IRB, the IRB will continue oversight of active studies until closure or a mutually agreed-upon transfer of the studies.

6. Upon request or when required by law, AdventHealth Orlando will execute an Authorization Agreement with the relying organization, which documents respective authorities, roles, responsibilities, and communication between AdventHealth Orlando and the relying organization.

7. Investigators and <research personnel> ultimately report to the [Organizational Official] for HRPP issues and are to:

   a) Obtain informed consent for <Human Research> when required by the IRB.

   b) Follow the obligations described in "HRP-070 POLICY: Investigator Obligations "

   c) Follow applicable policies and standard operating procedures of the HRPP.

8. Legal counsel works with the [Organizational Official] on HRPP issues and is responsible to:

   a) Determine who is a <Legally Authorized Representative>, <Child>, and <Guardian>.

   b) Provide legal advice related to the HRPP to the [Organizational Official], IRB, and investigators.

   c) Determine who is an agent for purposes of engagement.

   d) Identify relevant state and international laws.

   e) Resolve conflicts among applicable laws.

9. The Office of Research Integrity works with the [Organizational Official] on HRPP issues as follows:

   a) The Office of Research Integrity is responsible to review projects for compliance with HRPP requirements. This includes study audits.

   b) The Office of Research Integrity has the authority to decide whether financial interests <Related to the Research> and the management, if any, allow approval of the <Human Research>.

10. The Office of Sponsored Programs works with the [Organizational Official] on HRPP issues as follows:

    a) The Office of Sponsored Programs is responsible to review research study contracts and grants for compliance with HRPP requirements.

11. The Research Oversight Committee works with the [Organizational Official] by independently reviewing research compliance matters the [Organizational Official] delegates to their authority.

D. Written Procedures

1. AdventHealth Orlando makes written materials describing the HRPP available to all members of AdventHealth Orlando through its Web site at https://drupal02.floridahospital.org/irb/.

2. AdventHealth Orlando makes written materials describing the HRPP available to sponsors, CROs, and investigators upon request when those materials apply to the requestor

3. When written materials are changed, AdventHealth Orlando communicates to affected individuals through one or more of the following actions:

   a) Email communications
   b) Web-site postings
   c) Direct outreach at organizational meetings
   d) Training
   e) Mentoring

E. Reliance Agreements

1. For federally funded research that must follow <2018 Requirements> (with the exception of exempt research for which IRB review is not required by regulation) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institutions, the institution and the organization operating the IRB must document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy[1].

F. Questions, Concerns, and Feedback

AdventHealth Orlando solicits questions, concerns, and feedback.

1. AdventHealth Orlando solicits questions, concerns, and feedback by making the document "BROCHURE: Should I Take Part in Research (HRP-900)" available on its Web site and available to investigators to provide to the public

2. Individuals should address questions, suggestions, concerns, or complaints about the IRB or human research protection program; allegations of undue

[1]For example, in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol.

influence, <Allegations of Noncompliance> or findings of <Noncompliance> orally or in writing to:

AdventHealth Orlando Institutional Review Board

Administrator: Janice Turchin, CIP, IRB

Address: 901 N. Lake Destiny Road, Suite 400
Maitland, FL 32751

Phone: 407-200-2677

Fax: 407-303-2567

Email: FH.IRB.General@adventhealth.com

AdventHealth Orlando Compliance Hotline:
888-92-GUIDE (48433)

3. Individuals may also contact the [Organizational Official] at:

Chief Scientific Officer: Steven Smith, MD

Address: 901 N. Lake Destiny Road, Suite 400
Maitland, FL 32751

Phone: 407-303-7115 (Main #)

Fax: 407-303-2567

4. AdventHealth Orlando takes steps to protect employees who report in good faith from retaliation and harassment. Immediately report such concerns to the [Organizational Official] or to the AdventHealth Orlando Compliance Hotline (888-92-GUIDE (48433)).

Definition(s)

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

2018 Requirements or Revised Rule: The Federal Policy for the Protection of Human Subjects requirements contained in 45 CFR §46 Subparts A as revised January 18, 2017, as well as Subpart B, C, and D, exclusive of requirements for reporting to, certification by, or review by a federal department of agency head.

Allegations of Noncompliance: An unproven assertion of <Noncompliance>.

Children: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Continuing Noncompliance: A pattern of <Noncompliance> that is likely to continue without intervention or failure to work with the IRB to resolve <Noncompliance>.

Guardian: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

HRPP Personnel: Individuals involved in the oversight of research.

Human Research: Any activity that is <Human Research as Defined by HHS> or <Human Research as Defined by FDA>.

Human Research as Defined by FDA: An individual who is or becomes a participant in <Research as Defined by FDA>, either as a recipient of the test article or as a control, or an individual on whose specimen an investigational device is used.

Human Research as Defined by HHS: For <Research as Defined by HHS> subject to <Pre-2018 Requirements>: A living individual about whom an investigator conducting <Research as Defined by HHS> obtains (1) data through <Intervention> or <Interaction> with the individual, or (2) information that is both <Identifiable Information> and <Private Information>.

For <Research as Defined by HHS> subject to <2018 Requirements> or <Hybrid Requirements>: A living individual about whom an investigator conducting <Research as Defined by HHS>:

a) Obtains information or biospecimens through <Intervention> or <Interaction> with the individual, and uses, studies, or analyzes the information or biospecimens; or
b) Obtains, uses, studies, analyzes, or generates <Identifiable Private Information> or <Identifiable Biospecimens>.

Hybrid Requirements: <2018 Requirements> exclusive of 45 CFR §46.103(e), §46.109(e), §46.116(a)(5), §46.116(b)(9), §46.116(d)(7)-(9), §46.116(e)(1)-(2), §46.116(f)(1)-(2), §46.116(f)(3)(ii).
ICH-GCP Definition of Clinical Trial: Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Institutional Clearance: Action required and provided by the Office of Sponsored Programs (OSP) in order to initiate a research project.

Interactions: Communication or interpersonal contact between investigator and <subject>.

Interventions: Physical procedures by which information or biospecimens are gathered and manipulations of the <Human Subject as Defined by HHS> or the <Human Subject's as Defined by HHS> environment that are performed for research purposes.

Legally Authorized Representative: An individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

a) At AdventHealth Orlando, this is the Legally Authorized Person (LAP)
b) For <Research as Defined by HHS> NOT subject to FDA regulations and subject to <2018 Requirements> or <Hybrid Rule>: Where there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective <Human Subject as Defined by HHS> to the <Human Subject's> participation in the procedure(s) involved in the research.

Noncompliance: Failure to follow the regulations or the requirements or determinations of the IRB.

Pre-2018 Requirements or Original Rule: The Federal Policy for the Protection of Human Subjects requirements contained in 45 CFR 46 §46 Subparts A as published in the 2016 edition of the Code of Federal Regulations, as well as Subpart B, C, and D, exclusive of requirements for reporting to, certification by, or review by a federal department of agency head.

Related to the Research: A financial interest is <Related to the Research> when the financial interest is in the sponsor or the product or service being evaluated.

Research Personnel: Individuals involved in designing, conducting, or reporting of research.

Serious Noncompliance: <Noncompliance> that may adversely affect the rights and welfare of subjects.

a) For <Human Research> conducted or funded by DOD, <Serious Noncompliance> is failure of a person, group, or institution to act in accordance with this Instruction and its references such that the failure could

adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

Suspension of IRB Approval: Temporary or permanent withdrawal of IRB approval for some or all research procedures short of <Termination of IRB Approval>.

Termination of IRB Approval: Withdrawal of IRB approval for all research procedures where the IRB does not anticipate re-opening the study.

Unanticipated Problem 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)

U.S. Department of Health and Human Services (HHS). (April 18, 1979). *Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* Belmont Report. Office of Human Research Protection (OHRP). Retrieved March 7, 2016 from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html.

Related Document(s)

"HRP-070 POLICY: Investigator Obligations"

Keywords

HRP.010