Table of Contents

What is the purpose of this manual?

This document is designed to guide you through policies and procedures related to the conduct of human research that are specific to this organization.

General information regarding human research protections and relevant federal regulations and guidance is incorporated into the required human protections training. For additional information see below: "What training does my staff and I need in order to conduct human research?"

What is Human Research?

"POLICY: Human Research Protection Program (CW AHC 108)" defines the activities that this organization considers to be "Human Research." An algorithm for determining whether an activity is human research can be found in the "WORKSHEET: Human Research (HRP-421)." Use this document for guidance, keeping in mind that the IRB makes the ultimate determination in questionable cases as to whether an activity constitutes human research subject to IRB oversight.

You are responsible not to conduct human research without prior IRB review and approval. If you have questions about whether an activity is human research, contact the IRB Office who will provide you with a determination. If you wish to have a written determination, provide a written request to the IRB Office.

If you have questions about whether an activity requires IRB review, contact the IRB Office.

What is the Human Research Protection Program?

A Human Research Protection Program or HRPP is an organization-wide system to protect human subjects in research. It is described in "POLICY: Human Research Protection Program (CW AHC 108)."

What training do my staff and I need to conduct human research?

All members of the research team involved in the design, conduct, or reporting of the research must complete training.

Investigators and staff conducting research must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training program.

The CITI site can be accessed at http://www.citiprogram.org/.

On a case-by-case basis, the IRB can approve alternative training.

Training is valid for a three-year period, after which time the training must be repeated.

This section describes the training requirements imposed by the IRB. You may have additional training imposed by other federal, state, or organizational policies. Additional details regarding required training can be found in "SOP: Research Personnel (CW AHC 252)."

Members of the research team who have not completed human research protections training may not take part in aspects of the research that involve human subjects.

Physicians providing clinical care are not required to complete training for the following research:

- Expanded access for individual patients (single-patient IND)
- Emergent use of a test article
- Compassionate use of a device

Commented [MM1]: Should we add compassionate use of a device?

Should we add the HUD specific requirement? For example under a separate section:

Physicians providing clinical care using a Humanitarian Use Device (HUD) must complete the HUD short course within CITI.

What are the obligations of individuals who conduct human research?

The obligations of individuals who conduct human research can be found in these documents:

- POLICY - Investigator Obligations in Research (CW AHC 112)
- POLICY - Prompt Reporting Requirements in Research (CW AHC 111)
- SOP – Informed Consent Process & Written Documentation of Consent (CW AHC 216)
- INVESTIGATOR GUIDANCE - Additional DOD Obligations (HRP-810)
- INVESTIGATOR GUIDANCE - Additional ED Obligations (HRP-813)
- INVESTIGATOR GUIDANCE - Additional FDA Obligations (HRP-815)
- INVESTIGATOR GUIDANCE - Additional ICH-GCP Obligations (HRP-816)

How do I submit new human research to the IRB?

Complete the "FORM: Initial Review Application (HRP-200)," attach all requested documents, and provide to the IRB Office. Maintain electronic copies of all information submitted to the IRB in case revisions are required. **NOTE: If after IRB approval, any information in this Application changes, resubmit a copy of this document with revisions for IRB review.**

How do I write an Investigator Protocol?

You may use "TEMPLATE PROTOCOL (HRP-504)" as a starting point for drafting a new Investigator Protocol and reference the instructions in italic text for the information the IRB looks for when reviewing research. **NOTE: If after IRB approval, any information in the protocol changes, resubmit a copy of this document with revisions for IRB review.**

OR

"PROTOCOL SUPPLEMENT (HRP-504A)" - This document will be required to provide information to supplement an external multi-centered research protocol. **NOTE: If after IRB approval, any information in this supplement changes, resubmit a copy of this document with revisions for IRB review.**

How do I create a consent document?

You may use "TEMPLATE Consent (HRP-500)", "TEMPLATE Consent for Minimal Risk Research (HRP-500)" or sponsor model consent form to create a consent document. Most

consent documents, summaries, and consent scripts must include the required and additional appropriate disclosures in Section 4 of "WORKSHEET: Criteria for Approval (HRP-400)."

Date the revisions of your consent documents to ensure that you use the most recent version approved by the IRB.

What are the different regulatory classifications that research activities may fall under?

Submitted activities may fall under one of the following five regulatory classifications:

- Not "Human Research": Activities that do not meet the organizational definition of "Human Research" do not fall under IRB oversight. The criteria for whether an activity is human research is in "WORKSHEET: Human Research (HRP-421)" Contact the IRB Office if you are uncertain whether an activity is human research.
- "Human research that does not engage the institution": Some human research requires review by an IRB, but is not the responsibility of the organization. The criteria for this determination is in "WORKSHEET: Engagement (HRP-422)" Contact the IRB Office if you are uncertain whether human research is the responsibility of the organization.
- Exempt: Certain categories of human research may be exempt from regulation but require IRB review. It is the responsibility of the organization, not the investigator, to determine whether human research is exempt. Review the "WORKSHEET: Exemption (HRP-423)" for the categories of research that may be exempt.
- Review Using the Expedited Procedure: Certain categories of human research are not exempt but may qualify for review using the expedited procedure, meaning that the project may be approved by a single designated IRB reviewer, rather than the convened board. Review the "WORKSHEET: Expedited Review (HRP-424)" for the categories of research that may be reviewed using the expedited procedure.
- Review by the Convened IRB: Non-exempt human research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB.

What are the decisions the IRB can make when reviewing proposed research?

The IRB may approve research, require modifications to the research to secure approval, table research, or disapprove research:

- Approve: Made when all criteria for approval are met. See "How does the IRB decide whether to approve human research?" below.
- Conditionally Approve: Made when IRB members require specific modifications to the research before approval can be finalized. The IRB describes the required modifications and their reasons, and gives the investigator an opportunity to respond to the IRB in person or in writing.

Commented [MM2]: Do we want to remove this or revise to be more clear that a determination is required?

Commented [MM3]: Same here.

- Defer: Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications that might make the research approvable. The IRB describes the recommended modifications and their reasons, and gives the investigator an opportunity to respond to the IRB in person or in writing.
- Disapprove: Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications the might make the research approvable. The IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

How does the IRB decide whether to approve human research?

The criteria for IRB approval for exempt research can be found in the "WORKSHEET: Exemption (HRP-423)" and for non-exempt research in "WORKSHEET: Criteria for Approval (HRP-400)." The latter worksheet references other checklists that might be relevant. All checklists and worksheets can be found on the IRB web site.

These checklists are used for initial review, continuing review, and review of modifications to previously approved human research.

You are encouraged to use the checklists to write your protocol in a way that addresses the criteria for approval.

What will happen after IRB review?

The IRB will provide you with a written decision indicating that the IRB has approved the human research, requires modifications to secure approval, or has disapproved the human research.

- If the IRB has approved the human research: The human research may commence once all other organizational approvals have been met. IRB approval is usually good for a limited period of time which is noted in the approval letter.
- If the IRB conditionally approved your research and you accept the modifications: Make the requested modifications and submit them to the IRB per the due date on the IRB notification. If all requested modifications are made, the IRB will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the modifications, write up your response and submit it to the IRB.
- If the IRB deferred the human research: The IRB will provide a statement of the reasons for deferral and suggestions to make the study approvable, and give you an opportunity to respond in writing. In most cases if the IRB's reasons for the deferral are addressed in a modification, the human research can be approved
- If the IRB disapproved the human research: The IRB will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the IRB directly at an IRB meeting.

How do I submit continuing review?

Complete the "FORM: Continuing Review Application (HRP-202)," attach all requested documents, and provide to the IRB Office. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If the continuing review application is not received by the date requested in the approval letter, you will be restricted from submitting new human research until the completed application has been received.

How do I submit a modification?

Complete the "FORM: Modification Application (HRP-203)," attach all requested documents, and provide to the IRB Office. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

How do I submit a protocol exception request?

A protocol exception is a one-time, intentional/planned action or process that deviates from the IRB-approved study protocol. It is intended for one occurrence and/or applied to a single individual.

Complete the "FORM: Protocol Exception Request (HRP-230)," attach all requested documents, and provide to the IRB Office. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

How do I close out a study?

Complete the "FORM: Continuing Review Application (HRP-202)," and attach all requested supplements. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If you fail to submit a continuing review form to close out human research, you will be restricted from submitting new human research until the completed application has been received.

How long do I keep records?

Maintain signed and dated consent documents for at least seven years after completion of the research.

Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least seven years after completion of the research.

If your human research is sponsored, funded, or FDA-regulated there may be additional requirements. Contact the sponsor, funding agency, or IRB for additional information.

What if I need to use an unapproved drug, biologic, or device and there is no time for IRB review?

Contact the IRB office or IRB chair immediately to discuss the situation. If there is no time to make this contact, review the guidance and worksheet below that is most relevant, follow the requirements, contact the IRB office or IRB chair by the close of the next business day, and use FORM - Emergent Use Report (HRP-222).

- INVESTIGATOR GUIDANCE: Emergent & Non-Emergent Use of Test Articles (HRP-826)
- WORKSHEET: Emergency Use Drugs and Biologics (HRP-451)
- WORKSHEET: Emergency Use Devices (HRP-452)
- WORKSHEET: Compassionate Use Devices (HRP-453)

If you are using an unapproved drug or biologic, use the "TEMPLATE: Consent for Emergency Use (HRP-502)" to prepare your consent document.

FDA considers emergency use of an unapproved drug or biologic to be research and the individual getting the test article to be a subject. FDA does not consider emergency use of an unapproved device to be research. However, FDA guidance recommends following similar rules.

Individuals getting an unapproved drug, biologic, or device without prior IRB review cannot be considered a "subject" as defined by DHHS and their results cannot be included in prospective "research" as that term is defined by DHHS.

How do I get additional information and answers to questions?

This document and the policies and procedures for the Human Research Protection Program are available on the IRB website.

You may contact the IRB Office at:

Janice Turchin, CIP, IRB Sr Manager
AdventHealth Institutional Review Board
800 N. Magnolia Avenue, Suite 500
Orlando, FL 32803
407-200-2677 office
Email: ORL.IRB.General@AdventHealth.com