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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 (HRP-010)" 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 (HRP-010)."

What training does 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 involving human subjects must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training program. Investigators and staff conducting clinical trials must also complete the online CITI GCP 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.

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.

What are the obligations of individuals who conduct human research?

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

- INVESTIGATOR GUIDANCE - Investigator Obligations (HRP-800)
- INVESTIGATOR GUIDANCE - Prompt Reporting Requirements (HRP-801)
- INVESTIGATOR GUIDANCE - Informed Consent (HRP-802)
- INVESTIGATOR GUIDANCE - Documentation of Informed Consent (HRP-803)
- INVESTIGATOR GUIDANCE - Additional DOD Obligations (HRP-810)
- INVESTIGATOR GUIDANCE - Additional DOE Obligations (HRP-811)
- INVESTIGATOR GUIDANCE - Additional DOJ Obligations (HRP-812)
- INVESTIGATOR GUIDANCE - Additional ED Obligations (HRP-813)
- INVESTIGATOR GUIDANCE - Additional EPA Obligations (HRP-814)
- INVESTIGATOR GUIDANCE - Additional FDA Obligations (HRP-815)
- INVESTIGATOR GUIDANCE - Additional ICH-GCP Obligations (HRP-816)

Who can serve as a principal investigator (PI)?

The following table outlines the PI eligibility requirements:

Position/Title	**PI Eligibility**
UMMS & UMMHC employed faculty	Eligible upon faculty appointment at any rank (refer to Investigator Manual: http://www.umassmed.edu/ccts/irb/investigator-manual/)
UMMS & UMMHC Affiliate Faculty	Eligible if paid by UMMS or UMMHC; otherwise may be a co-investigator
Adjunct Faculty	Not eligible; may serve as co-investigator with any necessary IRB reliance agreements
Visiting Faculty	Eligible while at UMMS if approval is received by the sponsoring Department Chair and the Institutional Official
Retired & Emerita Faculty	Eligible if approval is received by the Department Chair and the Institutional Official
Non-Faculty	Eligible if paid employee of UMMS or UMMHC and provided a faculty advisor oversees the conduct of the research; Onsite vendor employees with UMMS or UMMHC posts are similarly eligible with a faculty advisor and any necessary reliance agreements
Fellows, Residents, Trainees and Students	Eligible, provided a faculty advisor oversees the conduct of the research and if allowed by the Department (refer to Investigator Manual: http://www.umassmed.edu/ccts/irb/investigator-manual/)

Faculty employed by other UMASS campus (Amherst, Boston, Dartmouth, & Lowell)	Not eligible; may serve as co-investigator with any necessary IRB reliance agreements

Exceptions to the PI eligibility requirements may be granted upon approval by the Department Chair and Institutional Official.

Can a student or trainee be principal investigator (PI)?

If the Principal Investigator is a student, resident, fellow, or other trainee, the UMass IRB requires that a Faculty Advisor be appointed to oversee the conduct of the research. As Faculty Advisor, this individual is expected to oversee and train the student investigator in matters of appropriate research compliance, protection of human subjects and proper conduct of research. The Faculty Advisor is also responsible to assure that the research is conducted in accordance with Institutional Policies and Procedures and the Investigator Manual (HRP-910). The IRB may, at its discretion, require a faculty member to function as PI, with a student, resident or other trainee functioning in a co-investigator role. This decision will be made on a case-by-case basis.

How do I submit new human research to the IRB?

Complete the "FORM: Initial Review (HRP-200) (embedded in eIRB as a smart form)," 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 a continuing review application is not received by the date requested in an approval letter, you will be restricted from submitting new human research until the completed application has been received.

If Clinicaltrials.gov compliance requirements are not met, you will be restricted from submitting new human research until the requirements have been satisfied.

How do I write an Investigator Study Plan?

You may use "TEMPLATE Investigator Study Plan (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. You may use any format or style as long as the required information is included.

How do I create a consent document?

You may use "TEMPLATE Consent (HRP-500)" or "TEMPLATE Consent for Minimal Risk Research (HRP-500)" to create a consent document. You may use any format or style as long as the required information is included.

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 four 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 in cases 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 in cases 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 from IRB review. "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 IRB Administration's "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.
- Modifications Required to Secure Approval: 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.
- Defer: Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications the 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)" for exempt human research 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. 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 (HRP-202) (embedded in eIRB as a smart form)," 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 (HRP-203) (embedded in eIRB as a smart form)," 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 (HRP-202) (embedded in eIRB as a smart form)," attach all requested supplements, and provide the requested number of copies to the IRB Office. 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 three years after completion of the research.

Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least six 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 worksheet below that is most relevant, follow the requirements, and contact the IRB office or IRB chair by the close of the next business day:

- 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 Web Site at https://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/ , http://www.umassmed.edu/ccts/irb/forms_templates/, and http://www.umassmed.edu/ccts/irb/.

You may contact the IRB Office at:

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