

**Investigator Manual[[1]](#endnote-1)**

**HRP-103**

Revised December 1, 2023

**Table of Contents**

[Scope 3](#_Toc99023708)

[What is the purpose of this manual? 3](#_Toc99023709)

[What is Human Research? 3](#_Toc99023710)

[What is the Human Research Protection Program? 3](#_Toc99023711)

[What training does my staff and I need to conduct Human Research? 4](#_Toc99023712)

[What financial interests do my staff and I need to disclose to conduct Human Research? 5](#_Toc99023713)

[How do I submit new Human Research to the IRB? 5](#_Toc99023714)

[How do I request to rely on an external IRB? 5](#_Toc99023715)

[How do I request that this IRB serve as the IRB of record (sIRB) for my collaborative or multi-site research study? 6](#_Toc99023716)

[How do I write an Investigator Protocol? 6](#_Toc99023717)

[How do I create a consent document? 7](#_Toc99023718)

[Do I need to obtain informed consent in order to screen, recruit, or determine the eligibility of prospective subjects? 7](#_Toc99023719)

[What are the different regulatory classifications that research activities may fall under? 8](#_Toc99023720)

[What are the decisions the IRB can make when reviewing proposed research? 8](#_Toc99023721)

[How does the IRB decide whether to approve Human Research? 9](#_Toc99023722)

[What will happen after IRB review? 9](#_Toc99023723)

[What are my obligations after IRB approval? 9](#_Toc99023724)

[What are my obligations as the overall study PI for an sIRB study? 12](#_Toc99023725)

[What are my obligations as investigator when relying on an external IRB? 12](#_Toc99023726)

[How do I document consent? 13](#_Toc99023727)

[How do I submit a modification? 14](#_Toc99023728)

[How do I submit continuing review? 14](#_Toc99023729)

[How do I close out a study? 14](#_Toc99023730)

[How long do I keep records? 15](#_Toc99023731)

[How do I get additional information and answers to questions? 15](#_Toc99023732)

## Scope

Throughout this document “institution” refers to the University of Massachusetts Boston.

## What is the purpose of this manual?

This document, HRP-103 - INVESTIGATOR MANUAL, is designed to guide you through policies and procedures related to the conduct of Human Research that are specific to this institution. See the HRP-103a - INVESTIGATOR MANUAL – APPENDICES for additional requirements and guidance.

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?

HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN defines the activities that this institution considers to be “Human Research.” An algorithm for determining whether an activity is Human Research can be found in the HRP-310 - WORKSHEET - Human Research Determination, located on the IRB Web site: <https://www.umb.edu/orsp/research_committees/irb/do_you_need_review>. Use this document for guidance as to whether an activity meets either the DHHS or FDA definition of Human Research, 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 (or an institutional review and determination of exempt Human Research). 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.

## What is the Human Research Protection Program?

HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN describes this institution’s overall plan to protect subjects in Human Research.

* The mission of the Human Research Protection Program.
* The ethical principles that the institution follows governing the conduct of Human Research.
* The applicable laws that govern Human Research.
* When the institution becomes “engaged in Human Research” and when someone is acting as an agent of the institution conducting Human Research.
* The types of Human Research that may not be conducted.
* The roles and responsibilities of individuals within the institution.

## What training does my staff and I need to conduct Human Research?

This section describes the training requirements imposed by the IRB. You may have additional training imposed by other federal, state, or institutional policies.

**Human Research Protections Training:**

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

The UMass Boston CITI Single Sign-On (SSO) link can be accessed at: <https://www.umb.edu/research/orsp/institutional-review-board-irb/required-training/>

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

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

Investigators will be restricted from submitting new Human Research until the required training has been completed.

**Good Clinical Practice (GCP) Training for NIH Clinical Trial Investigators and Staff:**

Effective January 1, 2017 – NIH expects all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP).

Recipients of GCP training are expected to retain documentation of their training. GCP training should be refreshed at least every three years in order to stay up to date with regulations, standards, and guidelines.

Training in GCP may be achieved through the CITI online training module (GCP for social behavioral researchers) or equivalent training accepted by NIH.

**Student PIs:**

If the Principal Investigator is a graduate student, the UMass Boston IRB requires that a Faculty Advisor be appointed to oversee the conduct of the research. As Faculty Advisor, this individual is expected to train and oversee 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-103).

The IRB may, at its discretion, require a faculty member to function as PI, with a student functioning in a co-investigator role (e.g., thesis projects). This decision will be made on a case-by-case basis.

Undergraduate students should not be the PI. A faculty member should serve as PI.

## What financial interests do my staff and I need to disclose to conduct Human Research?

Individuals involved in the design, conduct, or reporting of research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards are considered to have an institution responsibility.

All individuals involved in the design, conduct, or reporting of research are required to disclose the financial interests in the electronic IRB system.

* On submission of an initial review.
* As part of continuing review.
* Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

Individuals with reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center are required to disclose the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration of the travel.

Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:

* Joining the institution
* Financial conflicts policies are revised in a manner that changes investigator requirements
* Non-compliant with financial conflicts policies and procedures

Additional details can be found in HRP-055 - SOP - Financial Conflicts of Interests.

## How do I submit new Human Research to the IRB?

Complete HRP-211 - FORM - Basic Study Information and attach all requested supplements using the Kuali Protocols module. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Before submitting the research for initial review, you must:

* Obtain the financial interest status (“yes” or “no”) of each research staff.
* Obtain the agreement of each research staff to their role in the research.

## When is single IRB review required?

Any cooperative nonexempt human subjects research subject to the Common Rule requires use of single IRB. This requirement applies to that portion of the research that is conducted in the United States. See Appendix A-10.

## When will this IRB serve as the IRB of record (sIRB) or rely on an external IRB?

For criteria used to determine whether this institution will serve as the sIRB, refer to HRP-833 -WORKSHEET - Considerations for Serving as the sIRB. For criteria used to determine whether this institution will rely on an external IRB, refer to HRP-832 - WORKSHEET - Considerations for Relying on an External IRB. An Authorization Agreement(s) must be in place before this IRB can serve as the sIRB or rely on an external IRB.

## When should I submit a request to rely on an External IRB?

For studies where this institution is a participating site (pSite), requests to rely on an external IRB should generally be submitted after the reviewing IRB (sIRB) has agreed to serve as the sIRB and approved the study (e.g., lead site protocol), including consent templates and other document templates.

## How do I request to rely on an external IRB?

Complete HRP-811 - FORM - Request External IRB Review (Basic Site Information), and indicate that an external IRB will serve as the IRB of record. Attach all requested supplements and provide to the IRB Office using the Kuali Protocols module. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

## When should I consult with this IRB when planning a study for which this IRB will be asked to serve as the IRB of record (sIRB)?

If you will request this IRB to serve as the reviewing IRB (sIRB) for cooperative research, contact the IRB Office prior to submitting grant or other funding applications to determine whether this IRB will agree to serve as the sIRB for the study.

## How do I request that this IRB serve as the IRB of record (sIRB) for my collaborative or multi-site research study?

Complete HRP-211 - FORM - Basic Study Information, and indicate that this is a multi-site or collaborative research study and that this IRB is being asked to serve as the IRB of record. Attach all requested supplements and provide to the IRB Office using the Kuali Protocols module. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

## How do I write an Investigator Protocol?

Use the HRP-503 - PROTOCOL TEMPLATE 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. Here are some key points to remember when developing an Investigator Protocol:

* The italicized bullet points in the HRP-503 - PROTOCOL TEMPLATE serve as guidance to investigators when developing an Investigator Protocol for submission to the IRB. All italicized comments are meant to be deleted prior to submission.
* When writing an Investigator Protocol, always keep an electronic copy to ensure you use the most recent version approved by the IRB. You will need to modify this copy when making changes to the Investigator Protocol.
* If you believe your activity may not be Human Research, contact the IRB Office prior to developing your Investigator Protocol.
* Note that, depending on the nature of your research, certain sections of the template may not be applicable to your Investigator Protocol. Indicate this as appropriate.
* We recommend that you date the revisions of your Investigator Protocol to ensure that you use the most recent version approved by the IRB.
* You may not involve any individuals who are members of the following populations as subjects in your research unless you indicate this in your inclusion criteria as the inclusion of subjects in these populations has regulatory implications.
	+ Adults unable to provide legally effective consent
	+ Individuals who are not yet adults (infants, children, teenagers)
	+ Pregnant women
	+ Prisoners
* If you are conducting community-based participatory research, you may contact the IRB Office for information about:
	+ Research studies using a community-based participatory research design
	+ Use of community advisory boards
	+ Use of participant advocates
	+ Partnerships with community-based institutions or organizations

## How do I create a consent document?

Use the HRP-502 - TEMPLATE CONSENT DOCUMENT to create a consent document.

Note that all long form consent documents and all summaries for short form consent documents must contain all of the required and all additional appropriate elements of informed consent disclosure. Review the “Long Form of Consent Documentation” section in the IRB’s HRP-314 - WORKSHEET - Criteria for Approval to ensure that these elements are addressed. When using the short form of consent documentation, the appropriate signature block from HRP-502 - TEMPLATE CONSENT DOCUMENT should be used on the short form.

If your research study meets the requirements for an exemption and there are interactions with subjects, you may use an abbreviated process for obtaining consent. Consent can be verbal, but you must provide the following information to participants through an information sheet or written script:

* The subject is being asked to participate in a research study;
* A description of the procedure(s) the participant will be asked to complete;
* Participation is voluntary; and
* The investigator’s name and contact information.

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

## Do I need to obtain informed consent in order to screen, recruit, or determine the eligibility of prospective subjects?

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, OR

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

The research protocol should include information about how potential subjects will be identified and recruited in order for the IRB to be able to determine whether informed consent for these activities is required.

Contact the IRB Office with additional questions or for further guidance regarding the requirement to obtain HIPAA authorization or a waiver to obtain HIPAA authorization for recruitment purposes.

## 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 must meet the institutional definition of “Human Research” to fall under IRB oversight. Activities that do not meet this definition are not subject to IRB oversight or review. Review the IRB Office’s HRP-310 - WORKSHEET - Human Research Determination for reference. Contact the IRB Office in cases where it is unclear whether an activity is Human Research.
* Exempt: Certain categories of Human Research may be exempt from regulation but require IRB review. It is the responsibility of the institution, not the investigator, to determine whether Human Research is exempt from IRB review. Review the IRB Office’s HRP-312 - WORKSHEET - Exemption Determination for reference on the categories of research that may be exempt.
* Review Using the Expedited Procedure: Certain categories of non-exempt Human Research 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 HRP-313 - WORKSHEET - Expedited Review for reference on the categories of research that may be reviewed using the expedited procedure.
* Review by the Convened IRB (Full Board): 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, defer research or disapprove research:

* Approval: 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 (Conditional Approval): Made when IRB members require specific modifications to the research before approval can be finalized.
* Deferred: Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.
* Disapproval: Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.
* Tabled: Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting.

## How does the IRB decide whether to approve Human Research?

The criteria for IRB approval can be found in the HRP-312 - WORKSHEET - Exemption Determination for exempt Human Research and the HRP-314 - WORKSHEET - Criteria for Approval for non-exempt Human Research. 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 Investigator 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 institutional 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 requires modifications to secure approval 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 defers 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 disapproves 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.

## What are my obligations after IRB approval?

1. Do not start Human Research activities until you have the final IRB approval letter.
2. Do not start Human Research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources.
3. 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.
4. 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.
5. Update the IRB office with any changes to the list of study personnel.
6. Personally conduct or supervise the Human Research. Recognize that the investigator is accountable for the failures of any study team member.
	1. Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB, and in accordance with applicable federal regulations and local laws.
	2. When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
	3. Do not modify the Human Research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
	4. Protect the rights, safety, and welfare of subjects involved in the research.
7. Submit to the IRB:
	1. Proposed modifications as described in this manual. (See “[How do I submit a modification?](#_How_do_I)”)
		1. Single subject protocol exceptions should be submitted via the modification process.
	2. A continuing review application as requested in the approval letter. (See “[How do I submit continuing review?](#_How_do_I_1)”)
	3. A continuing review application when the Human Research is closed. (See “[How Do I Close Out a Study?](#_How_do_I_2)”)
8. Report any of the information items on the HRP-214 - FORM - Reportable New Information to the IRB online in Kuali within five business days of the investigator becoming aware of any of the following items:
	1. Information that indicates a new or increased risk, or a new safety issue. For example:
		1. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
		2. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
		3. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
		4. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
		5. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
		6. Any changes significantly affecting the conduct of the research
	2. Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably related** to the research procedures.
		1. A harm is “unexpected” when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
		2. A harm is “probably related” to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.
	3. Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
	4. Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g. FDA Form 483.)
	5. Written reports of study monitors.
	6. Failure to follow the protocol due to the action or inaction of the investigator or research staff.
	7. Breach of confidentiality.
	8. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
	9. Incarceration of a subject in a study not approved by the IRB to involve prisoners.
	10. Complaint of a subject that cannot be resolved by the research team.
	11. Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
	12. Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects).
9. Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
10. Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees.”)
11. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)
12. See additional requirements of various federal agencies in Appendix A. These represent additional requirements and do not override the baseline requirements of this section.
13. If the study is a clinical trial and supported by a Common Rule agency, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms. The form must be posted after recruitment closes, and no later than 60 days after the last study visit. The PI is responsible for the posting and not the IRB. Please contact the study sponsor with any questions.
	1. If certain information should not be made publicly available on a Federal website (e.g. confidential commercial information), the supporting Federal department or agency may permit or require redactions to the information posted. Contact the Federal department or agency supporting the clinical trial for a formal determination.
	2. Contact the supporting Federal department or agency sponsor with any other questions regarding consent form posting obligations.
14. All NIH-funded clinical trials are expected to register and submit results information to Clinicaltrials.gov, as per the ["NIH Policy on Dissemination of NIH-Funded Clinical Trial Information"](https://grants.nih.gov/policy/clinical-trials/reporting/index.htm) for competing applications and contract proposals submitted on or after January 18, 2017. The PI is the responsible party for this requirement. To obtain access to the Clinicaltrials.gov Protocol Registration and Results System, contact either orsp@umb.edu or irb@umb.edu.

## What are my obligations as the overall study PI for an sIRB study?

1. Coordinate with HRPP personnel to determine whether this institution’s IRB can act as the single IRB for all or some institutions participating in the study or if an external IRB will assume oversight.
2. Identify whether any IRB fees will be charged for this study and address any budget considerations.
3. Identify all sites that will be engaged in the human research and requiring oversight by the IRB.
4. Ensure that all sites receive a request to rely on the reviewing IRB and that all institutional requirements are satisfied before a study is activated at a relying site.
5. Collaborate with the reviewing IRB to document roles and responsibilities for communicating and coordinating key information from study teams and the IRB or HRPP at relying sites.
6. Respond to questions or information requests from study teams or the IRB or HRPP staff at relying sites.
7. Provide relying site investigators with the policies of the reviewing IRB.
8. Provide relying site investigators with the IRB-approved versions of all study documents, including an approved consent template.
9. Help prepare and submit IRB applications on behalf of all sites. This includes initial review, modifications, personnel updates, reportable new information and continuing review information for all sites.
10. Establish a process for obtaining and collating information from all sites and submitting this information to the reviewing IRB. This includes site-specific variations in study conduct, such as the local consent process and language, subject identification and recruitment processes and local variations in study conduct.
11. Provide relying sites with this HRP-103 - Investigator Manual.
12. Fulfill any communication responsibilities as outlined in the IRB reliance agreement and investigator protocol.
13. Ensure that consent forms used by relying sites follow the consent template approved by the reviewing IRB and include required language as specified by the relying sites.
14. Provide site investigators with all determinations and communications from the reviewing IRB.
15. Submit reportable new information from relying sites to the reviewing IRB in accordance with the terms outlined in the authorization agreement or communication plan.
16. Report the absence of continuing review information from relying sites if they do not provide the required information prior to submission of the continuing review materials to the reviewing IRB. Notify the relying site of their lapse in approval and applicable corrective actions.
17. Provide study records to the relying institution, review IRB or regulatory agencies upon request.

## What are my obligations as investigator when relying on an external IRB?

1. Obtain appropriate approvals from this institution prior to seeking review by another IRB.
2. Comply with determinations and requirements of the reviewing IRB.
3. Prepare consent and other study documents that are consistent with those approved by the sIRB (e.g., use the approved consent template to create site-specific documents).
4. Provide the reviewing IRB with requested information about local requirements or local research context issues relevant to the IRB’s determination prior to IRB review.
5. Notify the reviewing IRB when local policies that impact IRB review are updated.
6. Cooperate in the reviewing IRB’s responsibility for initial and continuing review, record keeping and reporting and providing all information requested by the reviewing IRB in a timely manner.
7. Disclose conflicts of interest as required by the reviewing IRB and comply with management plans that may result.
8. Promptly report to the reviewing IRB any proposed changes to the research and not implement those changes to the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
9. When enrolling participants, obtain, document and maintain records of consent for each participant or each participant’s legally authorized representative.
10. Promptly report to the reviewing IRB any unanticipated problems involving risks to participants or others according to the requirements specified in the reliance agreement.
11. Provide the reviewing IRB with data safety monitoring reports in accordance with the reviewing IRB’s reporting policy.
12. Report non-compliance, participant complaints, protocol deviations or other events according to the requirements specified in the reliance agreement.
13. Specify the contact person and providing contact information for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the reviewing IRB.
14. Fulfill any communication responsibilities as outlined in the IRB reliance agreement, investigator protocol, and any other relevant documentation provided by the external IRB.
15. Determine which UMass Boston institutional requirements and other local UMass Boston reviews apply to your study and ensure all are met.

## How do I document consent?

Use the signature block approved by the IRB. Complete all items in the signature block, including dates and applicable checklists.

The following are the requirements for long form consent documents:

* The subject or representative signs and dates the consent document.
* If the subject/representative is physically unable to sign the consent form, note this on the consent form and document the method used for communication with the prospective subject/representative and the specific means by which their agreement was communicated.
* The person obtaining consent signs and dates the consent document.
* Whenever the IRB or the sponsor require a witness to the oral presentation, the witness signs and dates the consent document.
* For subjects or representatives who cannot read and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document.
* A copy of the signed and dated consent document is to be provided to the subject.

The following are the requirements for short form consent documents:

* The subject or representative signs and dates the short form consent document.
* The person obtaining consent signs and dates the summary.
* The impartial witness (fluent in both English and the language spoken by the subject/representative) to the oral presentation signs and dates the short form consent document and the summary. The witness and the interpreter may be the same person.
* Copies of the signed and dated consent document and summary are provided to the person(s) signing those documents.

## How do I submit a modification?

Complete HRP-213 - FORM - Modification, attach all requested supplements, and provide to the IRB Office using the Kuali Protocols module. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Please note that research must continue to be conducted without inclusion of the modification until IRB approval is received. Updates to the list of study personnel also represent a modification to the research.

## How do I change (transfer responsibility) to a new principal investigator?

Changes of PI often prompt changes to other parts of the study. Review all consent/assent forms, recruitment materials and other documents to make certain they have been updated to reflect the change. The current PI may transfer responsibility to a new PI by submitting a modification (See “[How do I submit a modification?](#_How_do_I)”).

If the current PI is leaving the institution but will remain a study team member, please contact the IRB Office to determine if a reliance agreement is appropriate.

If the current PI is leaving the institution and plans to take research data or specimens with them, there are contractual agreements that may be needed in order to share individual level human subjects research data/specimens.

If a PI goes on an unanticipated leave or there is an abrupt departure from the institution, this should be reported to the IRB by a current member of the study team as soon as possible. Complete and submit HRP-214 - FORM - Reportable New Information.The submission should include whether the unanticipated leave is temporary or permanent, and whether responsibilities will be transferred to a new PI.

## How do I submit continuing review?

Complete HRP-212 - FORM - Continuing Review, attach all requested supplements, and provide to the IRB Office using the Kuali Protocols module. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If the continuing review involves modifications to previously approved research, submit a modification using HRP-213 - FORM - Modification. The two forms are combined when “Renew & Amend” is selected in Kuali.

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.

If the approval of Human Research expires all Human Research procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Continuing Human Research procedures is a violation of institutional policy. If current subjects will be harmed by stopping Human Research procedures that are available outside the Human Research context, provide these on a clinical basis as needed to protect current subjects. If current subjects will be harmed by stopping Human Research procedures that are not available outside the Human Research context, immediately contact the IRB chair and provide a written list of the currently enrolled subjects and why they will be harmed by stopping Human Research procedures.

## How do I close out a study?

Complete HRP-212 - FORM – Closure (Final Report), attach all requested supplements and provide to the IRB Office using the Kuali Protocols module. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If you fail to submit a closure 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 your Human Research records, including signed and dated consent documents for at least three years after completion of the research unless otherwise required by law. Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least six years after completion of the research unless otherwise required by law.

If your Human Research is sponsored, contact the sponsor before disposing of Human Research records.

## 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.umb.edu/research/orsp/institutional-review-board-irb/>.

If you have any questions or concerns, about the Human Research Protection Program, contact the IRB Office at:

University of Massachusetts Boston

Institutional Review Board

Office of Research and Sponsored Programs

100 Morrissey Boulevard

Boston, MA 02125-3393

irb@umb.edu

617-287-5374

If you have questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program that cannot be addressed by contact the IRB Office, follow the directions in HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN under “Reporting and Management of Concerns.”

1. This document satisfies AAHRPP element I.1.A, I.1.C-I.1.E, I-3, I.4.C, I.5.C, I.5.D, I.6.B, I.7.A-I.7.C, I-9, II.2.A, II.2.C, II.2.G, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.C-II.3.C.1, II.3.E, II.3.F, II.3.G, II.4.A, II.4.B, II.5.A, II.5.B, III.1.A, III.1.B, III.1.D, III.1.E, III.1.F, III.2.A, III.2.C, III.2.D [↑](#endnote-ref-1)