

Baystate Medical Center Institutional Review Board

IRBNet: Instructions and Tips for the Researcher

If you are unfamiliar with the IRBNet system, please review the training materials on our eWorkplace page (Departments→Academic Affairs→IRB) prior to proceeding with your application.

New Project Submissions:

IMPORTANT: The first submission (package #1) for all research projects must be to Sponsored Programs Administration (SPA). The SPA office serves as the institutional “registrar” for all research projects (human, animal, bench), community service grants/contracts, educational grants, projects requiring the review of the Institutional Biosafety Committee, and other sponsored activities across Baystate Health, including all resident research projects. Registration with the institution is accomplished via the submission of the “Core Data Form” to SPA.

New Project Submissions to the IRB:

Creating “Package 2” for submission to the IRB

1. Select study from “Study Manager” page.
2. Select “Project History”
3. Select “Create New Package”
4. Select “New Document Package”
5. Add “Core Data Form” to Package
 - a. Scroll down on the page to locate the “Core Data Form” previously submitted to SPA and click on the pencil icon
 - b. Review the Core Data Form and update as needed, “Save & Exit” when done.
6. Review and update the “Ancillary Services Worksheet” if the project will require ancillary services or additional committee approvals (i.e., Safety, Radiation Safety).
7. Complete IRB Basic Application, Part 1 (on-line document). As you complete this form, please note the instructions to complete supplemental forms.
8. Share the project with “Write Access” with any member of the research team who needs to contribute to the application.
9. Locate in the BH IRB library and complete and upload the IRB Basic Application, Part 2 (unless instructed otherwise in Part 1), applicable Supplemental forms, and Conflict of Interest and Commitment Questionnaires (for every member of the study team).

Note: To avoid later confusion, be certain to name the forms, questionnaires, etc. as they are named in the library
10. Upload the Protocol, Consent Form(s)*, Assent*, Advertisements*, Questionnaires*, Diaries*, other Subject Materials*, etc. (*if applicable). Use a clear naming convention such as type of document plus version date so that documents can easily be identified throughout the life of the study.
11. Upload Conflict of Interest/Commitment Questionnaires for each member of the study team. Label COI [Name, Date].
12. Link the User Profile for each member of the study team to the submission. See training materials in IRBNet under Forms and Templates for detailed instructions.
13. Share the project with:
 - a. All other members of the study team for electronic signature; restrict “Full Access” to those few individuals who should be able to submit and will receive all communications related to the project

(PI required and one or two members of the study team). Other team members should be assigned either Read or Write Access.

- b. Ancillary Services/Committees for electronic signature (“Read Access”) as instructed on Ancillary Services Worksheet.
- c. Additional required signatories (i.e., research with residents as subjects requires electronic signature of the Dean (Dr. Hinchey)
- d. Clinical Department Reviewer(s) (“Read Access”) if applicable; see Department Specific Requirements below.
- e. Department Chair or Equivalent (“Read Access”) for electronic signature. **NOTE: The Department Chair must be the final signature.** By signing the Department Chair attests that the study has scientific merit and that the research team is appropriately qualified and has the time and resources necessary to complete the study as described.

*Note: If the user cannot be located on the Share Project page then:

1. Check to make sure the proper Organization has been selected.
2. Contact the user to make sure they have registered on IRBNet (registration occurs the first time a user accesses IRBNet).

14. Submit the package to the “Baystate Health IRB”

Department Specific Requirements:

1. Anesthesia
 - Print out a complete copy of the initial submission package and provide to Dr. Neil Connelly for Research Committee Review and the investigator and a review committee member signature prior to requesting the electronic signature of Dr. Bailin.
2. Medicine
 - Please include the Scientific Review Committee (SRC) forms in your IRB submission package along with the documentation required by the IRB. SRC forms are available on [eWorkplace](#) and within IRBNet in the IRB Forms & Templates section. “Share” (Read Access) your submission with Dr. Jay Steingrub. Dr. Steingrub will determine if review by the SRC is necessary or if accelerated review for feasibility and merit is sufficient. Include the following statement in the IRBNet “share” notification: “*For consideration for SRC review or department sign-off.*” Electronic signature by Dr. Steingrub or Dr. Higgins is necessary before the IRB will accept the submission. If reviewed by the SRC include the letter of approval in the IRB submission.
 - Cancer Services; Adult (non-surgical): Signature by Dr. Mertens, Final Signature by Dr. Higgins. Include the BRCP Clinical Research Review Committee minutes in the submission package. Investigator-initiated projects must be shared with and signed by Dr. Steingrub as described above.
3. Obstetrics and Gynecology
 - Print out a complete copy of the initial submission package and provide to Pete St. Marie for departmental review and a review committee member signature prior to requesting the electronic signature of Dr. Daniel Grow.
4. Pathology
 - “Share” (Read Access) your submission with Dr. James Mueller for department scientific review and electronic signature prior to requesting the electronic signature of Dr. Richard Friedberg.
5. Pediatrics

- All pediatric protocols require review and electronic signature by Dr. Lindsey Grossman. When your proposal is ready for submission, send Dr. Grossman a separate e-mail via outlook with a brief description of the proposed project and the IRBNet number with a request for her review and signature.
6. Surgery
 - Send your protocol and consent electronically to Barbara Burkott, RN, CCRP for departmental review. Surgery research team will notify Dr. Richard Wait when a project is prepared for his signature prior to IRB submission.
 7. Division of Health Care Quality
 - Electronic signature by the Department Chair under whom the investigator has their faculty appointment is required.

Checklist: New Submissions

* denotes include if applicable

- Core Data Form
- Ancillary Services Worksheet*
- IRB Basic Application, Part 1
- IRB Basic Application, Part 2*
- Applicable Supplemental Forms:
 - Supplement A Human Subjects Research Determination*
 - Supplement B Preparatory to Research*
 - Supplement C Emergency Use Report*
 - Supplement D Request for Exempt Determination*
 - Supplement E Request for Expedited Review*
 - Supplement F CIRB Facilitated Review*
 - Supplement G Collaborative Research*
 - Supplement H Research Involving Children*
 - Supplement I Research Involving Prisoners*
 - Supplement J Research Involving Pregnant Women, Fetuses, and Neonates*
 - Supplement K Research Involving Subjects with Impaired Decision Making Capacity*
 - Supplement L Waiver or Alteration of Consent and/or HIPAA*
 - Supplement M Establishment of a Data Repository*
 - Supplement Mm Use of Existing Data*
 - Supplement N Establishment of a Tissue Repository*
 - Supplement Nn Use of Specimens Obtained from a Repository*
 - Supplement O Research Involving the Internet*
 - Supplement P Investigational Drugs or Devices*
 - Supplement Q In Vitro Diagnostic Devices*
 - Supplement R Humanitarian Use Devices*
- Conflict of Interest/Conflict of Commitment Questionnaires for each member of the Research Team
- Link to CVs and CITIs of each member of the Research Team (to be considered current, CITI Basic or Refresher must have been completed within the past 3 years).
- Protocol
- Investigator's Brochure(s)*
- Consent Form(s)*
- Assent Form(s)*
- Recruitment Materials*
- Subject Materials (questionnaires, diaries, etc.)*
- Form 1572*
- Federal Grant Application*
- NIH approved Sample Informed Consent Document if NIH-funded multicenter clinical trial*
- Electronic Signatures:
 - Each member of the research team
 - Ancillary Services/Committees*
 - Other required signatures (i.e. Dean)*
 - Department- Specified Signatures*
 - Department Chair (final signatory)

Responding to the IRB:

The results of the IRB review and the related documents can be accessed on the Project Overview page.

If the IRB has required modifications to the study, required additional information, or deferred the study, you respond by creating a new package.

Refer to the document titled: [“Subsequent package submissions on IRBNet”](#) for detailed instructions.

Important: When responding to the IRB ALWAYS:

- Include a memo with a point-by-point response. Label the Memo “Letter: Response to the IRB” in IRBNet.
- If revisions have been made to previously submitted documents (consent forms, protocol, questionnaires, etc.), include both a “tracked changes” version and a “clean” version. This rule does not apply to the Core Data Form or IRB Basic Application 1.
- All responses to the IRB must be electronically signed by the Principal Investigator (PI) and the person completing the submission (if not the PI).

Modification Requests (Amendments), Protocol Deviation Reports, Unanticipated Problem Reports and other interim reporting

Interim reports and requests to the IRB are made by “Creating a New Package”. Refer to the document titled: [“Subsequent package submissions on IRBNet”](#) (available in the IRB Document Library) for detailed instructions.

Important:

- Select the template application for the type of interim request or report from the Document Library
- Name the document with the name from the Document Library (Request for Modification, Protocol Deviation Report, etc.) to easily identify the document and avoid later confusion
- If revisions have been made to previously submitted documents (consent forms, protocol, questionnaires, etc.), include both a “tracked changes” version and a “clean” version. This rule does not apply to the Core Data Form or IRB Basic Application 1.
- If adding a study team member, update and include the Core Data Form and be certain to upload the team member’s Conflict of Interest/Commitment Questionnaire, and Link their User Profile to the submission.. New study team members cannot begin work on the project until approved by the IRB. The person being added must sign the package in addition to the Principal Investigator and the person completing the submission.
- All interim applications/reports must be electronically signed by the Principal Investigator (PI) and the person completing the submission (if not the PI).

Continuing Review Reports:

Continuing Review Reports to the IRB are made by “Creating a New Package”. Refer to the document titled: “Subsequent package submissions on IRBNet” for detailed instructions (available in the IRB Document Library).

Note: Baystate Medical Center has 2 IRBs; each meets one time per month. Studies stay with the IRB that initially approved the protocol. In order to assure that there is time to get the on to the agenda for the correct board and to allow sufficient time for the researcher to respond to any modification requirements or requests for information; **Continuing Review Reports are due to the IRB 60 days prior to expiration.** Failure to submit your Continuing Review Report on time puts your study at risk of expiration and a required hold on all study activities until approval is granted.

Important:

- Select the template application for Continuing Review Report from the Document Library
- Name the document “Continuing Review Report [dated]” to avoid later confusion
- Upload Conflict of Interest/Commitment Questionnaires for each member of the study team. Link their User Profile to the submission. The CITI Basic or Refresher must have been completed within the past 3 years to be considered current. Conflict of Interest/Commitment Questionnaires must be updated versions (not simply carried forward from previous submissions).
- Upload any relevant publications, study reports, etc. as directed in the Continuing Review Report.
- All Continuing Review reports must be electronically signed by the Principal Investigator (PI) and the person completing the submission (if not the PI).

Checklist: Continuing Reviews

* denotes include if applicable

- Continuing Review Report
- Publication(s) related to the research per the instructions on the continuing review report*
- Any un-submitted reports identified while completing the continuing review report*
- Conflict of Interest and Commitment Questionnaire for each member of the research team
- Link each member of the research teams CITI documentation to the submission package