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Logging In

The IRB system is secure, which means only authorized individuals have access to it. When you log in to the system, you get a personalized view of the information and possible actions pertinent to you.

To log in:
1. Locate your HUID number and password
2. Navigate to irb.harvard.edu
3. Ensure the “HUID” tab is selected
4. Enter your HUID and Password in the appropriate spaces
5. Click the “Login” button
6. Once authenticated, you will be taken into ESTR, to your personal workspace.

If you are unable to log in, contact the ESTR Help Desk at ESTRhelp@harvard.edu

Creating a New Study

You can create a new study for IRB review by entering information into a series of online forms. The number of forms included may change based on the answers you provide. The forms tell you where to attach files to provide supporting information. The forms may contain required information identified by a red asterisk (*), you cannot proceed without providing that information. A required attachment to the Basic Information form is a Word document that describes the research: either the Protocol Template or the Not Human Subjects Research Determination Request. Additional documents should be attached to the forms where appropriate, such as recruiting, consenting and debriefing subject material. It is recommended that these documents be prepared prior to creating the new study; templates and guidance are available on your IRB website.

The simplest approach is to follow the forms in order, answering the questions and clicking Continue to save your information and move to the next form. When you reach the end of the series of forms, click the Finish button.

Note: A continuing review, modification, or RNI (reportable new information) submission can be handled similarly to a study. For differences, see Submitting Continuing Reviews and New Information.

Tips: If a study team member plans to create a new study which is similar to a previous one, the PI on the previous study can complete the Copy Submission activity to create a partially completed form to update and further edit prior to submission to the IRB for review.

To create a new study for review:
1. From My Inbox, under My Current Actions, click Create New Study.
2. Fill in the applicable boxes, answer the questions, and attach appropriate documents.
3. Click Continue to move to the next form.
4. Click the ‘jump to’ menu to go to a specific section (be careful to save before jumping to another page).

5. To save or exit the SmartForm at any time, click on “Save” and “Exit” button in the top toolbar. Exit will take you to that submission’s workspace.

6. When you reach the final page, click **Finish** to exit the study.

   **Important!** The study has not been submitted for review yet. For instructions, see Submitting the Study for Review.

**Tips:**

Reference the **Library** (linked on the left side of any workspace screen) any templates/forms that are requested within the SmartForm, along with guidance materials.

A red asterisk (*) precedes each question that requires an answer. If you cannot answer a required question at this time, or if you need to stop and continue at a later time, you can save and return to the submission later. You must provide all required information before you can submit the study for review.

**What to include in the SmartForm**

The SmartForm is the series of web-pages (or forms) where you can input specific information about a study. The following section describes what information should go into each space of the SmartForm.

**SmartForm Section: Basic Information**

1. **Title of study.** Enter the complete study title. Please avoid use of quotation marks in the study title.

2. **Short title.** The short title identifies the study throughout the system, such as in your inbox and in an IRB reviewer’s list of submissions to review. This should be 80 characters or less, and should not contain quotation marks. If left blank, the system will automatically pull in the first 80 characters of the (long) study title.

3. **Brief description or abstract.** Enter a brief description of the study or the study abstract. This should be 225 words or less.
4. **Name of Principal Investigator.** Enter the name of the Principal Investigator. For details on who may be listed in this space, please visit your IRB website or Investigator Manual.

This field will default to the name of the person completing the form. It may be changed by selecting clear and typing the name in the space provided (a list will appear with names from which to select), or you can click the select option to search the list of names. Use the “%” symbol to replace portions of a name which are unclear or possibly not spelled correctly. This is called a “wildcard” character.

5. **Does the investigator have a financial interest related to this research?** Indicate if the Principal Investigator has a financial interest. For more information regarding what constitutes a financial interest, please visit your IRB website. If an individual has a financial interest, complete and attach “FORM: Financial Interest Disclosure Form” to the Supporting Documents page of the SmartForm.

6. **Select the study's department.** Indicate the name of the Principal Investigator or Faculty Sponsor’s department for this study.

Type the department name in the space provided (a list will appear with options from which to select), or you can click the select option to search the list of available departments and schools. Use the “%” symbol to replace portions of a word of which may be unclear or possibly not spelled correctly. This is called a “wildcard” character.

7. **Are you requesting that an external IRB act as the IRB of record for this study?** Select Yes if you are submitting an application requesting that a Harvard IRB rely on the review of another IRB. Select No if you are requesting that a Harvard IRB review and approve the study.

If you selected Yes, question 8 on the Basic Information SmartForm will disappear (it is not needed when requesting a reliance agreement between two IRBs), and you will click Continue to proceed to the External IRB sub page.

**SmartForm Sub-Section: External IRB**

On the following page you will need to enter information about the External IRB that will serve as the IRB of Record for the study. Contact your IRB for more instructions on External IRBs and/or assistance with completing and submitting this form.

1. **External IRB:** Click Select to indicate which institution will serve as the IRB of Record. If the reviewing institution is not listed, select Other.

2. **IRB Authorization Agreement or Request Form:**
   - To request that the Harvard IRB rely on a Harvard Catalyst institution, visit this [link to the Catalyst form](#). You will be expected to login using your HUID and PIN, eCommons, or HarvardKey login. Attach a copy of the completed Catalyst form to question 6.
   - To request that the Harvard IRB rely on a non-Catalyst institution, attach "FORM: IRB Authorization Request."

3. **Approval letter from external IRB:** Upload the External IRB’s approval letter here, if available. If local approval is not available at the time of submission, a copy must be submitted to the IRB prior to beginning any human subjects research at the external site(s).

4. **Initial approval date by external IRB:** Enter date of initial IRB approval if/when known.

5. **Last date of approval period:** Enter date of the most recent IRB approval if/when known.

6. **Supporting documents:** Upload any supporting documents such as a completed Catalyst Request Form, protocol submitted to the External IRB, or IRB Authorization Agreement Request Form.

8. **Attach the Research Protocol or Not Human Subjects Research Determination Request Form.**

Select and use the template provided on the SmartForm (or on your IRB website) that is appropriate for your project and the IRB to which you are submitting. Attach a copy of the completed protocol template, or if this application represents a request for a “Not Human Subjects Research determination”, attach “FORM: Not Human Subjects Research Determination.” Of note, a research
A protocol is required for Exemption Requests. Be sure to name the file in a manner that identifies it as your protocol.

**SmartForm Section: Funding Sources**

On this page include any pending/awarded funding sources or financial support for this study. Leave questions 1 and 2 blank to indicate that there is no funding for this study. Reminder: If the funding status changes following IRB determination, submit a modification to this study.

1. **Identify funding that has been submitted as a grant proposal to your sponsored programs office.** Find and add all funding sources listed in the Harvard Grants Management Application Suite (GMAS) that are associated with this study.

   Begin typing a piece of the grant PI full name (first then last name) or the funding source (a list will appear with options from which to select), or you can click the “add” option to search the list of available funding sources. Use the “%” symbol to replace portions of a word of which may be unclear or possibly not spelled correctly. This is called a “wildcard” character.

2. **Identify other non-sponsored funding sources for the study.** List all other funding sources. Attach a complete copy of the funding application or agreement for these listed sources to the Supporting Documents page of the SmartForm, when applicable, and remove or black-out any salary information.

**SmartForm Section: Study Team Members**

The Study Team Members page of the SmartForm should include the name of individuals that a) have contact with human subjects, b) have access to data that is identifiable (including data that is indirectly identifiable using a coding system or key); or c) are responsible for the design, conduct, or reporting of the research.

**Tips:**

- Do not list the PI on this page.
- For studies with a non-faculty Principal Investigator and where the IRB requires, list the Faculty Sponsor on this page.
- Each of the individuals named as study team members must complete human subjects training (refer to your IRB website to learn about training requirements).
- Include non-Harvard collaborators who meet these criteria only in the absence of their local IRB review.

1. **List study team members with an HUID.** Click “Add” to include all team members who have an HUID.
   - If you would like a person on the study team to access ESTR, and his/her name does not appear in the search results; this individual must obtain an HUID. Please visit the ESTR support site for detailed instructions on how to obtain an HUID for use with ESTR.
   - Each of the individuals listed must complete human research training unless you clearly indicate that the individual is listed simply for access to this study record (in the Study Team Member details and via “Add comment” on the submission workspace).

   **Tip:** If an individual has a common name and more than one person with the same name appears, select one of the names. When in the submission workspace, view the “Project Contacts” tab to verify email addresses to ensure the correct person is associated with the study.

2. **List study team members without an HUID and/or attach other relevant documents.**
• If an individual’s name does not appear in the search results available, attach a completed “FORM: Non-Harvard Study Personnel Form”. This form should only list individuals who were not able to be listed under item 1 in the Study Team Members section of the SmartForm. Each of the individuals listed must complete human research training. Individuals only listed on this form will not have access to ESTR.
• Indicate whether each listed individual has a financial conflict of interest relating to the Human Research. For more information about what constitutes a conflict, please visit your IRB website. If an individual has a financial interest, complete “FORM: Financial Interest Disclosure Form” and attach it here.

SmartForm Section: Study Scope

1. **Are there external sites where the Investigator will conduct or oversee the research?** Mark yes here if there are any locations other than Harvard where this project will take place.

   **SmartForm Sub-Section: External Sites**
   
   Identify all locations other than Harvard where this project will take place, indicate details about the site as prompted on the External Site details. Upload information for each external site to the Supporting Documents SmartForm.

2. **Does the study involve the use of a drug in one or more persons other than use of an approved drug in the course of medical practice?** Indicate if drugs, biologics, foods or dietary supplements are used in the Human Research.

   **SmartForm Sub-Section: Drugs**
   
   Identify all drugs, biologics, foods and dietary supplements (approved and unapproved) being used in the Human Research. For each, indicate whether it has an IND number and for those that do, ensure that the application includes one of the following: (a) sponsor protocol with the IND number; (b) communication from the sponsor with the IND number; or (c) communication from the FDA with the IND number. Additionally attach the following items:

   • Investigator Brochure for each investigational drug involved in the Human Research.
   • Current Package Insert. Submit for each marketed drug involved in the Human Research.
   • Validation of IND#, e.g. FDA Approval letter or Sponsor Protocol.

3. **Does the study involve: (1) The use of a device in one or more persons that evaluates the safety or effectiveness of that device, or (2) Data regarding the use of a device on human specimens?** Indicate if a device is used in the Human Research.

   **SmartForm Sub-Section: Devices**
   
   Identify all devices being evaluated for safety or effectiveness or as a comparator (approved and unapproved). For each, indicate whether it has an IDE number and for those that do, ensure that the application includes one of the following: (a) sponsor protocol with the IDE number; (b) communication from the sponsor with the IDE number; or (c) communication from the FDA with the IDE number. Indicate whether the device is being submitted under the “Abbreviated IDE requirements” in 21 CFR 812.2(b). Additionally attach the following items:

   • Validation of IND# or IDE#, e.g. FDA Approval letter or Sponsor Protocol.
SmartForm Section: Consent Forms and Recruitment Materials

1. Consent, Assent, Permission, and HIPAA Authorization Forms: Use the templates appropriate to your IRB to create and attach the following items. Visit your IRB website for additional instructions regarding how to create consent materials:
   - Consent, Assent Forms, or Scripts including HIPAA Authorization Forms (as applicable).
     Consent/assent documents must include version date and/or version number. If any consent materials will be translated, attach “FORM: Translation Attestation” to the Supporting Documents section of the SmartForm which appears later in the submission process.
   - DHHS-approved sample consent document. Consent documents must include version date and/or version number. If consent materials will be translated, submit “FORM: Translation Attestation.”

2. Recruitment Materials: Each recruitment document, script, flyer, advertisement, etc. must include version date and/or version number. Guidance on what is appropriate to include and exclude within an advertisement can be found in “WORKSHEET: Advertisements” and/or “WORKSHEET: Payments.” Advertising material must include version date and/or version number. If any of materials will be translated, submit “FORM: Translation Attestation.” Worksheets are available for reference on your IRB website or in the Library section of ESTR (linked on the left side of submission and personal workspaces).

SmartForm Section: Supporting Documents

Attach supporting files, naming them as you want them to appear in the approval letter: Also, be sure to name the file itself in a manner that identifies it as associated with your study.

- Ancillary Approvals/Permissions. Submit approval letters or permissions from any additional office or organization reviewing this project (for example, a letter of support). If unavailable at the time of submission, plan to submit a copy to the IRB prior to implementing any study procedures.
- Data use agreements or other Agreements. Submit copies of any documents authorizing the use of data, or other contracts or agreements associated with the study.
- Debriefing Materials. If any of these materials will be translated, also submit a Translation Attestation Form.
- External Site Information. If question 1 in the SmartForm Section: Study Scope indicated that there are external sites where the research will be conducted or overseen, submit an approval notice from each external site identified in the SmartForm. If unavailable at the time of submission, plan to submit a copy to the IRB prior to beginning any human subjects research at the external site(s).
- Federal Department Requirements Checklists. Attach any required checklist associated with certain kinds of Federal funding (such as DOD, DOJ or EPA).
- Financial Interest Disclosure Form. Submit this form if the Principal Investigator self-identifies a financial conflict of interest related to the research on the SmartForm: Basic Information page. Forms for any other team members which self-identify a financial conflict of interest should be attached to the SmartForm: Study Team Members page.
- Foreign Language Documents. Submit all translated study materials.
- Funding Source Attachments. If not associated with GMAS and as applicable, submit a complete copy of the grant applications, subcontract, and/or any funding agreements regardless of funding source.
- Individual Investigator Agreement (IIA). When a non-Harvard collaborator will be covered under the Harvard IRB review and this person is not affiliated with another institution, submit this form here or attached a completed copy to the SmartForm: Study Team Members page.
- IRB Authorization Agreement (IAA) Request. When multiple institutions are engaged in the Human Research, submit this form allowing an investigator to designate Harvard as the Reviewing Institution...
(responsible for IRB review) or Relying Institution only when such agreements are with non-Harvard Catalyst institutions. To request such an agreement with a Harvard Catalyst institution, visit this [link].

- **PI's Current CV (ICH-GCP E6 Only).** Submit a copy of the Principal Investigator’s current (signed/dated) CV only when required by sponsor to follow the “International Council on Harmonisation – Good Clinical Practice E6.”

- **Radiation Safety Form.** If the Human Research involves the use of approved or unapproved diagnostic or therapeutic radiation outside routine clinical practice, complete and submit “FORM: Radiation Safety.”

- **Sponsor Protocol including DHHS-approved protocol.** Submit the sponsor protocol, if applicable.

- **Study Instruments/Tools.** Including all data collection instruments, questionnaires, surveys, focus group discussion guides, or interview guides. Do not include Case Report Forms. Study documents must include version date and/or version number. If any materials will be translated, submit “FORM: Translation Attestation.”

- **Translation Attestation Form.** Submit this form at the time of initial application if any study documents will be administered in languages other than English. Obtain the PI and translator’s signature. This form must also be submitted as part of a study modification when requesting approval for the use of new study documents that will be translated. Submit the locally-approved, translated documents to the IRB when they become available.

Upon selecting continue from this page, the browser will direct to the last page of the SmartForm where you will have the opportunity to select “finish” to return to the submission workspace.

**Important!** Clicking Finish does not send the study for review. The PI must click Submit (marked with a red arrow in the submission workspace) for the submission to proceed on for the next state of review.

**Checklist of Information to Attach**

Be prepared to attach several files to your study. While editing the study, several forms provide places to attach related files. In some cases, a template file is provided, such as for the protocol.

When attaching each file, name it as you want it to appear on the IRB approval letter and ensure the file name clearly indicates what the file is and the study to which it belongs.

Attach the information listed below (if relevant to your study) to the location identified.

<table>
<thead>
<tr>
<th><strong>Basic Information</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Research protocol OR Not Human Subjects Research Determination Request Form</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>External IRB</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• IRB Authorization Agreement or Catalyst Cede Review Request Form</td>
</tr>
<tr>
<td>• External IRB Approval Letter (if available)</td>
</tr>
<tr>
<td>• Any other relevant External IRB information for Harvard IRB consideration.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Funding Information: Funding Sources page, with each source</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant related attachments should be included on the “Supporting Documents” page.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Study Team Members: Page to add study team members, with each staff member</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Study Personnel Form, listing team members who do not have an HUID and cannot be listed with item 1</td>
</tr>
<tr>
<td>• Individual Investigator Agreement for non-Harvard Collaborators without an institutional affiliation.</td>
</tr>
</tbody>
</table>
• Completed Financial Interest Disclosure Forms
• Updated Human Subjects Training information, if not already stored in ESTR.

**External Sites: External site page to add other institutions engaged in the research**

*External site related attachments should be included on the “Supporting Documents” page.*

**Drug Details: Drugs page, with each drug, or on main Drugs page if not specific to one drug**

- Package insert
- Investigator brochure
- Verification of each IND number
  - Sponsor protocol with the IND number
  - Communication from the FDA or sponsor with the IND number

**Devices Details: Devices page, with each device, or on main Devices page if not specific to one Device**

- Product labeling/device instructions
- Investigator brochure
- Verification of each IDE number (one of these):
  - Sponsor protocol with the IDE number
  - Communication from the FDA or sponsor with the IDE number

**Consent Forms and Recruitment Materials**

- Consent documents
  - HHS-approved consent forms
  - For non-written consent, a script of the information provided orally to the subjects
- Parental Permission, and Assent documents
- HIPAA Authorization Forms
- Recruitment Materials; including fliers, advertisements, and scripts

**Supporting Documents: All other relevant information**

- Conflict of Interest Committee’s determination for each financial interest related to the research
- Material to be seen or heard by the subjects; such as surveys or questionnaires
- Debriefing Materials
- Translation Attestation Form
- External site information
- Grant Materials (if the grant is not included in GMAS)

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**Editing a Submission**

You can continue to make changes to a study until you submit it for IRB review. You can also make changes if the IRB requests clarifications (except during committee review) or modifications. **Note:** steps indicated here can also be completed for Modifications, Continuing Review and RNI submissions.

**To edit a study before it has been submitted:**

1. From My Inbox, click the name of the study to open it.  
   **Note:** If the study does not appear in your inbox, see Accessing a Submission.
2. Click **Edit Study** on the left. For Modifications or Continuing Reviews, click Edit Submission.
3. Make changes as appropriate. When updating a study document previously submitted to the IRB, revise it in tracked-changes format and replace the original document with the tracked-changes version. When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.
4. Exit the study.

**Tip:** Choose one of these ways to exit:
Click the Exit link. If prompted to save the study, click Yes.
Click Continue on each form, and then click the Finish button on the final form.

If you have submitted the study and you need to make edits, or edits are requested from an Ancillary Reviewer, you can still make edits to the study without having to make a special request to the IRB to open the study record.

To edit a study after it has been submitted:
1. Go to the Submissions page (linked on the left of your Inbox page)
2. From the All Submissions or In Review tab, click the name of the study to open it. See Accessing a Submission for more instructions.
3. Click Withdraw on the left.
4. (Optional) Use the comment box space, or document upload, to provide additional information. Do not upload any study documents here; study document should be uploaded to the SmartForm.
5. Click OK. The PI, any PI Proxy, the Primary Contact and IRB Coordinator will receive a notice that the submission has been withdrawn. The submission will be returned to the Pre-Submission state where you can make edits. After edits are completed, the PI or PI Proxy must complete the Submit activity again, to send it back to the IRB for review.

Tip: When the submission is in pre-submission or clarifications requested, click Discard to completely remove a submission from further consideration by the IRB.

Checking the Study for Errors
Checking the study for errors and omissions helps you include all the relevant information, which is critical for receiving a timely review of your study.

Using these types of error checking helps you supply all the information the IRB needs:

- **Automatic system error checking** identifies any omitted answers to required questions on the form when you click Continue. A red asterisk (*) precedes each blank or question that requires an answer. Keep in mind that the system cannot catch every omission while you edit the study if you skip questions that cause more forms to be added to your study.

- **Visually inspecting the forms** to see what you may have missed, especially:
  - Questions that are relevant to your study but are not required for all studies
  - Documents that should be attached (see Checklist of Information to Attach)

To perform a visual inspection, open the study and look through the forms in order. To open the study, see Editing a Submission.

**Using the Hide/Show Errors option** to find and correct all errors before submitting the study. The system automatically checks for errors when the PI attempts to submit the study. However, if you are filling out the forms on behalf of the PI, it is best to check the study for errors before the PI attempts to submit it, using the steps below.

**To use Hide/Show Errors to find and correct errors:**
1. Open the study, as explained in Editing a Submission.
2. From the top navigation area, click Hide/Show Errors.

   The Error/Warning Messages pane appears at the bottom of the window, listing all the current errors and where to find them.

<table>
<thead>
<tr>
<th>Message</th>
<th>Field Name</th>
<th>Jump To</th>
</tr>
</thead>
<tbody>
<tr>
<td>This is a required field.</td>
<td>Is Study Under IND</td>
<td>Drugs</td>
</tr>
<tr>
<td>This is a required field.</td>
<td>Devices</td>
<td>Devices</td>
</tr>
<tr>
<td>This is a required field.</td>
<td>Device Type</td>
<td>Devices</td>
</tr>
</tbody>
</table>

3. For one of the errors listed, click the link in the Jump To column to go to the form containing the error.
4. Click Continue to identify the specific questions on the form with errors.
5. Fill in the missing information.
6. Click Refresh in the Error/Warning Messages pane to update the list of errors.
7. Continue correcting errors until no errors are listed.

### Submitting the Study for Review

After entering all required information into the SmartForm and attaching files, the Principal Investigator must submit the study for IRB review.

**Tips:**

- Make sure you attach all applicable information to the study, as identified in Checklist of Information to Attach.
- Check for missing information before attempting to submit the study, as described in Checking the Study for Errors. Any errors or omissions not corrected are shown when attempting to submit the study and must be corrected before you can submit it for review.

**To submit the study for IRB review:**

**Important!** Only the Principal Investigator can complete the following steps for an initial application.

1. Log in to irb.harvard.edu.
2. Make sure you are in My Inbox.
   
   **Note:** If you do not see My Inbox, click the My Inbox link (top right part of the page).
3. Click the name of the submission to open it. It should be in the Pre-Submission state.
4. Click the red Submit button from the My Current Actions list on the left.

5. The system will conduct an ‘error check’ to identify if any required questions were missed.

Tip: If any errors or warnings are shown, click the link in the Jump To column to go to the form containing the problem. For more information, see Checking the Study for Errors. When all errors are corrected, try submitting the study by clicking Submit again.

6. Click OK to agree to the PI assurance statement presented on the screen.

If you would like to separately refer to the PI assurance statement:

- Before completing the activity, click on the Submit activity, but choose cancel to close the window after reading.
- Once the Submit activity is completed, click on the name of the activity on the History details of the workspace to read elements of the activity form.

When an initial study, modification or continuing review is submitted to the IRB office; the PI, PI Proxy and Primary Contact receive a notice confirming that the activity is completed. This notice includes the PI assurance statement.

What to Expect After Submitting

Submitting information to the IRB initiates a series of activities that may include:

- Review within your department
- Pre-review by an IRB staff member
- Review by the IRB committee or a designated reviewer
- Communication of the IRB decision to the investigator

Any of these may lead to a request for the study team to take further action, such as providing clarifications or modifying the study. Whenever the study team needs to act, the PI receives an e-mail notification, and the study appears in My Inbox for all study team members when they log in to the IRB system.
Important! Make sure the appropriate person is listed as the primary contact to receive e-mail and see the study in My Inbox (along with the PI and any PI proxies, who also receive these). By default, the person who created the study is the primary contact. See Changing the Primary Contact.

Checking the Status of Your Study

You can see a diagram showing the state of your study within the IRB review process by opening the study. The bubble shaded dark blue indicates the present status in the workflow. For example:

You can easily open your study from one of the following lists (depending on its status):
- My Inbox
- IRB In-Review Studies
- IRB Active Studies

For instructions about opening your study from these lists, see Accessing a Submission.

Communicating with Staff during Review

During review (and after), you can complete the Add Comment activity to:
- Post a note to the submission history and
- If selected, send a notice to:
  - PI/PI Proxy and Primary Contact
  - Study Team Members and/or
  - The assigned IRB Coordinator (If the IRB Coordinator box is selected and there is no assigned IRB Coordinator, a notice is sent to all members of the IRB office.)

Important!

- The information in the comment is visible to all individuals with access to the submission even if they are not selected as notice recipients.
- Do not attach items which are part of the regulatory review.
- If a submission is in the Clarifications Requested state, use the Submit Response activity to send information back to the IRB for continued review.

Finding Determination Letters and Approved Documents

To find determination letters:
1. Log in to irb.harvard.edu.
2. Navigate to an approved submission (see Accessing a Submission for more instructions).
3. View the initial determination letter from the IRB/IRB Office at the top right of the workspace:
OR

1. Log in to irb.harvard.edu.
2. Navigate to an approved submission (see Accessing a Submission for more instructions).
3. Click the Follow-on Submissions tab and click the “Correspondence Letter” link to see any/all Modification or Continuing Review letters.

**Tip:** To view a letter, simply click on any Correspondence link and to save a letter, right click and select ‘Save Link As.’

**To find approved documents:**

1. Log in to irb.harvard.edu.
2. Navigate to an approved study, see Accessing a Submission for more instructions.
3. Click the “Documents” tab on the main study workspace.
4. Click on the appropriate document link to view the version you’re looking for. To save a document, right click and select ‘Save Link As.’

**Important!** A watermark stamp will only appear on Consent Materials, Recruitment Materials/Scripts, and Debriefing Materials. The IRB does not stamp documents with approval dates.

**Accessing a Submission**

You may want to open a specific submission to view or update its contents, submit it for review, review it, or take other actions.

**Note:** Your access to a study is personalized based on your role in the system and the role you play in relation to the particular study. In addition, the actions you can take on a study are personalized.

**To open a study,** click its name when you find it in a list of studies.
To find a list that includes the study, try these quick suggestions:

<table>
<thead>
<tr>
<th>Check this list...</th>
<th>For...</th>
<th>How to find this list</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>My Inbox</strong></td>
<td>Studies assigned to you for action, such as a study you are:</td>
<td>Click the <strong>My Inbox</strong> link in the top right navigation header.</td>
</tr>
<tr>
<td></td>
<td>- Preparing to submit</td>
<td>Your Name [My Inbox] Logoff</td>
</tr>
<tr>
<td></td>
<td>- Preparing a requested clarification to submit a response</td>
<td></td>
</tr>
<tr>
<td><strong>IRB All Submissions tab</strong></td>
<td>All studies, continuing reviews, modifications, and reportable new information (RNI) entered into the system that you have permissions to view</td>
<td>Click <strong>IRB</strong> in the top left navigation area (or the Submissions link in the Shortcuts area) and select the <strong>All Submissions</strong> tab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Tip:</strong> Try filtering this list by the study name or principal investigator. Next to Filter by, select <strong>Name</strong> or <strong>Investigator</strong>. Then type the beginning of the name and click <strong>Go</strong>.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>View the <strong>State</strong> column to see where the submission is in the review process.</td>
</tr>
</tbody>
</table>

**Responding to a Request for Clarifications or Modifications**

At any stage during the review process, the IRB may request clarifications to the study. Similarly, the official IRB determination may be that the study requires changes (or additional modifications) before research can begin.

Both situations require the study staff to take similar actions. In either case, the PI, any PI proxy, and the study’s primary contact will receive a system notification requesting either clarifications or modifications. The study also appears in My Inbox for each member of the study team.

**Important!**

- Any study team member can update the study and submit a response.
- Failure to respond promptly slows the review and approval process for your submission. In some cases, your submission may be rescheduled for review at a later IRB meeting because the committee requires your response before making a decision.
To view the details of the request and respond with the changes:

1. From My Inbox, click the name of the study to open it.
2. Locate the details of the request, as described here:
   - **For Clarification Requested**: In the Activity column under Clarification Requested, read the request details.
     
   ![Image of Clarification Requested]

   If applicable, click the **read more** link to display the remaining text.

   - **For Modifications Required**: Click the letter link near the top of the page on the right side. The letter contains the modification requirement details.

     ![Image of Modifications Required]

3. Edit the study to incorporate changes as needed. For instructions, see [Editing a Study](#).
   
   **Notes:**
   - In most cases, you can update all aspects of the study, including adding, updating, or removing attached documents.
   - When updating a study document previously submitted to the IRB, revise it in tracked-changes format and replace the original document with the tracked-changes version. When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.
   - If clarifications were requested during Committee Review, you cannot edit the study, and you see the View Study button instead. In that case, respond to the reviewer by commenting in the Submit Response form, as described in the next step.

4. Click **Submit Response** to return the study to the reviewers.

   **Notes:**
   - The Submit Response form gives you space to type a point-by-point response to the requests and to attach a file. However, any permanent study information should be incorporated into the SmartForm itself.
   - If clarifications were requested during committee review, you may be asked to make changes to the study after the review is complete.
   - For an RNI submission, click Submit RNI Response instead.

5. Click **OK**.
The study returns to the review process.

For information about completing an action plan for an RNI submission, see Responding to Action Required.

### Changing Documents on Your Study

You may need to modify a study's documents when:

- The IRB requires changes prior to approval.
- Submitting a modification to an approved study.

**To change documents prior to study approval:**

**Note:** These steps apply if the IRB decision was modifications required, disapproved, or deferred.

1. From My Inbox, click the name of the study to open it.
2. Click the **Documents** tab.
3. Click the document in the Draft column and save it to your computer.
4. Open the document.
5. Enable the Track Changes feature and update the document.
6. When finished, replace the original study document with the tracked-changes version by clicking “Update” beside the document on the SmartForm. When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.

**To change documents on an approved study:**

1. Click **IRB** in the top left navigation area and select the **Active** tab.
2. Click the name of the approved study.
3. Click the Documents tab.

4. Click the document in the Final column and save it to your computer.

Tip: In some cases, you may only be able to use the draft document because the final document is a PDF. In this case, the draft document may contain tracked changes and comments. To make its content match the final PDF, use the review features in Word to accept all the changes and remove any comments. Use this clean document as a starting point for your revisions.

<table>
<thead>
<tr>
<th>Draft</th>
<th>Category</th>
<th>Final</th>
</tr>
</thead>
</table>

5. Open the document and revise it in tracked-changes format.

6. When finished, replace the original document with the tracked-changes version in the modification by clicking “Update” beside the current version for the document. When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.

Managing Principal Investigator (PI) Proxy

The Principal Investigator may assign proxy permissions so that system activities only available to PIs can be completed by another member of the study team. The PI Proxy must be a member of the approved study team with current human subjects training certification.

The purpose of assigning a system-based proxy is to assist with the management of follow-on submissions (Modifications and Continuing Reviews). PI Proxy permissions do not imply that the named proxy has PI responsibilities; only the Principal Investigator and Faculty Sponsor (if there is one) hold Principal Investigator responsibilities.

Important! A PI Proxy can only be assigned by the PI on an approved, non-ceded study. Any initial study application that has not yet been approved will need to be granted IRB approval before a proxy can be assigned. Any study for which the review has been ceded to an External IRB, assigning a PI Proxy is not permitted.

To assign a PI Proxy:

1. Log in to irb.harvard.edu.
2. Navigate to an approved study, see Accessing a Submission for more instructions.
3. On the main study workspace (marked in the center as “Submission type: Initial Study”), under My Current Actions, click Assign PI Proxy.
4. A pop up will appear where you can select the individual(s) you would like to designate as PI Proxy. The list will show only approved study team members. If an individual you wish to assign as PI Proxy is not listed, they first must be added to the study via a Modification.

5. Check any/all of the individuals you wish to make PI Proxy, review the PI assurance statement

6. Click OK.

7. All updates to PI Proxy will be recorded on the main study workspace, capturing the name, date, and time that the PI completed the activity, serving as record of the PI assurance of compliance.

To review the PI assurance that appears on the activity form, click on the activity name in the History.

Once a PI Proxy has been assigned, the Proxy:

- Can submit follow-on submissions and study materials on behalf of the PI.
- Will receive all system notifications pertaining to the study.
- Cannot assign additional proxies; the PI is the only person who is able to designate a PI Proxy.

**Tip:** Faculty Sponsors listed on any student project will not receive system notifications by default. Faculty Sponsors may be added as a PI Proxy so that they will receive system notifications about the study.

**To remove a PI Proxy:**

1. Log in to irb.harvard.edu.

2. Navigate to an approved study (see Accessing a Submission for more instructions).

3. On the main study workspace (marked in the center as “Submission type: Initial Study”), under My Current Actions, click Assign PI Proxy.

4. A pop up will appear where you can deselect the individual(s) you would like to remove PI Proxy permissions from.

5. Uncheck any/all of the individuals you wish to remove PI Proxy permissions from, review the PI assurance statement

6. Click OK.

7. All updates to PI Proxy will be recorded on the main study workspace, capturing the name, date, and time that the PI completed the activity, serving as record of the PI assurance of compliance.

To review the PI assurance that appears on the activity form, click on the activity name in the History.

**Tip:** Any PI Proxy that is removed from the study via a Modification to study team members will be automatically removed as PI Proxy.
Adding/Changing the Primary Contact

By default, in addition to the PI and PI Proxy, the Primary Contact is a recipient of all system emails (including notification of IRB determination, or when the IRB requests clarifications). Changing the Primary Contact does not require a modification that gets reviewed by the IRB. Making this change takes effect immediately and can be changed at any time. For example, it may help to provide a contact person in addition to the PI if the PI does not check e-mail frequently. The primary contact can also edit the study just as a study team member can.

Notes:

- To change the primary contact, you must be a member of the study team or the IRB coordinator assigned to the study.
- By default, the person who created the study in the system is the primary contact.
- The PI and any PI proxy continue to receive notifications regardless of the primary contact assignment.
- Modifications or continuing reviews have the same primary contact as the initial study. To change the primary contact on these submissions, do so in the main study workspace.
- Indicating a person as Primary Contact is for administrative purposes and does not give permission for this individual to work with human subjects. If the Primary Contact also has human subjects responsibilities, their involvement with human subjects must be reviewed by the IRB before they may begin that portion of their work.

To change the primary contact:

1. Log in to irb.harvard.edu
2. Navigate to a study (see Accessing a Submission for more instructions).
3. On the main study workspace (marked in the center as “Submission type: Initial Study”),
4. Click Assign Primary Contact from the My Current Actions list on the left.

   | My Current Actions
   | View Study
   | Assign Primary Contact

   A new window opens.

5. Click Clear to remove the current contact.
6. Begin typing the name of the new contact.
   A list of matching names appears.
7. Click on the correct name using the mouse. The name should appear as a blue link in the space provided.
8. Click OK.

You will be directed back to the main study workspace, and the Primary Contact will be updated in the top part of the page.
Managing Guests with View-Only Permissions to the Study

During the course of a project, you may want to add a guest who can view your study and its documents. Guests have view-only permissions and cannot make edits to the study or create follow-on submissions. Adding/removing a guest does not require a Modification to the study itself.

To add/remove a guest to the study:

9. Log in to irb.harvard.edu
10. Open the study by clicking the study’s name. (For instructions about finding the study, see Accessing a submission.)
11. Click Manage Guest List from the My Current Actions list on the left.
   A new window opens.
12. Review the existing list that appears of people who can view the study without being on the guest list.
13. To add a guest, begin typing the name of the new contact in the search box at the bottom.
   A list of matching names appears.
   Click on the correct name using the mouse.
   Click OK.
14. To remove a guest, click Remove on the right next to their name.
   Click OK.

Creating Modifications, Continuing Reviews and New Information

The table below summarizes how to get started submitting each type of information to the IRB.

<table>
<thead>
<tr>
<th>To submit this type of information...</th>
<th>...start here...</th>
<th>...and click this button</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modifications to an active study</td>
<td>From the Active tab, click the study name (see Accessing a)</td>
<td>Create Modification, Create Continuing Review</td>
<td>You can submit a continuing review and a modification at the same time. The first form prompts you to identify the type of information to submit.</td>
</tr>
<tr>
<td>Continuing review updates</td>
<td></td>
<td>Create Study Closure</td>
<td></td>
</tr>
<tr>
<td>To submit this type of information...</td>
<td>...start here...</td>
<td>...and click this button</td>
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<td>for an active study</td>
<td>Submission)</td>
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</tr>
<tr>
<td>Request to close study</td>
<td></td>
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<td></td>
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<tr>
<td>New information or an adverse event report</td>
<td>For new information about a particular study, start from the Active tab and click the study name (see Accessing a Submission)</td>
<td>Report New Information</td>
<td>Report new information as soon as you become aware of it. The form identifies the types of information you must report.</td>
</tr>
<tr>
<td>New study for review</td>
<td>My Inbox</td>
<td>Create New Study</td>
<td>See Creating a New Study.</td>
</tr>
<tr>
<td>Updates to a new study that hasn't been submitted for IRB review yet</td>
<td>Within the study (see Accessing a Submission)</td>
<td>Edit Study</td>
<td>See Editing a Study.</td>
</tr>
</tbody>
</table>

### Submitting a Modification Request

Making any changes to the approved research will require a modification that must be reviewed and approved by the IRB before the changes go into effect. Refer to the **What to include in the SmartForm section** for more instructions.

**To submit a Modification on an approved project to the IRB:**

1. Log in to irb.harvard.edu
2. Navigate to an approved study workspace (see Accessing a Submission for more information).
3. Click the “Create Modification” button.
4. Select “Modification”
5. Select one or both types of modification on the first page of the SmartForm.

**Note:** ESTR will only allow one ‘Study team member information’ and one ‘Other parts of the study’ modification to be open at a time.
6. By selecting 'Continue' the system will guide you through some questions about the requested change, and take you to a copy of the SmartForm.

7. Make all changes directly into the SmartForm (for example, if you are making changes to the approved protocol document, navigate to the “Basic Information” page and “Update” the protocol document with the newest version).

   **Note:** Do not “delete” any documents unless they are being removed from the study as part of the modification request.

   **Important!** Updating the SmartForm not send the submission for review.  
The PI or PI Proxy must click **Submit (marked with a red arrow in the submission workspace)** for the submission to proceed on for the next state of review.

### Submitting a Continuing Review Request

If the IRB determines that regular review is required for a study, the PI, PI Proxy and Primary Contact will receive notification of approaching continuing review deadline in advance of study expiry. If the study indicates an expiration date or you receive notifications from the system, submission of a continuing review request is required to maintain IRB approval.

**To submit a continuing review request to the IRB:**

1. Log in to irb.harvard.edu
2. Navigate to an approved study workspace (see Accessing a Submission for more information).
3. Click the “Create Continuing Review” button.
4. In the SmartForm, select the “Continuing Review” type of submission.
   **Modification / Continuing Review / Study Closure**
   
   * What is the purpose of this submission?  
   To request Study Closure, select Continuing Review.
   
   **Continuing Review**
   
   **Modification**

5. Select “Continue” and complete the Continuing Review / Study Closure Information SmartForm Page.
6. Once all the information is completed, the PI or PI Proxy must select “Submit” from the ‘My Current Actions’ section on the left side of the screen (activity marked with a red arrow in the submission workspace).
Submitting a Study Closure Request

Study closure is appropriate when:
(a) the research is permanently closed to enrollment;
(b) all participants have completed all research-related interventions/interactions;
(c) collection of private identifiable information is completed, and
(d) analyses of private identifiable information is completed.

Under close-out status, analyses of de-identified data and manuscript preparation can occur indefinitely.

To submit a study closure request to the IRB:
1. Log in to irb.harvard.edu
2. Navigate to an approved study workspace (see Accessing a Submission for more information).
3. Click the “Create Study Closure” button.
4. In the SmartForm, select the “Continuing Review” type of submission.
5. Select “Continue” and complete the Continuing Review / Study Closure Information SmartForm Page. For study closure requests ensure that the top four boxes under Research Milestones section are true and checked off.
6. Once all the information is completed, the PI or PI Proxy must select “Submit” from the ‘My Current Actions’ section on the left side of the screen (activity marked with a red arrow in the submission workspace).

Submitting Reportable New Information

Reportable New Information (RNI) can be created in one of two places: the study workspace or your personal workspace. Creating the RNI from a single study workspace indicates that it is primarily associated with that study. Creating the RNI from your personal workspace (your Inbox) is used with a) you would like to submit an anonymous RNI or b) you are associating multiple submissions to a single RNI.

To submit an RNI to the IRB:
1. Log in to irb.harvard.edu
2. Navigate to:
   - An approved study workspace (see Accessing a Submission for more information) OR
   - My Inbox linked at the upper right of the screen
3. Click the “Report New Information” button.
4. In the SmartForm, fill in the necessary items for IRB review.
5. Select “Continue” and complete the forms.
6. Once all the information is completed, the person who created the RNI must select “Submit” from the ‘My Current Actions’ section on the left side of the screen (activity marked with a red arrow in the submission workspace).

**Important!** Updating the SmartForm not send the submission for review. The person who created the RNI (the “reporter”) must click Submit (marked with a red arrow in the submission workspace) for the submission to proceed on for the next state of review.

### Responding to Action Required for Reportable New Information (RNI)

After reviewing a new information report (or adverse event), the IRB may require specific actions to be taken in response to the reported issue. If this occurs the IRB will issue an Action Plan and assign an individual responsible for completing the required actions.

The system will send a notification to the individual responsible for completing the required actions on the RNI, as well as to the PIs, PI proxies, and primary contacts of all related studies. The RNI also appears in My Inbox of the individual responsible for completing the required actions.

**To view the Action Plan and respond to the IRB:**

1. From My Inbox, click the name of the RNI submission to open it.
2. View the details of the RNI submission and the Action Plan, as described here:
   - **Read the letter:** Click the letter link near the top of the page on the right side. The letter typically contains the Action Plan and a summary of the IRB’s decisions.
   - **Review the Action Plan:** Click the Action Plan tab and read the action plan listed there, plus any history of the action plan that might be helpful.
   - **Review the RNI submission details:** If you aren't already familiar with the details of the information report, read it by clicking View RNI on the left side.
3. Take action inside or outside the system to complete the action plan.

**Tip:** You can add related studies to the RNI submission to indicate that the information report applies to the studies. From the RNI submission, click Add Related Submission on the left.
If the Action Plan requires a change to a study, create a modification and submit it for review as mentioned earlier in this section (Creating Modifications, Continuing Reviews…). Then return to the RNI and add the modification using Add Related Submission. The study being modified must be added as a related submission before the modification can be added.

4. Click **Submit Action Response** to indicate that the action plan is complete.

   ![Submit Action Response](image)

   The Submit Action Response form gives you space to type notes and attach a file. Summarize the actions taken to resolve the reported issue and complete the action plan.

5. Click **OK**.

   The RNI submission is returned to the IRB to verify completion of the Action Plan.

### Finding More Information

<table>
<thead>
<tr>
<th>Resource</th>
<th>Description</th>
<th>How to Access It</th>
</tr>
</thead>
<tbody>
<tr>
<td>Help for a field or page</td>
<td>More information about a question or form.</td>
<td>Click <a href="#">next</a> next to the question or at the top of the form.</td>
</tr>
<tr>
<td>Help system</td>
<td>The full online help system, with search and table of contents. The online help contains procedures and information for all users.</td>
<td>6. Click the <strong>Help Center</strong> link on the left.</td>
</tr>
<tr>
<td>IRB Study Submission Guide</td>
<td>Instructions for submitting a study for review.</td>
<td>7. Click the <strong>Help Center</strong> link on the left.</td>
</tr>
<tr>
<td>IRB Study Reviewer's Guide</td>
<td>Instructions for reviewing an IRB submission.</td>
<td>8. On the Guides tab, click the name of the guide to open it.</td>
</tr>
<tr>
<td>IRB Staff Administration Guide</td>
<td>An overview of the IRB review and administration process.</td>
<td></td>
</tr>
<tr>
<td>IRB Library</td>
<td>Document templates, checklists, and IRB procedures.</td>
<td>Click the <strong>Library</strong> link on the left.</td>
</tr>
<tr>
<td>ESTR Support</td>
<td>External website with additional information about using ESTR</td>
<td><a href="estrsupport.fss.harvard.edu">estrsupport.fss.harvard.edu</a></td>
</tr>
<tr>
<td>ESTR Help Desk</td>
<td>Contact for help with ESTR access and use</td>
<td><a href="estrhelp@harvard.edu">estrhelp@harvard.edu</a></td>
</tr>
<tr>
<td>IRB Websites</td>
<td>Information about the IRB review process and requirements</td>
<td>▪ <a href="hsph.harvard.edu/ohra">HMS, HSDM, and HSPH (Studies in Longwood Medical Area only)</a></td>
</tr>
<tr>
<td>Resource</td>
<td>Description</td>
<td>How to Access It</td>
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<td></td>
<td>FAS, GSE, HKS, HBS, SEAS, HLS, GSD, HDS, and Radcliffe Institute (Studies in University Area only) at <a href="http://cuhs.harvard.edu">cuhs.harvard.edu</a></td>
<td></td>
</tr>
</tbody>
</table>
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