

IRB Study Submission Guide

Electronic Submission Tracking and Reporting (ESTR)

July 1, 2023

Table of Contents

Logging In	3
Creating a New Study	3
Requesting External IRB Review	19
Editing a Submission	31
Checking a Submission for Errors	32
Submitting a Study for Review	33
Checking the Status of a Submission	35
Accessing a Submission.....	35
Responding to a Request for Clarifications or Modifications.....	38
Changing Documents on a Study.....	41
Communicating with Staff during Review	43
Managing Related Projects.....	44
Finding Determination Letters and Approved Documents	46
Managing Principal Investigator (PI) Proxy.....	46
Changing the Primary Contact.....	49
Managing Guests with View-Only Permissions to the Study	50
Copying a Study	50
Creating a Follow-On Submission after Study Approval	52
Closing a Study.....	58
Generating Standard Reports	59
Finding More Information	61

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 [HarvardKey and password](#)
2. Navigate to irb.harvard.edu
3. Ensure the correct log in type tab is selected
4. Enter your credentials (HarvardKey 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

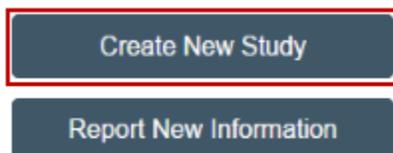
Creating a New Study

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 Save & Exit button.

To create a new study for review:

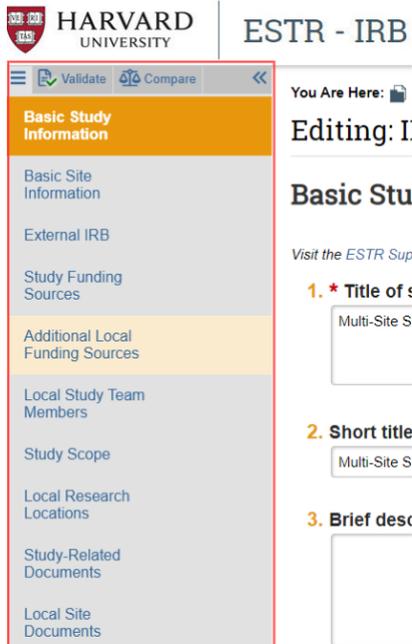
1. From the IRB page (linked in the top menu), click **Create New Study**.



2. Fill in the applicable boxes, answer the questions, and attach appropriate documents.
3. Click **Continue** to move to the next form. The Continue, Save, and Exit buttons will always appear in the lower-right corner of the page.



4. Use the navigation menu on the left-hand side of the page to go to a specific section. You can collapse this menu by clicking the << button, or if it is collapsed, click >> to expand it.



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



6. When you reach the final page, click **Save & Exit** to exit the study.

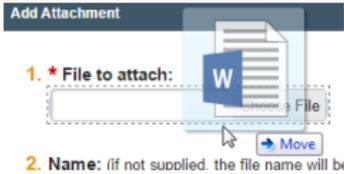
You can continue to edit the study until you submit it for review. See [Editing a Study](#).

Important! The submission has not yet been submitted for review. For instructions, see [Submitting Materials for Review](#).

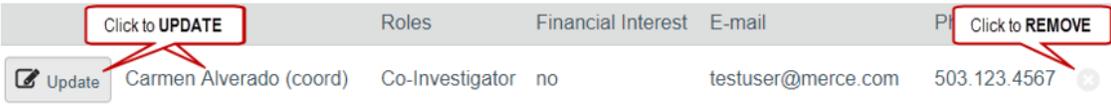
Tips:

- 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.

- Documents can be added to SmartForm spaces by dragging and dropping them from a location on your computer. There are two different ways to do this, depending on the prompt provided on the form.

Drag and Drop Document Sets	Drag and Drop Single Attachments				
Mouse-over to identify if documents can be added from the main page. This does not work in every attachment space.	Drag in single attachments after clicking the “add” button.				
<p>2. Supporting documents:</p> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> + Add Drag and drop files to upload </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;">Name</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="text-align: center;">There are no items to display</td> </tr> </tbody> </table>	Name	Description	There are no items to display		
Name	Description				
There are no items to display					
<p>Reminder: Always name document files wisely (such as with the study number and the document type in the name). The suggested best practice for file names: <i>StudyNumber_DocumentName_VersionNumber</i></p>					

- Items that are added but need to be removed may be either updated or removed in the following ways.

Update	Remove
Update items by either clicking on the button on the left side of the item or on the item itself (if no button appears to the left).	Remove items by clicking on the X to the right of the listed entry.
	

- A continuing review, modification, or RNI (reportable new information) submission can be handled similarly to a study. For differences, see [Creating a Follow-On Submission after Study Approval](#).

Reference the [Library](#) (linked under the IRB heading, at the top of any workspace screen) for 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 a Study 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.

Important! Completing elements of the SmartForm or Clicking “Save & Exit” does not send the study for review. The PI must click **Submit** (on the left, in the submission workspace) for the submission to proceed on for the next state of review.

SmartForm Section: Basic Study 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 the Dashboard 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. **What kind of study is this?**

The options selected here will show additional features in other sections of the system.

Choose **Multi-site** or **Collaborative study** where there is more than one site conducting the study, if there is a possible collaboration with non-Harvard researchers, or if it is unclear if there will be additional sites.

If requesting that Harvard rely on the review of another IRB:

- Only choose **Single-site study** in circumstances where Harvard is relying on a commercial IRB.

5. **Will an external IRB act as the IRB of record for this study?** For a multi-site study (MSS) or collaborative study:

Select Yes if an IRB outside your institution will review and approve this study -with permission from your institution's IRB.

For example:

- If you are a participating site in an MSS or collaborative study, select Yes.
- If you are the sIRB (single IRB) of record for a multi-site or collaborative study, select No.
- If you select Yes, see section: Requesting External IRB Review for additional instruction related to SmartForm page contents and submission requirements.

Important! This item on the SmartForm can only be edited until reliance is confirmed/pre-review is completed by IRB staff. If a selection is made and needs to be changed after reliance is confirmed/pre-review is completed, drafting and review of the submission can be restarted by completing the Copy Submission activity, making additional edits, and submitting the revised study.

6. **Will your IRB act as the single IRB of record for any other participating sites?** (only displays if question 4 is marked "Multi-site or Collaborative" AND question 5 is marked "no") Select Yes if you are submitting an application requesting that Harvard IRB review on behalf of any other institution or IRB (now or over the course of the study). Select No if you are sure that additional sites will complete their own review of the study.

Note that question 4 must be marked "Multi-site and Collaborative" AND question 5 must be marked "No" for sites to be added via the **Add/Manage Participating Sites** activity and for Harvard to confirm review on behalf of another IRB.

Important! For studies created before 12/15/17:

To manage existing Participating Sites: Revise the listing in the Research Locations (formerly “External Sites”) and Local Site, supporting documents areas of the SmartForm.

To propose any substantive changes to an existing Participating Site or to add new Participating Sites: Revise questions 4 and 5 on the Basic Information page of the SmartForm (during clarifications requested of via a modification to “other parts of the study”) to indicate that this is a multi-site/collaborative study (at question 4) where you are requesting that Harvard IRB review on behalf of another institution or IRB (at question 5). Once IRB staff review the request, they will work with you to include any additional needed documentation/context for review. After modification approval, you will be able to add the Participating Site via additional activity (Add/Manage Participating Sites), on the main study workspace.

7. **Lead Principal Investigator.** (only displays if question 4 is marked “Multi-site or Collaborative” AND question 5 is marked “Yes”). The options are limited to individuals with a Harvard ID/HarvardKey. If the Lead Principal Investigator name cannot be found on the list, leave this space blank. For details on who may be listed in this space, please visit your IRB website or Investigator Manual.
8. **Local Principal Investigator.** Enter the name of the **Harvard Principal Investigator**. The options are limited to individuals with a Harvard ID/HarvardKey. 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.

9. **Does the local principal 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 **Local Site Documents** page of the SmartForm, via the last document attachment prompt, when applicable.
10. **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.

If the department name does not appear on the list provided, contact estrhel@harvard.edu for guidance on which department

Once chosen, saved and submitted, the department cannot be changed during review. To change the department after a study is submitted (but before the first determination by the IRB):

1. Complete the Withdraw activity on the study in review

2. Click “Edit Study” to change the name of the department on the SmartForm
 3. Click “Save” then “Exit” on the SmartForm menu
 4. The PI must complete the Submit activity on the study to send it back to the IRB
11. **Attach only the research protocol or relevant request form.** (only displays if question 5 is marked “no”). 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 Request Form.” Of note, a research protocol is required for Exemption Requests. Be sure to name the file in a manner that identifies it as your protocol.

SmartForm Section: Study 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. **List any grant proposal that has been submitted to the sponsored programs office (SPA or OSP), any proposal that was created in GMAS, or any federal or other sponsored funding for the study.** Find and add all funding sources listed in the Harvard Grants Management Application Suite (GMAS) that are associated with this study.

To search for funding in the space provided, begin typing the grant project ID, the grant PI full name (first and last name), or the GMAS fund number and a list will appear with options from which to select.



If additional search options are needed, can click the ellipses [...] button 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. Click “Go” and select the correct funding source. Click “OK” on the pop up.

The screenshot shows a dialog box titled 'Select One or More GMAS'. It has a search filter section with 'Filter by' set to 'Investigator' and a search box containing 'john harv%'. There are 'Go', 'Clear', and 'Advanced' buttons. Below the search section is a 'Deselect All' button and a summary bar showing 'Total Selected: 1' and '1-9 of 9'. The main list has columns for Project ID, Investigator, Fund, and Sponsor Text. The first row is selected with a checkbox and contains: Project ID: 1284-01, Investigator: John Harvard, Fund: 99998, Sponsor Text: Department of Energy. The second row is unselected and contains: Project ID: 99867594-01, Investigator: John Harvard, Fund: (blank), Sponsor Text: NIH. At the bottom, there are 'OK' and 'Cancel' buttons.

2. **List any financial support for this project from a non-sponsored source such as a department, gift or Harvard program.** List all other funding sources. Attach a complete copy of the funding application or agreement for these listed sources to the **Local Site Documents** page of the SmartForm, via the last document attachment prompt, when applicable, and remove or black-out any salary information.

SmartForm Section: (Local) 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; or c) are responsible for the design, conduct, or reporting of the research. Take care to follow the instructions that display on the SmartForm page.

1. **List study team members with an HUID.**

- Individuals can be selected from a list of names. Begin typing a piece of the person's name in the space provided on the pop up, or you can click the "add" option to search the list of available names. Use the "%" symbol to replace portions of a name of which may be unclear or possibly not spelled correctly. This is called a "wildcard" character. Use the email address column for search or as a guide to selecting the correct person. If the correct person cannot be found via name or email, click the ellipses [...]. Choose a Filter by: option to search on a single criteria. Select UserID to search by 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 only/simplely for access to this study record by checking the ESTR-IRB Administrative Support Only role (in the Study Team Member details and via "Add comment" on the submission workspace).
 - * **Role in research:** 
 - Faculty Sponsor
 - Co-Investigator
 - Study Coordinator
 - Project Manager
 - Other Study Team Member
 - ESTR-IRB Administrative Support Only**
(no access to participants or data)
- 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 to item 2 on this page of the SmartForm.

2. **Attach Relevant Study Team Documents.**

- If an individual's name does not appear in the search results available in question 1 on this page of the SmartForm, 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.

Tips:

- Do not list the PI on this page.
- For studies with a non-faculty Principal Investigator and where the IRB requires (as applicable, [University Area](#) only), 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.
- Active training type and expiry date displays for Harvard team members both on the SmartForm page where the team member is added and on the Project Contacts tab in the workspace.

1. List study team members with an HUID: ?

Name	Roles	Financial Interest	E-mail	Active Training (with expiry)
[Name]	[Roles]	[Financial Interest]	[E-mail]	CITI - Biomedical Research Investigators - Refresher (4-25-2024) CITI - Social & Behavioral Research Investigators - Basic Course (4-25-2024)

- After adding individuals to the list under question 1, view the status of any required Human Subjects Training by going to the submission workspace and clicking on the Contacts tab. The tab also includes their current Human Subjects Training information on file and their training expiry date. If no training is listed, they do not have current active training.

Contacts

Principal Investigator

Name	School/Unit	Dept Affiliation	Title	Email	Financial Interest	Current Active Training (with expiry)	Profile Link
[Name]	[School/Unit]	[Dept Affiliation]	[Title]	[Email]	[Financial Interest]	Good Clinical Practice (GCP) (2-21-2023)	[Profile Link]

Study Team Members

Filter by: First Name [Search] + Add Filter X Clear All

First Name	Last Name	School/Unit	Dept Affiliation	Title	Email	Date Modified	Roles on Study	Financial Interest	Current Active Training (with expiry)	Profile Link
[First Name]	[Last Name]	[School/Unit]	[Dept Affiliation]	[Title]	[Email]	[Date Modified]	[Roles on Study]	[Financial Interest]	CITI - Social & Behavioral Research Investigators - 1042432 (3-24-2023)	[Profile Link]

SmartForm Section: Study Scope

1. **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, specify whether the drug is considered a biological material and indicate whether it has an IND number. For those that have an IND number, 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

2. **Does this study evaluate the safety or effectiveness of a DEVICE: 1) by using the device in one or more persons, 2) by using human specimens with the device, or 3) through the use of data from the device?** 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:

- Current Product Information, e.g., Device Manual. Submit for each investigational device involved in the Human Research.
- Validation of IND# or IDE#, e.g. FDA Approval letter or Sponsor Protocol

SmartForm Section: Local Research Locations

Identify other research locations where the investigator will conduct or oversee the research.

Indicate details as prompted on the research location details. For each location, the country is a required selection. If the location country is not available, select the option “[country not listed]”.

Upload information for each location to the **Local Site Documents** page of the SmartForm, via the last document attachment prompt, when applicable.

SmartForm Sub-Section: Study Related Documents

Note: This page only displays if SmartForm Section: Basic Study Information question 4 is marked “Multi-site or Collaborative” AND question 5 is marked “yes”; meaning that this is a study with sites,

where at least one site will rely on Harvard's review.

Important! This page of the SmartForm is intended to capture only documents that (1) have not been included in other sections of the SmartForm AND will be used at this site only.

1. **Consent, Assent, Permission, and HIPAA Authorization Forms (English versions):** 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 the foreign language versions of materials to the last section of this page of the SmartForm.
 - DHHS-approved sample consent document. Consent documents must include version date and/or version number.

If any of materials will be translated, attach the foreign language versions of materials to the last section on this page of the SmartForm.

2. **Recruitment Materials (English versions):** 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." Worksheets are available for reference on your IRB website or in the Library section of ESTR (linked at the top of the screen under the "IRB" heading). Advertising material must include version date and/or version number.

If any of materials will be translated, attach the foreign language versions of materials to the next section on this page of the SmartForm.

Attach other supporting files, naming each file as it should appear in the approval letter: Also, be sure to name the file itself in a manner that identifies it as associated with your study. The suggested best practice for file names: *StudyNumber_DocumentName_VersionNumber*

When uploading documents to this page, you are prompted to select the appropriate attachment category. Select the correct category when uploading the first version. Once chosen and saved, the attachment category cannot be changed. To change a category, a document must be removed and then re-uploaded with the new category.

Use the "other" category to attach non-document type attachments which must be part of the review (such as compressed/zip, video, audio, or htm file formats).

Items to attach to this section:

- **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.
- **Debriefing Materials.** If any of these materials will be translated, also submit a Translation Attestation Form.

- **Research Location Information.** If question 1 in the SmartForm Section: Study Scope indicated that there are research locations where the research will be conducted submit relevant approvals (such as a Community Advisory Board approval) or other information from each research location 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 location(s).
- **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.

SmartForm Section: Local Site Documents

This page of the SmartForm is intended to capture documents that will be used by Harvard researchers. Ensure that the document versions attached here are relevant to for the specific site under review. Use the main study submission for Harvard documents and use the Site SmartForm, to attach site specific versions, only when appropriate

1. **Consent, Assent, Permission, and HIPAA Authorization Forms (English versions):** 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 the foreign language versions of materials to the last section of this page of the SmartForm.
 - DHHS-approved sample consent document. Consent documents must include version date and/or version number.

If any of materials will be translated, attach the foreign language versions of materials to the last section on this page of the SmartForm.

2. **Recruitment Materials (English versions):** 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.” Worksheets are available for reference on your IRB website or in the Library section of ESTR (linked at the top of the screen under the “IRB” heading). Advertising material must include version date and/or version number.

If any of materials will be translated, attach the foreign language versions of materials to the next section on this page of the SmartForm.

Attach other supporting files, naming each file as it should appear in the approval letter: Also, be sure to name the file itself in a manner that identifies it as associated with your study. The suggested best practice for file names: *StudyNumber_DocumentName_VersionNumber*

When uploading documents to this page, you are prompted to select the appropriate attachment category. Select the correct category when uploading the first version. Once chosen and saved, the

attachment category cannot be changed. To change a category, a document must be removed and then re-uploaded with the new category.

Use the “other” category to attach non-document type attachments which must be part of the review (such as compressed/zip, video, audio, or htm file formats).

Items to attach to this section:

- **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.
- **Agreements.** Submit copies of any documents authorizing the use of data (not otherwise part of a related project associated with the main study using the “Manage Related Projects” activity), 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.
- **Research Location Information.** If question 1 in the SmartForm Section: Study Scope indicated that there are research locations where the research will be conducted submit relevant approvals (such as a Community Advisory Board approval) or other information from each research location 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 location(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.
- **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.

Upon clicking continue from this page, the browser will direct to the last page of the SmartForm where you will have the opportunity to select “**Save & Exit**” to return to the submission workspace.

What to Include in a Site SmartForm

The Site SmartForm is always associated with an additionally created Study SmartForm. The Site SmartForm represents the information associated with a relying IRB. The following section describes what information should go into each space of the Site SmartForm.

Important! For sites where Harvard is the Reviewing IRB: Create the Site SmartForm and share it for review by completing the **Add/Manage Participating Sites** activity in the main study workspace. During IRB review, this will create a site submission (with workspace) for your further edits.

When a study is created and marked as multi-site or collaborative, where Harvard will review for at least one site, the Site SmartForm may be completed with the following information. For existing projects, if a modification is required to indicate that a study is collaborative, with Harvard reviewing for at least one site, the modification must be approved before a site can be added.

Site SmartForm Section: Basic Site Information

1. **Short title.** The short title identifies the submission throughout the system, such as on the Dashboard 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 response to question 1.
2. **Local Principal Investigator.** The options are limited to individuals with a Harvard ID/HarvardKey. If the Local Principal Investigator name cannot be found on the list, enter the name of the **Harvard 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.

3. **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 **Local Site Documents** page of the SmartForm, via the document attachment prompt, when applicable.

4. **Brief description of activities this site will perform:** Provide information about activities taking place at this site.

Site SmartForm Section: Additional Local Funding Sources

On this page include only funding that will be managed through this site that is also not included with the main study SmartForm review.

Identify any additional organization supplying funding for the local site. List all other funding sources. Attach a complete copy of the funding application or agreement for these listed sources to the **Local Site Documents** page of the SmartForm, via the document attachment prompt, when applicable, and remove or black-out any salary information.

Site SmartForm Section: Local Site Documents

This page of the SmartForm is intended to capture documents that will be used by the site researchers, but under Harvard review. Ensure that the document versions attached here are relevant to for the specific site under review. **Use the main study submission for Harvard documents and use this page of the Site SmartForm to attach only versions of documents specific to this site, only when appropriate.**

Attach other supporting files, naming each file as it should appear in the approval letter: Also, be sure to name the file itself in a manner that identifies it as associated with your study. The suggested best practice for file names: *StudyNumber_DocumentName_VersionNumber*

When uploading documents to this page, you are prompted to select the appropriate attachment category. Select the correct category when uploading the first version. Once chosen and saved, the attachment category cannot be changed. To change a category, a document must be removed and then re-uploaded with the new category.

Use the “other” category to attach non-document type attachments which must be part of the review (such as compressed/zip, video, audio, or htm file formats).

Items to attach to this page:

- **Consent, Assent Forms, or Scripts including HIPAA Authorization Forms**
- **Recruitment Materials**
- **Study Instruments/Tools**
- **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.
- **Agreements.** Submit copies of any documents authorizing the use of data (not otherwise part of a related project associated with the main study using the “Manage Related Projects” activity), or other contracts or agreements associated with the site.
- **IRB/SmartIRB Cede Request or IRB Authorization Agreement (IAA).** 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). To request such an agreement with a SmartIRB participating institution, visit this [link](#).

Upon clicking continue from this page, the browser will direct to the last page of the SmartForm where you will have the opportunity to select “**Save & Exit**” to return to the submission workspace.

Checklist of SmartForm Attachments

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:

- When possible, ensure consent or recruitment materials have a one-inch margin.
- Attach non-document type attachments which must be part of the review (such as compressed/zip, video, audio, or htm file formats) to the supporting documents section, using the attachment category "other".
- Name the file 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. If document revision is needed, use the **Update** or Upload Revision option rather than deleting any files, whenever possible.

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.

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

✓	Document Type	SmartForm Page to Upload Document <i>(in order of appearance, as applicable)</i>	Question #
Study SmartForm: Relevant only for non-External IRB projects			
	Research Protocol, Repository Protocol, or Non-Human Subjects Research Request Determination Form	Basic Information	10
	Study Personnel Form (listing team members who do not have an HUID)	Study Team Members	2
	Human Subjects Training Certificate, if not already stored in ESTR	Study Team Members	2
	Study Team Financial Conflict of Interest Form	Study Team Members	2
	Individual Investigator Agreement for non-Harvard Collaborators without an institutional affiliation	Study Team Members (not for Site SmartForm)	2
	Drug Details, including package insert, verification of each IND number, or investigator brochure	Drugs (studies involving Drugs only)	1,2,3
	Device Details, including product labeling/device instructions with investigator brochure, or verification of each IDE number	Devices (studies involving devices only)	1,3
	Consent Forms (English version only)	Local Site Documents	1
	HIPAA Authorization Form (English version only)	Local Site Documents	1
	Consent Script, for non-written consent (English version only)	Local Site Documents	1
	Parental permission or Assent (English version only)	Local Site Documents	1
	Recruitment Materials, including fliers, advertisements and scripts (English version only)	Local Site Documents	2

✓	Document Type	SmartForm Page to Upload Document <i>(in order of appearance, as applicable)</i>	Question #
	Principal Investigator Financial Conflict of Interest Form (only if not previously attached)	Local Site Documents	last
	Surveys/Questionnaires/Interview Guide (Study Instruments/Tools)	Local Site Documents	last
	Non-English versions of Consent, Assent, Permission, Scripts or Recruitment Materials	Local Site Documents	last
	Research Location Information	Local Site Documents	last
	Debriefing Materials	Local Site Documents	last
	Grant materials or funding source attachments (if the grant is not included in GMAS)	Local Site Documents	last
	Agreements	Local Site Documents	last
	Ancillary Approvals/Permissions	Local Site Documents	last
	Federal Department Requirements Checklists	Local Site Documents	last
	PI's Current CV (ICH-GCP E6 Only)	Local Site Documents	last
	Radiation Safety Form	Local Site Documents	last
	Sponsor Protocol including DHHS-approved protocol	Local Site Documents	last
	Individual Investigator Agreement for non-Harvard Collaborators without an institutional affiliation (only if not previously attached)	Local Site Documents	last
	Consent Forms (English version only) which are generalized for use across many sites.	Study-Related Documents	1
	HIPAA Authorization Form (English version only) which are generalized for use across many sites.	Study-Related Documents	1
	Consent Script, for non-written consent (English version only) which are generalized for use across many sites.	Study-Related Documents	1
	Parental permission or Assent (English version only) which are generalized for use across many sites.	Study-Related Documents	1
	Recruitment Materials, including fliers, advertisements and scripts (English version only) which are generalized for use across many sites.	Study-Related Documents	2
	Surveys/Questionnaires/Interview Guide (Study Instruments/Tools) which are generalized for use across many sites.	Study-Related Documents	last
	Non-English versions of Consent, Assent, Permission, Scripts or Recruitment Materials which are generalized for use across many sites.	Study-Related Documents	last
	Debriefing Materials which are generalized for use across many sites.	Study-Related Documents	last
	Ancillary Approvals/Permissions which are generalized or are relevant for use across many sites.	Study-Related Documents	last

✓	Document Type	SmartForm Page to Upload Document <i>(in order of appearance, as applicable)</i>	Question #
Site SmartForm: Relevant only for non-External IRB projects that are marked as Collaborative studies, where Harvard will review for at least one site.			
	SmartIRB Cede Request Application (for when another IRB is relying on the Harvard IRB)	Local Site Documents	1
	Draft or Final IRB Authorization Agreement (IAA)	Local Site Documents	1
	Principal Investigator Financial Conflict of Interest Form (only if not previously attached)	Local Site Documents	1
	Grant materials or funding source attachments (if the grant is not included in GMAS and only if not previously attached)	Local Site Documents	1
	Site-specific study materials such as Consent, Assent, Recruitment or Data Collection tools or instruments.	Local Site Documents	1

Requesting External IRB Review

Overview

You can request that the Harvard IRB rely on the review of another IRB (referred to as External IRB or ceded review). This type of submission can be appropriate when a study is conducted at two or more different institutions, and instead of getting a separate IRB approval from each institution, an agreement is made for one institution to conduct the review and the other institution(s) to rely on that IRB's review.

This submission type is only appropriate if you are requesting that Harvard rely on the review of another IRB. Once submitted, the Harvard IRB will determine if a reliance agreement is possible or if Harvard IRB review is required. To instead have the Harvard IRB conduct the review of the study see [What to Include in a Study SmartForm](#).

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 Save & Exit button.

What to Include in the Initial Request for External IRB Review

To create a request for External IRB review see [Creating a New Study](#). 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.

Important! Completing elements of the SmartForm or clicking "Save & Exit" does not send this request for review. The Local PI must visit the submission workspace and click Submit (on the left, in the submission workspace) for the request to proceed on for the next state of review.

SmartForm Section: Basic Study Information (External IRB)

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 on the Dashboard 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. **What kind of study is this?**
The options selected here will show additional features in other sections of the system.

Select Multi-Site or Collaborative to allow for the entry/addition of information about study sites and if the project may involve:

- More than one site conducting the study (completely or in part), or
- Collaborators with primary affiliation with other institutions, or
- If it is unclear if there will be additional sites.

Select Single-site Study if the project **only** involves work at Harvard, by Harvard affiliated researchers. Note that a request for External IRB review will rarely be a Single-site type project.

Note: The remainder of this instruction in this section shows the longest possible form which displays when “Multi-Site or Collaborative” is selected here. However, expect the following pages to display based on the selection made:

Multi-Site or Collaborative

- Basic Study Information
- Basic Site Information
- External IRB
- Study Funding Sources
- Additional Local Funding Sources
- Local Study Team Members
- Study Scope
- Local Research Locations
- Study-Related Documents
- Local Site Documents

Single-site Study

- Basic Study Information
- External IRB
- Study Funding Sources
- Local Study Team Members
- Study Scope
- Local Research Locations
- Local Site Documents

5. **Will an external IRB act as the IRB of record for this study?** Select Yes. When you selected Yes, the attachment space on the Basic Information SmartForm will disappear (it is not needed when requesting External IRB review).

Important! This item on the SmartForm can only be edited until reliance is confirmed/pre-review is completed by IRB staff. If a selection is made and needs to be changed after reliance is confirmed/pre-review is completed, drafting and review of the submission can be restarted by completing the Copy Submission activity, making additional edits, and submitting the revised study.

6. **Lead Principal Investigator.** (only displays if question 4 is marked “Multi-site or Collaborative” AND question 5 is marked “Yes”). The options are limited to individuals with a Harvard ID/HarvardKey. If the Lead Principal Investigator name cannot be found on the list, leave this space blank. For details on who may be listed in this space, please visit your IRB website or Investigator Manual.

7. **Local Principal Investigator.** Enter the name of the **Harvard Principal Investigator**. The options are limited to individuals with a Harvard ID/HarvardKey. 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.

8. **Does the local principal 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 **Local Site Documents** page of the SmartForm, via the last document attachment prompt, when applicable.
9. **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.

If the department name does not appear on the list provided, contact estrhel@harvard.edu for guidance on which department

Once chosen, saved and submitted, the department cannot be changed during review. To change the department after a study is submitted (but before the first determination by the IRB):

5. Complete the Withdraw activity on the study in review
6. Click “Edit Study” to change the name of the department on the SmartForm
7. Click “Save” then “Exit” on the SmartForm menu
8. The PI must complete the Submit activity on the study to send it back to the IRB

SmartForm Section: Basic Local Site Information (External IRB)

Page only displays if this is a request for Harvard to rely on the review of another IRB and this is a multi-site or collaborative project.

Brief description of activities this site will perform: Provide information about activities taking place at Harvard or by Harvard researchers.

SmartForm Section: External IRB

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. **External study ID:** If available, the study number given by the External IRB.
3. **Specify the reason the study should be reviewed by an external IRB:** Write in the rationale for the request for Harvard to rely on another institution.
4. *** Activities at Harvard (local site) or performed by Harvard employees or agents (mark all that apply):**
 - Obtaining informed consent
 - Research interactions/intervention
 - Recruitment
 - Enrollment
 - Obtaining, collecting, or analyzing specimens
 - Obtaining, collecting, or analyzing data
 - Other (such as, Harvard is the prime awardee of federal funds or IRB is providing review services)

If other is marked, a "Describe:" field shows

If working with the specimens (mark all that apply, displays only if specimens marked above):

- Specimens will be obtained or collected
- Specimens will be used or analyzed
- Specimens will be banked for future research (not covered under this proposal)
- This work involves the creation of repository

What is the identifiability of the specimen (Displays and required if specimens is marked above)?

- Specimen will be directly labeled with personal identifying information (identifiable)
- Specimen will be labeled with a code that the research team can link to personal identifying information. This refers to when the research team is using a crosswalk document to link identifiable data to research specimen, and each is kept separately (coded)
- Specimen will not be directly identifiable but there will be a code held by the specimen source that links to the identities (coded). i.e., if receiving specimen from another site
- Specimen will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information (anonymous or de-identified)

Where will the work with specimens occur (Displays and required if specimens is marked above)?

- Remote or Outside of Harvard
- Harvard

If working with the data (mark all that apply, displays and required if Data is marked above):

- Data will be obtained or collected
- Data will be used or analyzed
- Data will be banked for future research (not covered under this proposal)
- This work involves the creation of repository

What is the identifiability of the data (displays and required if Data is marked above)?

- Data will be directly labeled with personal identifying information (identifiable)
- Data will be labeled with a code that the research team can link to personal identifying information. This refers to when the research team is using a crosswalk document to link identifiable data to research data and each data set is kept separately (coded)
- Data will not be directly identifiable but there will be a code held by the data source that links to the identities (coded). i.e., if receiving data from another site

- Data will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information (anonymous or de-identified)

Will data be managed by Harvard researchers either remotely or at Harvard? For example, will you be responsible for these data or use Harvard resources to store the data?

- Yes/No selection displays and required if Data is marked above

Where will the work with the data occur?

- Remote or Outside of Harvard
- Harvard

5. **Type(s) of research participants you will be working with (includes their data or specimens):**

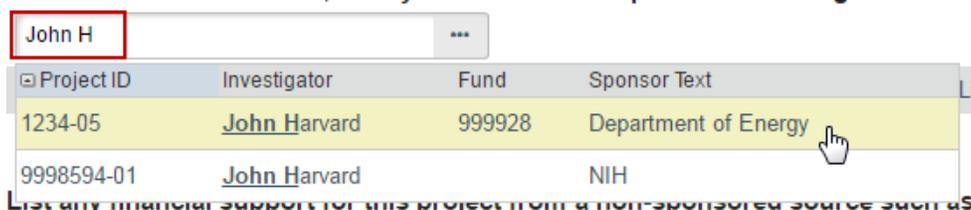
- No subjects
- Healthy subjects
- Adults (as defined by state law)
- Harvard Medical School Program in Medical Education faculty and/or students (as a focus)
- Harvard graduate students (as a focus)
- Harvard undergraduate students (as a focus)
- Harvard employees/staff in dept/unit/lab (as a focus)
- Vulnerable population (as defined by state law or regulation)
 - Children (including newborns, infants, children age 2 and over)
 - Pregnant Women/Fetuses
 - Prisoners
 - Persons with impaired decision making

SmartForm Section: Study Funding Sources (External IRB)

On this page include any pending/awarded funding sources or financial support for this study, with the IRB of record. Leave questions 1 and 2 blank to indicate that there is no non-Harvard funding for this study. You will have an opportunity later in the forms to indicate funding sources specific to the Harvard site. Reminder: If the funding status changes following IRB determination, submit a modification to this study.

1. **List any grant proposal that has been submitted to the sponsored programs office (SPA or OSP), any proposal that was created in GMAS, or any federal or other sponsored funding for the study.** Find and add all funding sources listed in the Harvard Grants Management Application Suite (GMAS) that are associated with this study.

To search for funding in the space provided, begin typing the grant project ID, the grant PI full name (first and last name), or the GMAS fund number and a list will appear with options from which to select.



If additional search options are needed, can click the ellipses [...] button 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. Click “Go” and select the correct funding source. Click “OK” on the pop up.

Select One or More GMAS

Filter by: Investigator | john harv% | Go | Clear | Advanced

Deselect All

Total Selected: 1 | 1-9 of 9

Project ID	Investigator	Fund	Sponsor Text
<input checked="" type="checkbox"/> 1284-01	John Harvard	99998	Department of Energy
<input type="checkbox"/> 99867594-01	John Harvard		NIH

Total Selected: 1 | 1-9 of 9

OK | Cancel

- List any financial support for this project from a non-sponsored source such as a department, gift or Harvard program.** List all other funding sources.

SmartForm Section: Additional Local Funding Sources (External IRB)

Page only displays if this is a request for Harvard to rely on the review of another IRB and this is a multi-site or collaborative project. On this page include only funding that will be managed through this site that is also not included with the main study SmartForm review.

Identify any additional organization supplying funding for the local site. List all other funding sources. Attach a complete copy of the funding application or agreement for these listed sources to the **Local Site Documents** page of the SmartForm, via the document attachment prompt, when applicable, and remove or black-out any salary information.

SmartForm Section: (Local) Study Team Members (External IRB)

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; or c) are responsible for the design, conduct, or reporting of the research. Take care to follow the instructions that display on the SmartForm page.

- List study team members with an HUID.**

- Individuals can be selected from a list of names. Begin typing a piece of the person’s name in the space provided on the pop up, or you can click the “add” option to search the list of available names. Use the “%” symbol to replace portions of a name of which may be unclear or possibly not spelled correctly. This is called a “wildcard” character. Use the email address column for search or as a guide to selecting the correct person. If the correct person cannot be found via name or email, click the ellipses [...]. Choose a Filter by: option to search on a single criterion. Select UserID to search by 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 by checking the ESTR-IRB Administrative Support Only role (in the Study Team Member details and via “Add comment” on

the submission workspace).

- **Role in research:** ?
 - Faculty Sponsor
 - Co-Investigator
 - Study Coordinator
 - Project Manager
 - Other Study Team Member
 - ESTR-IRB Administrative Support Only (no access to participants or data)**

- 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 to item 2 on this page of the SmartForm.

2. Attach Relevant Study Team Documents.

- 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.
- Upload any relevant training, if needed.

Tips:

- Do not list the PI on this page.
- For studies with a non-faculty Principal Investigator and where the IRB requires (as applicable, [University Area](#) only), 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).
- After adding individuals to the list under question 1, view the status of any required Human Subjects Training by going to the submission workspace and clicking on the Project Contacts tab.

The screenshot displays the 'Contacts' tab in a submission workspace. It features two main sections: 'Principal Investigator' and 'Study Team Members'. Both sections have a table with columns for Name, School/Unit, Dept Affiliation, Title, Email, Financial Interest, Current Active Training (with expiry), and Profile Link. The 'Current Active Training (with expiry)' column is highlighted with a red box in both sections. In the 'Principal Investigator' section, the training record is 'Good Clinical Practice (GCP) (2-21-2023)'. In the 'Study Team Members' section, the training record is 'CITI - Social & Behavioral Research Investigators - 1042432 (3-24-2023)'. There is also a search filter for 'First Name' and a '+ Add Filter' button.

SmartForm Section: Study Scope (External IRB)

1. **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

2. **Does this study evaluate the safety or effectiveness of a DEVICE: 1) by using the device in one or more persons, 2) by using human specimens with the device, or 3) through the use of data from the device?** 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:

- Current Product Information, e.g., Device Manual. Submit for each investigational device involved in the Human Research.
- Validation of IND# or IDE#, e.g. FDA Approval letter or Sponsor Protocol

SmartForm Section: Research Locations (External IRB)

Identify other research locations where the (Harvard) investigator will conduct or oversee the research. Indicate details as prompted on the research location details. For each location, the country is a required selection. If the location country is not available, select the option “[country not listed]”.

Upload information for each location to the **Local Site Documents** page of the SmartForm, via the last document attachment prompt, when applicable.

SmartForm Sub-Section: Study Related Documents (External IRB)

Page only displays if this is a request for Harvard to rely on the review of another IRB and this is a multi-site or collaborative project.

Important! This page of the SmartForm is intended to capture only documents that (1) have not been included in other sections of the SmartForm AND will be used across all sites involved in the project.

1. **Consent, Assent, Permission, and HIPAA Authorization Forms (English versions):** 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 the foreign language versions of materials to the last section of this page of the SmartForm.
 - DHHS-approved sample consent document. Consent documents must include version date and/or version number.

If any of materials will be translated, attach the foreign language versions of materials to the last section on this page of the SmartForm.

2. **Recruitment Materials (English versions):** 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.” Worksheets are available for reference on your IRB website or in the Library section of ESTR (linked at the top of the screen under the “IRB” heading). Advertising material must include version date and/or version number.

If any of materials will be translated, attach the foreign language versions of materials to the next section on this page of the SmartForm.

Attach other supporting files, naming each file as it should appear in the approval letter: Also, be sure to name the file itself in a manner that identifies it as associated with your study. The suggested best practice for file names: *StudyNumber_DocumentName_VersionNumber*

When uploading documents to this page, you are prompted to select the appropriate attachment category. Select the correct category when uploading the first version. Once chosen and saved, the attachment category cannot be changed. To change a category, a document must be removed and then re-uploaded with the new category.

Use the “other” category to attach non-document type attachments which must be part of the review (such as compressed/zip, video, audio, or htm file formats).

Items to attach to this section:

- **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.
- **Debriefing Materials.** If any of these materials will be translated, also submit a Translation Attestation Form.
- **Research Location Information.** If question 1 in the SmartForm Section: Study Scope indicated that there are research locations where the research will be conducted submit relevant approvals (such as a Community Advisory Board approval) or other information from each research location 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 location(s).
- **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.

SmartForm Section: Local Site Documents (External IRB)

This page of the SmartForm is intended to capture documents that will be used (only) by the Harvard researchers. Ensure that the document versions attached here are relevant to for the specific site under review.

Attach other supporting files, naming each file as it should appear in the approval letter: Also, be sure to name the file itself in a manner that identifies it as associated with your study. The suggested best practice for file names: *StudyNumber_DocumentName_VersionNumber*

When uploading documents to this page, you are prompted to select the appropriate attachment category. Select the correct category when uploading the first version. Once chosen and saved, the attachment category cannot be changed. To change a category, a document must be removed and then re-uploaded with the new category.

Use the “other” category to attach non-document type attachments which must be part of the review (such as compressed/zip, video, audio, or htm file formats).

Items to attach to this page:

- **Consent, Assent Forms, or Scripts including HIPAA Authorization Forms**
- **Recruitment Materials**
- **Study Instruments/Tools**
- **IRB/SmartIRB Cede Request or IRB Authorization Agreement (IAA).** 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). To request such an agreement with a SmartIRB participating institution, visit this [link](#).
- **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 (other than Data Use Agreements negotiated at Harvard).
- **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.
- **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.

Upon clicking continue from this page, the browser will direct to the last page of the SmartForm where you will have the opportunity to select “**Save & Exit**” to return to the submission workspace. **The PI must click Submit** (marked with a **red arrow** in the submission workspace) for the submission to proceed on to the IRB for review.

Updating External IRB Review

When Harvard relies on the review of another IRB, the submission will be accepted into an Active or External IRB state (status).

Continuing Review or Closure of a project reviewed by an External IRB

To provide a status update (for continuing review or closure) of the Harvard site, the Harvard Principal Investigator must visit the associated site workspace to complete the **Report Continuing Review Data** activity (on the left side of the site workspace). Within the activity, provide status information and relevant attachments. To request closure, indicate the request in the text box provided on the activity. Note that only the Harvard Principal Investigator (named on the Harvard Site SmartForm) will see/have access to the Report Continuing Review Data activity.

Modification to a project reviewed by an External IRB

Important! Multi-site studies in the External IRB state (created prior to October 2015) cannot be edited via modification. Contact the IRB office to determine if an update is required. If one is required, the submission will need to be recreated under new requirements and processes.

For **multi-site or collaborative projects in the Active state**, study revisions and updates that are reviewed by the IRB of record can be recorded by either:

- a) **Updating Study Details** to provide an update to Harvard about general status or study content and provide a copy of the approval letter from the IRB of record. Updating Study Details will allow for updates to the following pages:
 - Basic Study Information (such as PI or PI fCOI reporting)
 - External IRB Details (such as an updated determination)
 - Study Funding (including changes to a related GMAS project)
 - Study Scope (regarding the involvement of drugs or devices)
 - Study-Related Documents

OR

- b) **Creating a Site Modification** to provide information about revisions to Harvard site-specific information or activities and provide a copy of the approval letter from the IRB of record. Creating a Site Modification will allow for updates to the following pages:
 - Study team and research location
 - Harvard Study Team (such as new or removed team members)
 - Harvard Research Locations
 - Other parts of the site
 - Harvard Site Information (such as Harvard PI or Harvard PI fCOI)
 - Additional Local Funding Sources (funding that is non-sponsored and not listed in GMAS)
 - Harvard-Specific Documents

For **single site projects in the External IRB state**, study revisions and updates that are reviewed by the IRB of record can be recorded by **Updating Study Details** to provide an update to Harvard about general status or study content and provide a copy of the approval letter from the IRB of record. There is no option to create a Site Modification for these studies. Updating the Study Details will make all pages of the original SmartForm available for editing, including:

- Basic Study Information (such as PI or PI fCOI reporting)

- External IRB Details (such as an updated determination)
- Study Funding (including changes to a related GMAS project)
- Study Scope (regarding the involvement of drugs or devices)
- Study-Related Documents

Update Study Details

1. Log in to irb.harvard.edu
2. Navigate to the External IRB's associated site workspace (see [Accessing a Submission](#) for more information on finding the External IRB record, and clicking the site link).
3. Click the "Update Study Details" button on the submission workspace, a SmartForm will open. Based on the selection, this option will only display the External IRB, Study Funding Sources, Study Scope, and Study-Related Documents pages of the SmartForm to edit.
4. Provide a brief description of the contents of the updates.
5. By selecting 'Continue' the system take you to a copy of the Site SmartForm. Refer to the [What to Include in the Initial Request for External IRB](#), Site SmartForm section for additional instructions for what is required for each element of this SmartForm.
6. Follow the remaining steps to [Edit a Submission](#) or Save & Exit when edits are complete.
7. The PI or PI Proxy must click Finalize Updates (on the left side of the submission workspace) for the Harvard IRB to be notified that an update has occurred.

Create Site Modification

1. Log in to irb.harvard.edu
2. Navigate to the External IRB's associated site workspace (see [Accessing a Submission](#) for more information on finding the External IRB record, and clicking the site link).
3. Click the "Modify Site or "Create Site Modification" button on the site workspace, a SmartForm will open. For Modification scope, if "other parts of the site" is chosen, this option will allow for edits to only the Additional Local Funding Sources, Local Research Locations and Local Site Documents pages of the SmartForm to edit. If "team members" is chosen, this option will allow for edits to the Local Study Team Members page of the SmartForm. One or both options may be selected when indicating the scope of the modification on the SmartForm.

Note: If the "Modify Site" or "Create Site Modification" button is not visible, be sure that: (1) a primary contact is assigned to the site and (2) as appropriate, an IRB coordinator is assigned to the site. One or both of these additions will update the workspace for the "Modify Site" or "Create Site Modification" button to display.

4. Provide a brief description of the contents of the modification, along with the scope.
5. By selecting 'Continue' the system take you to a copy of the Site SmartForm. Refer to the [What to Include in the Initial Request for External IRB](#), Site SmartForm section for additional instructions for what is required for each element of this SmartForm.
6. Follow the remaining steps to [Edit a Submission](#) or Save & Exit when edits are complete.
7. The PI or PI Proxy must click Submit (marked with a red arrow in the submission workspace) for the submission to proceed on to the IRB for review.

Finding External IRB Review Projects by Report

To generate a report listing all studies where you serve as the Harvard Principal Investigator (PI) where Harvard has ceded IRB review to another institution:

1. Log in to irb.harvard.edu
2. Click **IRB** in the top navigator.
3. Click **Reports** in the IRB sub-menu. The **Standard Reports** tab is the default view.
4. Under Standard Reports, locate the [All External Studies Report](#) on the list and click the hyperlink.
5. A report will appear listing all submissions where you are listed as the Harvard PI on a project where Harvard has ceded IRB review to another institution.
6. Report results can be exported to Excel from the results pop up window (see below for more information).

For more general information, reference the [Generating Standard Reports guidance](#).

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 Modification/Updates, Continuing Review, and RNI submissions.

To edit a study before it has been submitted:

1. From the Dashboard, click the name of the study to open it.
Note: If the study does not appear in the Dashboard, see [Accessing a Submission](#).
2. Click **Edit Study** (or site) 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. Choose one of these ways to exit:
 - Click the **Exit** link. If prompted to save the study, click **Save Changes & Exit**.
 - Click **Continue** on each form, and then click the **Save & Exit** button on the Next Steps page of the 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 (click “IRB” on the menu at the top of the 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. Completing the Withdraw activity only affects the submission. If a modification or continuing review on an approved study is being withdrawn, it will only withdraw that submission and will not affect the current status of the study.

(Optional) On the withdraw activity pop up, 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.

4. Click **OK**. The PI, any PI Proxy, the Primary Contact and IRB Coordinator will receive a notice that the submission has been withdrawn.
5. 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.
6. Exit the study. Choose one of these ways to exit:
 - Click the **Exit** link. If prompted to save the study, click **Save Changes & Exit**.
 - Click **Continue** on each form, and then click the **Save & Exit** button on the Next Steps page of the form.
7. 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 in review, click **Discard** to completely remove a submission from further consideration by the IRB. Completing the Discard activity only affects the submission.

- If an initial submission is discarded in error, it can be recreated, edited and resubmitted by completing Copy Submission on the discarded study record.
- If a modification or continuing review on an approved study is discarded, it will only discard that submission and will not affect the current status of the study.

Checking a Submission 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 the following items. To perform a visual inspection, open the study and look through the forms in order. To open the study, see [Editing a Submission](#).
 - 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](#))

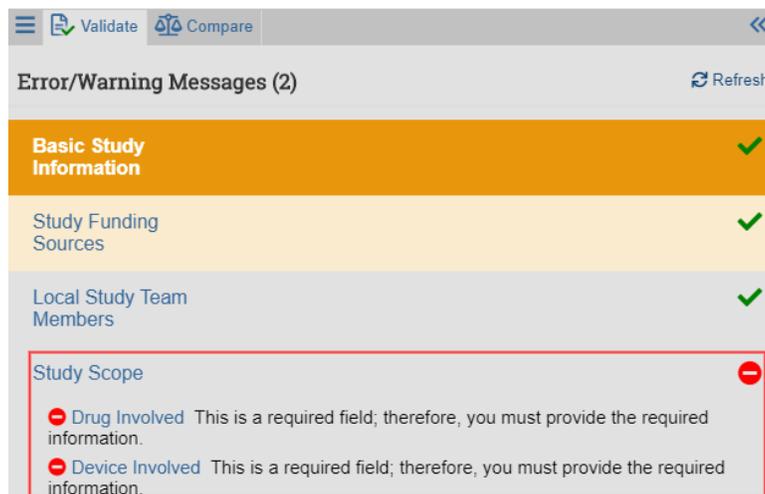
- **Using the Validate option** to find and correct all errors before submitting the study. The system automatically checks for missing required information when the PI attempts to submit the study. However, if you are filling out the forms on behalf of the PI, it is best to check the study for errors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

To use Validate to find and correct missing information

1. Open the study, as explained in [Editing a Submission](#).
2. From the left-hand navigation area, click **Validate**.



3. The left-hand navigation area expands to show Error/Warning Messages, listing all the current errors and where to find them.



4. For any error listed, click the link in the error message to go to the form containing the error.
5. Click **Continue** to identify the specific questions on the form with errors.
6. Fill in the missing information.
7. Click **Save** to record your changes and update the list of errors in the Error/Warning Messages pane.
8. Continue correcting errors until no errors are listed.

Submitting a 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. Once a study is approved, the PI can assign a proxy to submit modifications or continuing reviews on his/her behalf. See [Managing Principal Investigator \(PI\) Proxy](#).

1. Log in to irb.harvard.edu
2. Make sure you are in My Inbox. If you do not see My Inbox, click the **Dashboard** link (in the top navigation menu).
3. Click the name of the submission to open it. It should be in the Pre-Submission state.

My Inbox

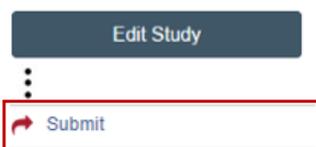
This Inbox lists submissions where action is required. To find addi

ID	Name	Date Modified	State
IRB17-0014	Searching for signs of life	1/23/2017 6:39 PM	Pre-Submission

If the study does not appear on this list, perhaps it was already submitted, or it does not include you as a study team member. To find the study, try clicking **IRB** in the top left navigation area. If you do not see it in that list, see [Accessing a Submission](#) for more ideas.

4. Click the **Submit** button (under the dark buttons) from the Next Steps list on the left.

Next Steps



The system will conduct an 'error check' to identify if any required questions were missed. If any errors or warnings are shown, click the link in the left-hand navigation menu 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.

5. Click **OK** to agree to the PI assurance statement presented on the pop-up 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.
- Refer to the IRB Library, Other Reference Tab to view of the assurance text.

When an initial study, modification/update 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 also includes reference to the PI assurance statement.

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 action, the PI/PI Proxy and Primary Contact receive an e-mail notification, and the study appears in the Dashboard 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 the Dashboard (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 Study Primary Contact](#).

Checking the Status of a Submission

You can see a diagram showing the IRB review status (state) of your submission by opening the submission and viewing the submission workspace (webpage). The bubble shaded orange indicates the present status in the workflow. For example, the following image indicates that this submission has been sent to the IRB office for review and review is not yet completed:



To find out more about what each status (state) means, please view the [ESTR Glossary](#).

You can easily open your submission from one of the following lists (depending on its status):

- Dashboard
- IRB In-Review Studies
- IRB Active Studies

For instructions about opening your submission from these lists, see [Accessing a Submission](#).

Accessing a Submission

You may want to go to a specific submission workspace (webpage) to view or update its contents, submit it for review, review it, or take other actions. Note that your access to a submission is

personalized based on your role in the system and the role you play in relation to the particular submission. In addition, the actions you can take on a submission are personalized.

To view a submission workspace (webpage), click the submission name when you find it in a list of studies.

To find a list that includes the submission name:

- **Dashboard** (only items that require attention): Click the **Dashboard** link in the top navigation header. This list displays submissions assigned to you for action, such as submissions you are preparing to submit or submit response to a requested clarification



OR

- **IRB** (all items to which you have access): Click **IRB** in the top navigation header and select the **All Submissions** tab. The lists display workspaces for all studies, continuing reviews, modifications, and reportable new information (RNI) entered into the system that you have permissions to view.



Tips:

- Try filtering this list by the study name or principal investigator. Next to Filter by, select **Name** or **Investigator**. Then type the beginning of the name and click **Go**.
- View the **State** column to see where the submission is in the review process.

Managing Submission Permissions

Permissions on a submission are different, depending on your role on the study. The Principal Investigator, study team and guest permissions are different than IRB office staff, and ancillary and IRB reviewers. Principal Investigators, study team members and guests have the following permissions:

Action	User Role(s)
Receives ESTIR system notifications	Principal Investigator, Primary Contact, PI Proxy
Can create submissions on behalf of the PI <i>All types of submission</i>	Principal Investigator, Primary Contact, PI Proxy, Study Team Member
Can submit initial submissions	Principal Investigator Only
Can submit follow-on submissions on behalf of the PI <i>Modifications/updates, continuing review, and closures</i>	Principal Investigator, PI Proxy

Can complete the Copy Submission activity	Principal Investigator
Modification required to add or update this role	Principal Investigator (using modification to “Other Parts of the Study”), PI Proxy, Study Team Member (using modification to “Study Team Members”). Note: The PI Proxy must be a study team member, but Proxy assignment does not require a modification
Has approval to conduct human subjects research activities/is listed on the personnel roster	Principal Investigator, PI Proxy, Study Team Member
Has view-only access to the submission	Guest

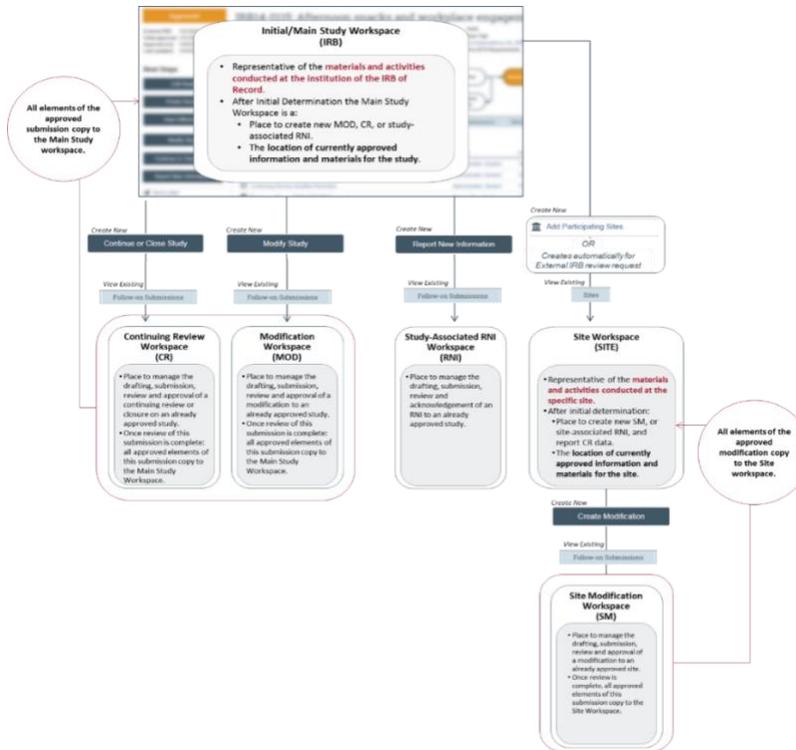
*To manage permissions per project, see sections for how to [change a primary contact](#), [assign proxies](#), [change study team members](#), [copy a study](#), and [add guests](#).

**For view access to many records in a department, school, or under the purview of an IRB, see [Requesting Viewer Access to ESTR-IRB, Agreements-DUA, or Data Safety](#) for expanded guest access.

Submission Workspace Overview

Initial/Main-study, Continuing Review, Modification/Update and Reportable New Information submission workspaces are formatted similarly. The following general concepts apply to navigation:

- The Initial/Main study workspace (labeled with numbers IRB##-#### or #####) always has the most current approved information and materials for a study.
- The Site workspace (labeled with numbers SITE##-####) is always associated with a main study and will have the most current reviewed information for that site.
- Continuing Review, Modification/Update, and Reportable New Information workspaces are used actively during the review of that submission only. Once a determination is made (or the submission is discarded), Continuing Review, Modification/Update and Reportable New Information workspaces are used for reference only and should not be the go-to location for study information.



Workspace Regions

Image displays the Initial/Main study workspace for reference.

Dashboard Portal Agreements OAIR IRB

Submissions Meetings Library Reports Help Center

1 **Approved**

Entered IRB: 6/28/2022 2:14 PM
 Initial approval: 6/28/2022
 Initial effective: 6/28/2022
 Effective: 6/28/2022
 Approval end: 6/27/2023
 Last updated: 6/28/2022 2:38 PM

Next Steps

- [View Study](#)
- [Printer Version](#)
- [Modify Study](#)
- [Continue or Close Study](#)
- [Report New Information](#)

3

- [Assign Primary Contact](#)
- [Assign PI Proxy](#)
- [Manage Guest List](#)

IRB22-0471: Community Engagement and pet adoption

Principal investigator: Walter Bishop (irb-pi)
Submission type: Initial Study
Primary contact: Sanji Vins (Study Staff)
PI proxies:

IRB office: HUA
IRB coordinator: Olivia Dunham (irb-irbd)
Letter: [Correspondence_for_IRB22-0471.pdf\(0.01\)](#) ...
Regulatory authority: 2018 Requirements

4

```

            graph LR
            A[Pre-Submission] --> B[Pre-Review]
            B --> C[IRB Review]
            C --> D[Post-Review]
            D --> E[Review Complete]
            B --> B1[Clarification Requested]
            C --> C1[Clarification Requested]
            D --> D1[Modifications Required]
            B1 --> B
            C1 --> C
            D1 --> D
            
```

5

History Funding Contacts Documents Follow-on Submissions Reviews Snapshots Related Projects

6

Activity	Author	Activity Date
Copied Submission	Dunham (irb-irbd), Olivia	6/28/2022 2:42 PM
New Copy: IRB22-0473 Saif regression test 1.26.2 #2		
Letter Sent	Dunham (irb-irbd), Olivia	6/28/2022 2:38 PM
Correspondence_for_IRB22-0471.pdf		
Finalized Documents	Dunham (irb-irbd), Olivia	6/28/2022 2:33 PM

Region	Information in this region
1	<p>Status Visible in all workspaces, the status region will show:</p> <ul style="list-style-type: none"> The status of the submission once it is created and through the review process, Information about when a submission was sent to the IRB and updated, and Initial/Main study workspaces also display the initial and approval end (expiration) dates for reference, as applicable.

2	<p>Next Steps Visible in all workspaces, this set of blue buttons allows for:</p> <ul style="list-style-type: none"> • Editing or viewing the current submission SmartForm, • Displaying a printer version, • Viewing changes over time, and • On Initial/Main study workspaces only: Creating new Continuing Review, Modification, or Reportable New Information submissions for the study.
3	<p>Activities Visible on all workspaces, activity buttons display depending on the type of submission, the status of the submission, and your role on the study. Mostly, activities displayed take action on the submission only. However, Assign PI Proxy, Assign Primary Contact, Manage Related Projects, and Manage Guest List are only visible on the Initial/Main study workspace.</p>
4	<p>Submission Overview This section displays the following submission-specific items for reference:</p> <ul style="list-style-type: none"> • Number and name of the submission/workspace being viewed • PI, submission type, primary contact, PI Proxy/ies (if assigned), and IRB office and coordinator (if one is assigned) • IRB determination letter (labeled “Letter”), if a determination has been made • Regulatory Oversight to indicate if a submission is/was subject to review under pre-2018 Common Rule or 2018 Common Rule • Image of the state of review for the submission. Note that when viewing an Initial/Main study workspace the image may indicate “review complete” while an associated submission (such as a Continuing Review or Modification” is under review).
5	<p>Notification Area When the record has not yet been submitted for review, a reminder to complete the submit activity displays in this space. <i>Content blank in example image above.</i></p>
6	<p>Submission Tabs On a submission, the Initial/Main study workspace shows all current approved details (including documents and study team members) while all follow on submission workspaces display information that was proposed at the time of review and determination. Click on tabs to view:</p> <ul style="list-style-type: none"> • <u>History</u> Information about each action taken on a submission and in-brief view of comments. • <u>Funding</u> List of all funding listed on the SmartForm, with a link to GMAS, if applicable. • <u>Contacts</u> List of study team members listed on the SmartForm. The tab also includes their current Human Subjects Training information on file and their training expiry date. If no training is listed, they do not have current active training. Each team member is listed with a Date Modified, intended to show when any additions or revisions occur during review or modification. • <u>Documents</u> Draft and finalized documents submitted for review, with versioning information for each document • <u>Sites</u> Links to associated Site workspaces for a study (only visible on the <i>main study workspace</i> of collaborative projects where Harvard is the IRB of record for at least one site) • <u>Follow-on Submissions</u> Links to Continuing Review, Modification/update, or Reportable New Information workspaces for a study (only visible on the <i>main study workspace</i>) with quick access to all determination letters • <u>Reviews</u> View additional details about the review, including ancillary review details, data security level determinations, and completed checklists.

- [Snapshots](#) View of the application at each change in state (for example, the appearance of the SmartForm between pre-review and changes submitted)
- [Related Projects](#) Information about Agreements, Data Safety, and other IRB submissions which have been associated with the study via the Manage Related Projects activity (only visible on the main study workspace) including the current state of the related submission and a link to the related project workspace.

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 the Dashboard for each member of the study team.

Important! Any study team member can make changes to 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 the Dashboard, 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. 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.

IRB20-0541: Community Engagement and Pet Adoption Rates

Principal investigator: Rebecca Simms
 Submission type: Initial Study
 Primary contact: Rebecca Simms
 PI proxies:

IRB office: HMS
 IRB coordinator: Mary Little
 Letter: [Correspondence_for_IRB20-0541.pdf\(0.03\)](#) ...

Regulatory authority: 2018 Requirements

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.

Next Steps**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 [What to Include in a Reportable New Information SmartForm](#).

Changing Documents on a 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:

There are two ways to change documents (when the submission is in an editable state). These steps also apply if the IRB decision was modifications required, disapproved, or deferred.

A. Edit Document Directly in Office Online

Note: This option is only available for Microsoft XML documents (file extensions .docx, .xlsx, .pptx, and .vsdx).

1. From the Dashboard, click on the name of the submission to open the workspace.
2. Click Edit Study on the left. For modifications, click Edit Submission. The SmartForm will open.
3. Click the Update button to the left of the document.
4. Click the **ellipsis** next to the document and select the **Open in Word for the web** option or **Download Copy** to make edits and then upload the revision. (**Note:** If the word document extension is not .doc, there may be issues with opening the file in the web)

Edit Attachment

1. * File to attach:

 HRP-213-FORM-Non-Human Subjects Research Request Determination Form-revised.docx(0.02) 

Choose File

 View in Word for the web
 Open in Word for the web
 Download Copy
 Delete

2. Name: (if not supplied, the file name will be shown)

3. Version number:

5. The document will open in Office Online in a new tab. Make edits, enabling the Tracked Changes feature as needed, and close the tab once you have finished editing. Changes to the document will be saved automatically.
6. Complete any further updates and submit the changes for further review. See the section [Editing a Submission](#) for further details.

OR

B. Download a copy and upload a new version.

1. From the Dashboard, click the name of the submission to open the workspace
2. Click the **Documents** tab

History Funding Contacts **Documents** Sites Follow-on Submis

Filter by  Activity  Enter text to search  

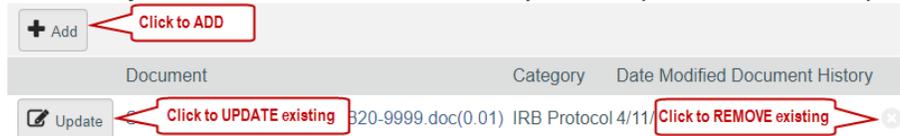
3. Click the name of the document in the Draft column and save it to your computer

Draft	Category
CUHS Template Research Protocol.doc	IRB Protocol
HRP-221_-_FORM_-	Financial Interes

4. Open the saved document and make edits (Enable the Tracked Changes feature as needed. When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.)
5. When finished with the changes, save the revised document on your computer
6. Go to the submission workspace and click **Edit Study** on the left. For Modifications or Continuing Reviews, click Edit Submission.

- Navigate to the location of the current document within the SmartForm by clicking Continue on the right
- Replace the original study document with the revised version by clicking “Update” beside the document on the SmartForm, or use other controls to make document changes.

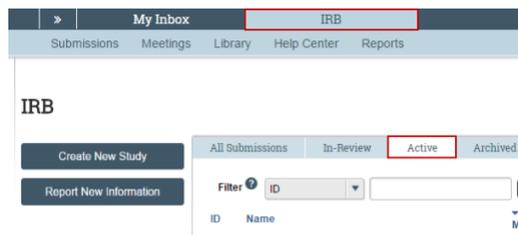
* Attach only the Research Protocol or relevant Request Form (see documents below):



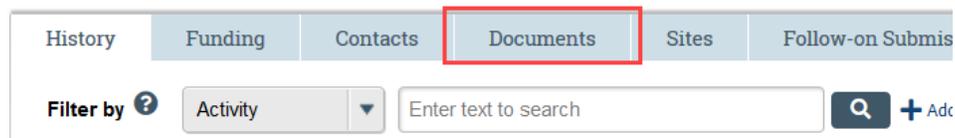
- Complete any further updates and submit the changes for further review. See the section [Editing a Submission](#) for further details.

To change documents on an approved study:

- Click **IRB** in the top left navigation area and select the **Active** tab.



- Click the name of the approved study.
- Click the **Documents** tab.



- Click the document in the Draft column and save it to your computer. In some cases, this document may contain previously approved tracked changes and comments. To update contents to match the current final-approved version, 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.
- Open the saved document and make edits (Enable the Tracked Changes feature as needed. When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.)
- When finished with the changes, save the revised document to your computer
- Go to the approved study workspace and create a modification to update the SmartForm and submit the proposed changes for IRB review. See the section [Creating a Follow-On Submission after Study Approval](#) for further details.

Communicating with Staff during Review

During review of a study OR site (and after), you can complete the **Add Comment** activity to:

1. Post a note to the submission history that all individuals with access to the submission may view, and
2. 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.)

During review of a site (and after), you can complete the **Correspond with Site** or **Correspond with sIRB** activity, and:

1. Send a notice to any person associated with the study or site, including the other IRB office contact.
2. Include the text in the activity within the email sent to the recipient(s), and
3. While not preferred, if a person chooses to reply to this notice: you will receive replies to this notice in your email inbox, rather than posted on the submission workspace.

Important!

- The information in these activities are 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.

Managing Related Projects

When a submission has other associated records in Data Safety, ESTR, and/or Agreements, completing the Manage Related Projects activity will connect the records across the systems so the reviewer may consider the status of associated records and any additional context of these associated records in the review.

This activity can be completed by the PI, PI Proxy, Primary Contact and members of the project team at any time in the review process.

To Manage Related Projects:

1. On the main protocol/study/agreement workspace (marked in the center as “Submission Type: Initial Protocol”), click the **Manage Related Projects** activity.



2. In the pop up, search for the related project by typing or pasting the its complete ID number into the search box (1). When it appears below, highlighted in yellow, click on the ID to choose the submission (2). You can also click the ellipses [...] to search the list of available submissions. One or more selected project(s) will appear on the list in the pop up.

Note: You may only search for submissions to relate by their IDs.

Manage Related Projects

Select Related Projects
Search for a project by **project ID**.

DAT19-0001 1 ...

ID

DAT19-0001 2

After project(s) have been selected above, click **OK**. Confirm selections by viewing the "Related Projects" tab on the workspace.

3. **Click OK** to create the relationship between projects and return to the workspace.

Click on the "Related Projects" tab of your protocol workspace to view related projects. Additional details about related projects will appear, including ID, name, state, date modified, and a link to the workspace of the related project. Confirm that you have selected the correct projects on this tab.

History	Funding	Project Contacts	Documents	Follow-on Submissions	Related Projects	Reviews	Snapshots
ID	Name	State	Modified Date	Project Link			
DAT19-0001	Data Safety	Pre-Submission	11/1/2019 3:27 PM	DAT19-0001			

Important! Notes about using Manage Related Projects

- Relationships between projects are bi-directional. Once you have created a relationship between projects, it will appear (within a few moments) on the "Related Projects" tab for both submissions. You do not need to manage the relationship in both places.
- You may only create relationships between two initial/main studies. Follow-on submissions (such as amendments/modifications and continuing reviews) are not available for selection.
- Project states may not update automatically. The correct state will always be displayed on the workspace of that project.

To remove a relationship between projects using the "Manage Related Projects" activity:

1. On the main protocol workspace (marked in the center as "Submission Type: Initial Protocol"), click the **Manage Related Projects** activity.

 **Manage Related Projects**

2. Remove projects by clicking on the "X" at the far right of the entry (1).

Manage Related Projects

Select Related Projects
Search for a project by **project ID**.

...

ID

DAT19-0001 1 ✕

After project(s) have been selected above, click **OK**. Confirm selections by viewing the "Related Projects" tab on the workspace.

2 **OK** **Cancel**

3. **Click OK (2)** to confirm the removal and return to the protocol workspace.

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 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 (Modification/Updates and Continuing Review or Closures). 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 after initial submission. Any study for which the review has been ceded to an External IRB, assigning a PI Proxy is not permitted.

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 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 Next Steps, click **Assign PI Proxy**.

 The image shows a button with a person icon and a plus sign, followed by the text "Assign PI Proxy".

4. A pop up will appear where you can select the individual(s) you would like to designate as PI Proxy by clicking on the ellipses [...] beside the space to enter a name. The secondary pop up 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 an approved Modification.
5. Check any/all of the individuals you wish to make PI Proxy, review the PI assurance statement
6. Click **OK**.

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.



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 Next Steps, click **Assign PI Proxy**.

 [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**.

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.



Important! Any PI Proxy that is removed from the study via a Modification to study team members will be automatically removed as PI Proxy.

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.
- Modification/updates 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.

Important! 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”), click **Assign Primary Contact** from the Next Steps list on the left.

Next Steps



A new window opens.

Click **Clear** to remove the current contact.

Begin typing the name of the new contact. A list of matching names appears.

Click on the correct name using the mouse. The name should appear as a blue link in the space provided.

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.

Long Walks on the Beach

Principal investigator: Glenn Rhee

Submission type: Initial Study

Primary contact: Carol Peletier

IRB coordinator: Rick Grimes

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:

1. Log in to irb.harvard.edu
2. Navigate to a study (see [Accessing a Submission](#) for more instructions)
3. Click **Manage Guest List** from the Next Steps list on the left. A new window opens.
4. Review the existing list that appears of people who can view the study without being on the guest list

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.

To **remove a guest** click Remove on the right, next to their name

5. Click **OK**

Copying a Study

Over the course of submission and review, it may be appropriate to copy the elements of one study into a new submission which then can be edited and submitted for review by the IRB. For example, it is appropriate to copy a study if:

- There are basic elements of a study (such as the list of study team members) that are similar to a new project that will be proposed;
- A study was discarded in error;
- A member of the IRB office requests that you copy the study; or
- A study received one of the following determinations from the IRB, and the mode of IRB review must now change:
 - Not Human Subjects Research/Not Research,
 - Human Research, Not Engaged, or
 - Determination under 45 CFR 46.118, proposals lacking definite plans for the involvement of human subjects.

Copying a submission will replicate all information on a study (including documents) into a new submission. A study can be copied at any time.

Note

- The record copied (including all attachments) must be reviewed and updated to comply with current policies and regulations prior to submission for review. **The new copy must be further edited and submitted by the PI for review by the IRB.**
- Only the PI can copy a study.
- The status of the copy is completely independent of the status and management of the original study.
- Only a Main/Initial Study (or Reportable New Information) can be copied. Other submissions, for example: Modification/Update or Continuing review cannot be copied.
- The new copy will include any 'related projects' and the [Manage Related Projects](#) activity must be completed to confirm or edit the list.
- If the copy was created in error, it can be discarded.

Important! Do not copy a study to propose changes to an active project or to request continued review. See [Creating a Follow-On after Study Approval](#) for instructions to create a modification, continuing review or study closure for an active project.

To copy a study:

1. Log in to irb.harvard.edu
2. Navigate to a study (see [Accessing a Submission](#) for more instructions)
3. Click **Copy Submission** from the Next Steps list on the left. A new window opens.
4. Write in the name of the new submission (this can also be edited after the submission is created).
5. Click **OK**

The copy activity will appear under the History tab of the study workspace. While the system is creating the copy, a progress note will appear.



6. Navigate to the new study by either:
 - Refreshing the page to view and click on a link to the new copy, or
 - Clicking Dashboard in the top navigator bar and click on the new submission.
7. Complete steps to edit the submission and submit it to the IRB for review. (see [Editing a Submission](#) for more instructions).

Creating a Follow-On Submission after Study Approval

All submissions associated with a study after the initial creation are called “follow-on” submissions. These include submission types: Modification/Update, Continuing Review, Site, and Reportable New Information.

To submit this type of information...	Start here...		Notes
Modifications to an active study Continuing review updates for an active study Request to close study	From the Active tab, click the study name (see Accessing a Submission)	<div data-bbox="626 478 964 541" style="background-color: #4a697d; color: white; text-align: center; padding: 5px; margin-bottom: 10px;">Modify Study</div> <div data-bbox="626 552 964 615" style="background-color: #4a697d; color: white; text-align: center; padding: 5px;">Continue or Close Study</div>	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. To request study closure, submit a Continuing Review. Based on the research milestones completed, the study may be closed. To modify an External IRB project, see Updating External IRB Review ,
Modification or update to an active site	From the Sites tab, click on the site name (see Accessing a Submission)	<div data-bbox="626 877 964 940" style="background-color: #4a697d; color: white; text-align: center; padding: 5px;">Modify Site</div>	You can submit a modification request which is specific to sites. To provide a status update or request site closure, complete the Report Continuing Review Data activity in the site workspace and indicate the request to close in the text of the activity.
New information or an adverse event report	For new information about a particular study, start from the Active tab and click the study name (see Accessing a Submission)	<div data-bbox="626 1262 964 1325" style="background-color: #4a697d; color: white; text-align: center; padding: 5px;">Report New Information</div>	Report new information as soon as you become aware of it. The form identifies the types of information you must report.

To submit this type of information...	Start here...		Notes
	For information affecting multiple studies, start in one of the studies and add studies within the form.		

What to Include in a Modification SmartForm

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.

Important! Updating the SmartForm does not send the submission for review.

The PI or PI Proxy must click **Submit (on the left, in the submission workspace)** for the submission to proceed on for the next state of review.

To create and 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 “Modify Study” button.
4. Select “Modification/Update”
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.
 - Selecting “Study team member Information” allows for update to the study team members listed on the study or study team member related documents (such as human subjects training certificates or Financial Conflict of Interest forms)
 - Selecting “Other parts of the study” allows for revision to:
 - The Principal Investigator, the Principal Investigator fCOI status, or associated Financial Conflict of Interest form(s)
 - The protocol
 - Any Basic Information, including changing the study type to collaborative research where Harvard will review on behalf of at least one site
 - Funding for the study
 - Study Scope and related elements such as additional study locations, or the study of drugs or devices
 - Consent, recruitment materials, study instruments/tools and any other non-personnel study documents.

Modification / Continuing Review / Study Closure

* What is the purpose of this submission?

To request Continuing Review OR Study Closure, select the Continuing Review option.

Continuing Review
 Modification/Update
[Clear](#)

Modification scope:

Study team member information
 Other parts of the study

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. Refer to the [What to include in the SmartForm](#) section for additional instructions for what is required for each element of the study SmartForm.
7. Follow the remaining steps to [Edit a Submission](#) or Save & Exit when edits are complete.
8. The PI or PI Proxy must click Submit (marked with a red arrow in the submission workspace) for the submission to proceed on to the IRB for review.

Tips:

- To change the Principal Investigator on an approved study, select the "Other parts of the study" Modification scope.
- Once a modification scope is selected and saved, it cannot be changed on that submission.
- If the Add/Manage Participating Sites activity is not available on the approved main study workspace, propose the addition of a site to an approved study by:
 - (1) Create a Modification to "other parts of the study"
 - (2) On the Basic Information page of the SmartForm, mark the study type as "Collaborative" and that "Yes" Harvard will review on behalf of at least one IRB; AND
 - (3) After modification approval, complete the "Add Participating Sites" activity on the main study workspace.
 If a site is added to an approved study, the IRB may request that the submission be accompanied by a modification to the study protocol.

What to Include in a Continuing Review SmartForm

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.

This submission is used only to provide an update to the IRB when required. Changes to an existing study must be proposed via a separate modification submission. Please see [What to include in a Modification SmartForm](#) for steps to complete a modification submission.

Important! Updating the SmartForm does not send the submission for review.

The PI or PI Proxy must click **Submit** (on the left, in the submission workspace) for the submission to proceed on for the next state of review.

To submit a continuing review or 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 “Continue or Close Study” 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 Continuing Review OR Study Closure, select the Continuing Review option.

Continuing Review
 Modification/Update
[Clear](#)

Select “Continue” and complete the Continuing Review / Study Closure Information SmartForm Page.

On this page of the SmartForm, complete the following items:

1. **Specify enrollment totals:** Enrollment includes the subjects who have undergone the initial informed consent process and who have agreed to participate in the research; or where a waiver has been approved by the IRB, enrollment includes the number of individuals whose data, documents, records, and/or specimens were utilized. Indicate enrollment totals in the table provided. This section is required and a value must be entered in every space.

Note: For studies with sites (created after December 2017) which have separate workspaces, visit the site workspaces to additionally complete the Report Continuing Review Data to report site-specific update details (including enrollment totals).

2. **Research milestones for enrollment / analysis:** The IRB will determine the mode of review (including if study closure is appropriate) based on what is marked in this space. Mark all items that currently apply. If subjects will continue to be enrolled or if no items apply, leave this section blank. To prepare, note that the following prompts appear in this space to mark, as appropriate:
 - Study is permanently closed to enrollment OR was never open for enrollment
 - All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
 - Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
 - Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
 - Remaining study activities are limited to data analysis
 - Study remains active only for long-term follow-up of subjects

Important! If the first four milestones are selected here, you will be required to confirm that you intend to close the study. If you do not intend to close the study, de-select the most appropriate item from the first four milestones.

3. **Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?** Indicate yes or no in this space. Attach any relevant documentation to question 5 on this page of the SmartForm.

4. **Check the items that are true since the last IRB review (initial review or last continuing review) for all sites approved by the Harvard IRB.** Mark all true items and provide an explanation of any unmarked items in the progress report attached to question 5 on this page of the SmartForm.

5. **Attach a brief summary of the study progress.** Address each item left unchecked in question 4 by attaching documentation. Use the optional template provided in the [Library](#) to, as applicable, attach a progress report along with any other supporting documents that contribute to the review of the submission.

Reference the [Library](#) for any templates/forms that are requested within the SmartForm, along with guidance materials.

Follow the remaining steps to [Edit a Submission](#) or Save & Exit when edits are complete.

The PI or PI Proxy must click **Submit** (on the left, in the submission workspace) for the submission to proceed on to the IRB for review.

What to Include in a Reportable New Information SmartForm

The purpose of this form is to provide required information to the IRB that does not qualify as a continuing review, request for closure, or proposed modification to a currently approved study.

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 Dashboard) is used when you would like to submit an anonymous RNI, visible only to you and the IRB office.

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

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
 - Dashboard or IRB pages linked in the top menu (if you do not want to associate this with a study)
3. Click the “Report New Information” button.
4. On the SmartForm, fill in the necessary items for IRB review.
 1. **RNI short title.** A way to uniquely identify this new information report in the system. This will appear as the submission ‘name’ in all workspaces.

 2. **Date you became aware of the information.** Indicate the date in the space provided.

 3. **Identify the categories that represent the new information.** Mark all that apply from the list provided on the form. Information that does not fit into one of the categories provided

does not need to be reported to the IRB as new information.

4. **Describe the new information.** Include relevant information and if the event is ongoing or resolved, including the number of participants affected, details regarding any new or increased risk or safety issue to participants or others, and procedures used to investigate the event and prevent a similar event from occurring again in the future. It is additionally helpful to note details such as:
 - Explanation of how the lapse occurred.
 - Strong corrective action plan in place to avoid a future lapse.
 - Timeline for when the lapse will be resolved, with either a CR or closure.
 - Confirmation that no human subjects research activities took place while lapsed.
 - Confirmation that there are no outstanding RNIs, pending issues/Mods, participant complaints/concerns, etc.
 - Verification that no prior lapses for this project have occurred before; confirm Related Submission is linked accurately.
 - Verification that the lapse was reported within our 5 business day reporting policy.
 - Verification that notification of lapse has been communicated to sponsor, local site/IRB, DSMB, etc., if/when applicable.
5. **In the submitter's opinion.** Mark yes or no to the questions provided. If it is marked that the study or consent requires revision, a [separate modification request](#) must be created and submitted for review.
6. **Related studies and modifications.** List all studies associated with this submission. Only active studies to which you have access will display in the search results and can be selected as associated with this submission. If this question is left blank, the RNI SmartForm you will be prompted to provide additional information.

SmartForm Sub-Section: Department

 1. **Associated Department.** Indicate the department associated with this RNI (for example the reporter's department or the department where the event occurred).
 2. **Investigator.** As applicable, indicate the investigator associated with this RNI.
7. **Attach files containing supporting information.** Attach any additional information required to complete review of this report (such as a DSMB report or report from external agency).

5. Follow the remaining steps to [Edit a Submission](#) or Save & Exit when edits are complete.

6. The person completing this form must click **Submit** (on the left, in the submission workspace) for the submission to proceed on to the IRB for 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 the Dashboard of the individual responsible for completing the required actions.

To view the Action Plan and respond to the IRB:

1. From the Dashboard, 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. If the Action Plan requires a change to a study, create a modification and submit it for review as mentioned in other sections ([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.

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.

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

Only the person named as the “Responsible Party” by the IRB can see and complete the Submit Action Response activity. If the response is prepared but the activity is not visible and cannot be completed, contact the assigned IRB contact to request assistance.

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

Closing a Study

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:

- Follow the steps described to create a [Continuing Review](#).
- Based on the contents of the submitted SmartForm, the IRB will determine the mode of review (including if study closure is appropriate).

Generating Standard Reports

The IRB system includes many standard reports regarding studies and reportable new information (RNI) to help you find relevant submissions and understand the overall operation of the IRB. In addition, Harvard custom reports are available in via the Custom tab of the Reports page. The reports provide links to the individual submissions, as well as sorting and filtering options.

Any user has access to reports, but the data in the reports is limited to the studies visible to the individual. For example, a Studies Involving Children report generated by a PI will include only the studies that person can see elsewhere in the system--studies for which the person is included on the study team or guest list. IRB coordinators, directors, and committee members generally have access to all report data.

To generate a standard report:

4. Log in to irb.harvard.edu
5. Click **IRB** in the top navigator.
6. Click **Reports** in the IRB sub-menu.

The list of standard reports appears. To find a custom report, click the **Custom Reports** tab.

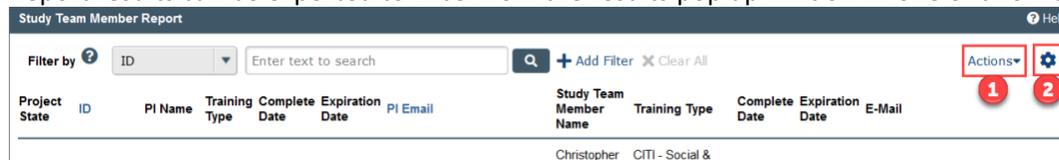
7. Identify the report to generate and click the link. The report appears, listing the relevant submissions.

Tips

- Try filtering the list by status. Next to Filter by, select **Status**. Then type the state to view, such as **Approved** for a study report or **Acknowledged** for an RNI report and click **Go**.
- If you or members of your office **require special access** to multiple studies or reports for a department or school, please contact your IRB office or estrhelp@harvard.edu for special access.

To generate a report listing you as the Principal Investigator (PI) and/or Study Team Member:

1. Log in to irb.harvard.edu
2. Click **IRB** in the top navigator.
3. Click **Reports** in the IRB sub-menu.
The list of standard reports appears; click the **Harvard Custom Reports** tab.
4. Locate the **Study Team Member Report** on the list and click the hyperlink.
5. A report will appear listing all submissions where you are either listed as the PI or listed as an approved Study Team Member.
6. Report results can be exported to Excel from the results pop up window in one of two ways



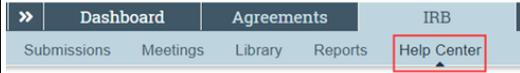
1. Click the **Actions** option to choose **Export to CSV**. The option will change to the words "please wait" until the export is prepared and (depending on your browser settings) it will save the file to your default folder or a pop up will appear for you to choose the location to save the file.

OR

2. Click the **gear icon** to choose **Export to CSV** at the bottom of the panel. The option will change to the words “please wait” until the export is prepared and (depending on your browser settings) it will save the file to your default folder or a pop up will appear for you to choose the location to save the file.

Note: Exporting a file may take time. If the file is large, you will see a status value display or the message “Please wait...”. It is important to wait for the process to run, rather than re-trying the export.

Finding More Information

Resource	Description	How to Access It
Help for a field or page	More information about a question or form.	Click the question mark icon  next to the question or at the top of the form.
Help system	The full online help system, with search and table of contents. The online help contains procedures and information for all users.	Click the Help Center sub-menu link at the top of the screen. 
IRB Study Submission Guide	Instructions for submitting a study for review.	Click the Help Center sub-menu link at the top of the screen. On the Guides tab, click the name of the guide to open it.
IRB Study Reviewer's Guide	Instructions for reviewing an IRB submission.	
IRB Staff Administration Guide	An overview of the IRB review and administration process.	
IRB Library	Document templates, checklists, and forms.	Click the Library sub-menu link at the top of the screen.
ESTR Support	External website with additional information about using ESTR	estrsupport.fss.harvard.edu
ESTR Help Desk	Contact for help with ESTR access and use	estrhelp@harvard.edu
IRB Websites	Information about the IRB review process and requirements	<ul style="list-style-type: none"> ▪ HMS, HSDM, and HSPH (Studies in Longwood Area only) at hsph.harvard.edu/orarc/irb ▪ FAS, GSE, HKS, HBS, SEAS, HLS, GSD, HDS, and Radcliffe Institute (Studies in University Area only) at cuhs.harvard.edu

This guide was created and edited by Harvard University based on materials originally produced by Huron Technologies, Inc.