



HARVARD

Human Research Protection Program

Electronic Submission Tracking and Reporting (ESTR)

Study Submission Guide

August 28, 2017

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Logging In

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

To log in:

1. Locate your [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

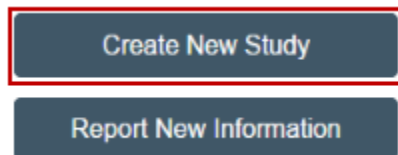
Creating a New Study

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.

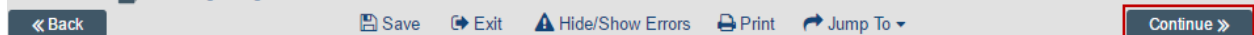
To create a new study for review:

1. From My Inbox or IRB pages (linked in the top menu), click **Create New Study**.

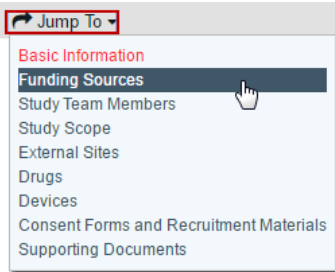


2. Fill in the applicable boxes, answer the questions, and attach appropriate documents.
3. Click **Continue** to move to the next form.

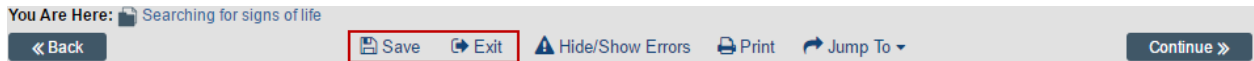
You Are Here: Searching for signs of life



4. Click the 'jump to' menu to go to a specific section (be careful to save before jumping to another page).



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



- 6. When you reach the final page, click **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 study has not been submitted for review yet. For instructions, see [Submitting the Study 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>	
<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>	

- 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** (marked with a red arrow in the submission workspace) for the submission to proceed on for the next state of review.

SmartForm Section: Basic Information

1. **Title of study.** Enter the complete study title. Please avoid use of quotation marks in the study title.
2. **Short title.** The short title identifies the study throughout the system, such as in your inbox and in an IRB reviewer's list of submissions to review. This should be 80 characters or less, and should not contain quotation marks. If left blank, the system will automatically pull in the first 80 characters of the (long) study title.
3. **Brief description or abstract.** Enter a brief description of the study or the study abstract. This should be 225 words or less.
4. **Name of Principal Investigator.** Enter the name of the Principal Investigator. For details on who may be listed in this space, please visit your IRB website or Investigator Manual.

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

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

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

If the department name does not appear on the list provided, contact estrhelph@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
7. **Are you requesting that an external IRB act as the IRB of record for this study?** Select Yes if you are submitting an application requesting that a Harvard IRB rely on the review of another IRB. Select No if you are requesting that a Harvard IRB review and approve the study.

If you selected Yes see section: Requesting External IRB Review.

8. **Attach only the research protocol or relevant request form.** Select and use the template provided on the SmartForm (or on your IRB website) that is appropriate for your project and the IRB to which you are submitting. Attach a copy of the completed protocol

template, or if this application represents a request for a “Not Human Subjects Research determination”, attach “FORM: Non-Human Subjects Research Request Determination 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: 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.

Project ID	Investigator	Fund	Sponsor Text
1234-05	John Harvard	999928	Department of Energy
9998594-01	John Harvard		NIH

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 for the

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

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 **Supporting Documents** page of the SmartForm, when applicable, and remove or black-out any salary information.

SmartForm Section: Study Team Members

The Study Team Members page of the SmartForm should include the name of individuals that a) have contact with human subjects, b) have access to data that is identifiable; 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 simply for access to this study record (in the Study Team Member details and via "Add comment" on the submission workspace).
 - 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. **List study team members without an HUID (by attaching the Non-Harvard Study Personnel Form) and/or attach other relevant 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.
- 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.

Principal Investigator						
Name	Financial Interest	Email	Training Type	Training Complete Date	Training Expiration Date	
Kara Thrace	no	StarB@battlestar.gov	CITI Training - 1155678	1/1/2015	1/1/2018	

Study Team Members							
First Name	Last Name	Roles on Study	Financial Interest	Email	Training Type	Training Complete Date	Training Expiration Date
Wade	Wilson	Faculty Sponsor	no	dpool@con.com	CITI Training - 56789	4/17/2016	4/17/2019
Dana	Scully	Co-Investigator	no	scully@fbi.gov	CITI - Social & Behavioral Research Investigators - 553367	9/19/2016	9/19/2019
Lando	Caltrissian	Other Study Team Member	no	lcaltrissian@cloudcity.gov	CITI Training - 45234	7/13/2013	7/13/2018

Other Study Team Member Information Document

HRP-220 Non-Harvard Study Personnel.doc
CITI Training for PI.doc
CITI Training Other.doc

SmartForm Section: Study Scope

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

SmartForm Sub-Section: External Sites

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

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

SmartForm Sub-Section: Drugs

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

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

3. **Does the study involve the use of a DEVICE in one or more persons that evaluates the safety or effectiveness of that device, or data regarding the use of a device on human specimens?** Indicate if a device is used in the Human Research.

SmartForm Sub-Section: Devices

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

- 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: Consent Forms and Recruitment Materials

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

2. **Recruitment Materials:** Each recruitment document, script, flyer, advertisement, etc. must include version date and/or version number. Guidance on what is appropriate to include and exclude within an advertisement can be found in “WORKSHEET: Advertisements” and/or “WORKSHEET: Payments.” 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 Supporting Documents section of the SmartForm which appears later in the submission process.

SmartForm Section: Supporting Documents

Attach supporting files, naming them as you want them to appear in the approval letter: Also, be sure to name the file itself in a manner that identifies it as associated with your study. 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 and if possible minimize use of the “other” category. 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. Items to attach to this page:

- **Ancillary Approvals/Permissions.** Submit approval letters or permissions from any additional office or organization reviewing this project (for example, a letter of support). If unavailable at the time of submission, plan to submit a copy to the IRB prior to implementing any study procedures.
- **Data use agreements or other Agreements.** Submit copies of any documents authorizing the use of data, or other contracts or agreements associated with the study.
- **Debriefing Materials.** If any of these materials will be translated, also submit a Translation Attestation Form.
- **External Site Information.** If question 1 in the SmartForm Section: Study Scope indicated that there are external sites where the research will be conducted or overseen, submit an approval notice from each external site identified in the SmartForm. If unavailable at the time of submission, plan to submit a copy to the IRB prior to beginning any human subjects research at the external site(s).
- **Federal Department Requirements Checklists.** Attach any required checklist associated with certain kinds of Federal funding (such as DOD, DOJ or EPA).
- **Financial Interest Disclosure Form.** Submit this form if the Principal Investigator self-identifies a financial conflict of interest related to the research on the SmartForm: Basic Information page. Forms for any other team members which self-identify a financial conflict of interest should be attached to the SmartForm: Study Team Members page.
- **Foreign Language Documents.** Submit all translated study materials.
- **Funding Source Attachments.** If not associated with GMAS and as applicable, submit a complete copy of the grant applications, subcontract, and/or any funding agreements regardless of funding source.
- **Individual Investigator Agreement (IIA).** When a non-Harvard collaborator will be covered under the Harvard IRB review and this person is not affiliated with another institution, submit this form here or attached a completed copy to the SmartForm: Study Team Members page.
- **IRB Cede Request Form.** When multiple institutions are engaged in the Human Research, submit this form allowing an investigator to designate Harvard as the Reviewing Institution (responsible for IRB review) or Relying Institution **only** when such agreements are with non-SmartIRB participating institutions. To request such an agreement with a SmartIRB participating institution, visit this [link](#).
- **PI's Current CV (ICH-GCP E6 Only).** Submit a copy of the Principal Investigator's current (signed/dated) CV **only** when required by sponsor to follow the “International Council on Harmonisation – Good Clinical Practice E6.”

- **Radiation Safety Form.** If the Human Research involves the use of approved or unapproved diagnostic or therapeutic radiation outside routine clinical practice, complete and submit “FORM: Radiation Safety.”
- **Sponsor Protocol including DHHS-approved protocol.** Submit the sponsor protocol, if applicable.
- **Study Instruments/Tools.** Including all data collection instruments, questionnaires, surveys, focus group discussion guides, or interview guides. Do not include Case Report Forms. Study documents must include version date and/or version number.

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 Study 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:

- Ensure consent or recruitment materials have at least a one inch margin.
- 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 #
	Research Protocol or Non-Human Subjects Research Request Determination Form	Basic Information	8
	IRB Cede Request Form or SmartIRB Online Reliance Request Form	External IRB (External IRB studies only)	3
	External IRB Determination Letter	External IRB (External IRB studies only)	4
	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	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)	Consent Forms and Recruitment Materials	1
	HIPAA Authorization Form (English version only)	Consent Forms and Recruitment Materials	1
	Consent Script, for non-written consent (English version only)	Consent Forms and Recruitment Materials	1
	Parental permission or Assent (English version only)	Consent Forms and Recruitment Materials	1
	Recruitment Materials, including fliers, advertisements and scripts (English version only)	Consent Forms and Recruitment Materials	2

✓	Document Type	SmartForm Page to Upload Document <i>(in order of appearance, as applicable)</i>	Question #
	Principal Investigator Financial Conflict of Interest Form	Supporting Documents	1
	Surveys/Questionnaires/Interview Guide (Study Instruments/Tools)	Supporting Documents	1
	Non-English versions of Consent, Assent, Permission, Scripts or Recruitment Materials	Supporting Documents	1
	External Site Information	Supporting Documents	1
	IRB Cede Request Form (for when another IRB is relying on the Harvard IRB)	Supporting Documents	1
	Debriefing Materials	Supporting Documents	1
	Grant materials or funding source attachments (if the grant is not included in GMAS)	Supporting Documents	1
	Data Use or other agreements	Supporting Documents	1
	Ancillary Approvals/Permissions	Supporting Documents	1
	Federal Department Requirements Checklists	Supporting Documents	1
	PI's Current CV (ICH-GCP E6 Only)	Supporting Documents	1
	Radiation Safety Form	Supporting Documents	1
	Sponsor Protocol including DHHS-approved protocol	Supporting Documents	1

Requesting External IRB Review

You can request that the Harvard IRB rely on the review of another (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 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 have the Harvard IRB conduct the review 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

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 the request for review. The PI must click **Submit** (marked with a red arrow in the submission workspace) for the submission to proceed on for the next state of review.

SmartForm Section: Basic Information

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

2. **Short title.** The short title identifies the study throughout the system, such as in your inbox and in an IRB reviewer's list of submissions to review. This should be 80 characters or less, and should not contain quotation marks. If left blank, the system will automatically pull in the first 80 characters of the (long) study title.
3. **Brief description or abstract.** Enter a brief description of the study or the study abstract. This should be 225 words or less.
4. **Name of Principal Investigator.** Enter the name of the Principal Investigator. For details on who may be listed in this space, please visit your IRB website or Investigator Manual.

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

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

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

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
7. **Are you requesting that an external IRB act as the IRB of record for this study?** Select Yes. When you selected Yes, question 8 on the Basic Information SmartForm will disappear (it is not needed when requesting External IRB review). Click Continue to proceed to the External IRB page.

SmartForm Sub-Section: External IRB

On the following page you will need to enter information about the External IRB that will serve as the IRB of Record for the study.

1. **External IRB:** Click Select to indicate which institution will serve as the IRB of Record. If the reviewing institution is not listed, select Other.
2. **IRB Cede Request Form or equivalent:**
 - To request that the Harvard IRB rely on a [participating institution](#) of the SmartIRB Master Reliance Agreement, visit [this link to the Online Reliance System](#).. If it is your first time using this system, you will need to “Request Access” before you can complete an IRB cede request
 - To request that the Harvard IRB rely on a non-SmartIRB institution, attach “FORM: IRB Cede Review Request”

3. **Approval letter from external IRB:** Upload the External IRB's approval letter here, if available. If local approval is not available at the time of submission, a copy must be submitted to the IRB prior to beginning any human subjects research at the external site(s).
4. **Initial approval date by external IRB:** Enter date of initial IRB approval if/when known.
5. **Last date of approval period:** Enter date of the most recent IRB approval if/when known.
6. **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.

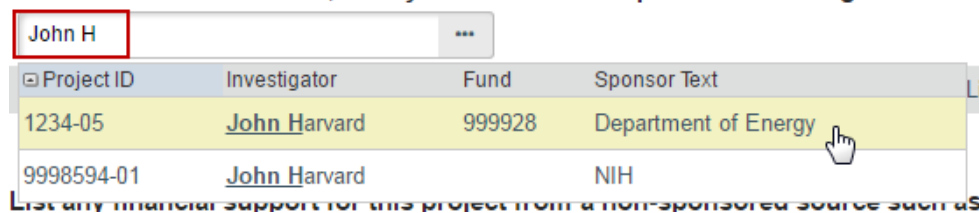
Important! After initial determination, when completing a Study Update on an External IRB project, an additional question regarding study closure will appear after question 6. Review and revise this question with every study update to ensure the study is closed appropriately.

SmartForm Section: Funding Sources

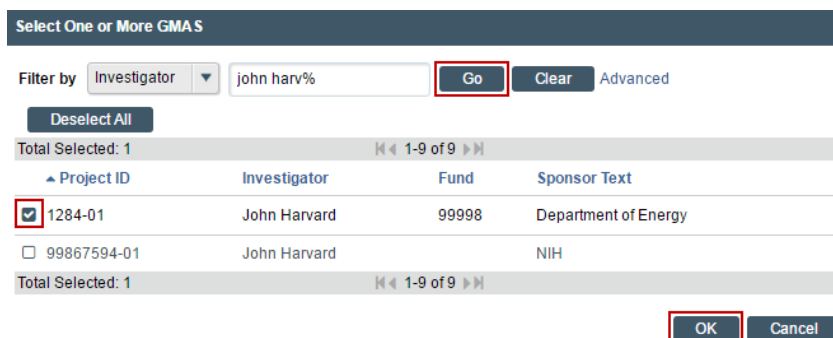
On this page include any pending/awarded funding sources or financial support for this study. Leave questions 1 and 2 blank to indicate that there is no funding for this study. Reminder: If the funding status changes following IRB determination, submit a modification to this study.

1. **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.



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 **Supporting Documents** page of the SmartForm, when applicable, and remove or black-out any salary information.

SmartForm Section: Study Team Members

The Study Team Members page of the SmartForm is disabled for External IRB submissions.

SmartForm Section: Supporting Documents

Attach supporting files: 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 and if possible minimize use of the “other” category. 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. Items to attach to this page:

- **Data use agreements or other Agreements.** Submit copies of any documents authorizing Harvard Investigator use of data, or other contracts or agreements associated with the study.
- **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.
- **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

After the Harvard IRB confirms External IRB review, you can provide an update to the submission, as applicable. The Update Study function allows for providing the Harvard IRB with:

- An update on the status of the study with the reviewing IRB, including closure; or
- An update to the information previously provided to the Harvard IRB (such as a change in funding).

To create and submit an update on an External IRB project:

1. Log in to irb.harvard.edu
2. Navigate to the External IRB workspace (see [Accessing a Submission](#) for more information).
3. Click the “Update Study” button, a SmartForm will open.
4. Provide a brief description of the contents of the update.
5. By selecting ‘Continue’ the system take you to a copy of the External IRB SmartForm. Refer to the [What to Include in the Initial Request for External IRB](#) section for additional instructions for what is required for each element of this SmartForm.

Important! After initial determination, when completing a Study Update on an External IRB project, an additional question regarding study closure will appear after question 6 on the SmartForm Sub-Section: External IRB. Review and revise this question with every study update to ensure the study is closed appropriately.

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.

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 My Inbox, click the name of the study to open it.
Note: If the study does not appear in your inbox, see [Accessing a Submission](#).
2. Click **Edit Study** on the left. For Modifications or Continuing Reviews, click Edit Submission.
3. Make changes as appropriate. When updating a study document previously submitted to the IRB, revise it in tracked-changes format and replace the original document with the tracked-changes version. When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.
4. Exit the study. 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.
4. (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.
5. Click **OK**. The PI, any PI Proxy, the Primary Contact and IRB Coordinator will receive a notice that the submission has been withdrawn.
6. 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.
7. 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.
8. After edits are completed, the PI or PI Proxy must complete the **Submit** activity again, to send it back to the IRB for review

Tip: When the submission is in pre-submission or clarifications requested, click **Discard** to completely remove a submission from further consideration by the IRB. Completing the Discard activity only affects the submission. If a modification or continuing review on an approved study is being 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.

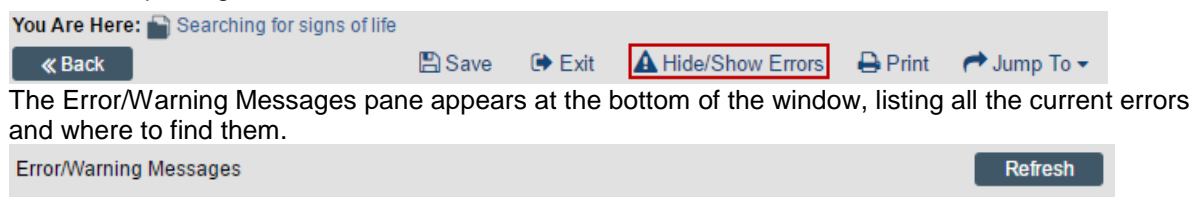
Using these types of error checking helps you supply all the information the IRB needs:

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

To use Hide/Show Errors to find and correct errors:

1. Open the study, as explained in [Editing a Submission](#).
2. From the top navigation area, click **Hide/Show Errors**.



You Are Here: [Searching for signs of life](#)

[← Back](#)
[Save](#)
[Exit](#)
[Hide/Show Errors](#)
[Print](#)
[Jump To ▾](#)

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

Message	Field Name	Jump To
⊖ This is a required field; therefore, you must provide the required information. Drug Involved	Drug Involved	Study Scope
⊖ This is a required field; therefore, you must provide the required information. irb Custom External Site	irb Custom External Site	External Sites

Refresh

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

Submitting 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](#).

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

My Inbox

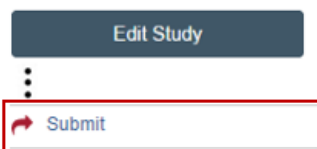
This Inbox lists submissions where action is required. To find addi

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.

- Click the **Submit** button (marked with a red arrow) 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 Jump To column to go to the form containing the problem. For more information, see [Checking the Study for Errors](#). When all errors are corrected, try submitting the study by clicking Submit again.
- 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.

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 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 act, the PI receives an e-mail notification, and the study appears in My Inbox for all study team members when they log in to the IRB system.**

Important! Make sure the appropriate person is listed as the primary contact to receive e-mail and see the study in My Inbox (along with the PI and any PI proxies, who also receive these). By default, the person who created the study is the primary contact. See [Changing the 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 dark blue 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):

- My Inbox
- IRB In-Review Studies
- IRB Active Studies

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

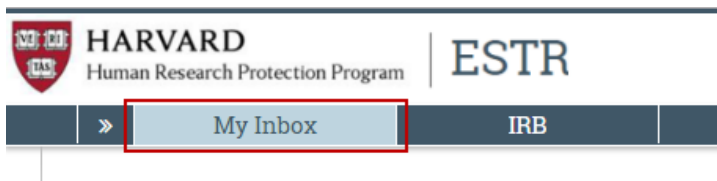
Accessing a Submission

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.

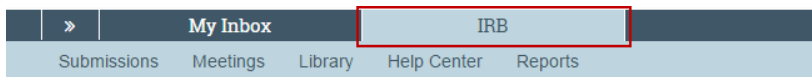
To find a list that includes the submission name:

- **My Inbox** (only items that require attention): Click the **My Inbox** 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

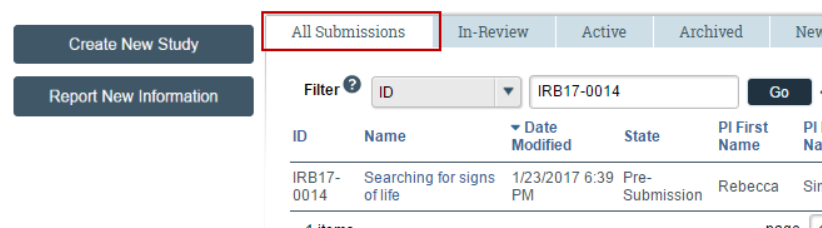


OR

- **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.



IRB



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:

ESTR Role*	Principal Investigator	Primary Contact	PI Proxy	Study Team Member	Guest
Receives ESTR system notifications ?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
Can create submissions on behalf of the PI? <i>All Types of Submission</i>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Can submit submissions on behalf of the PI? <i>Initial, Modification/Update, Continuing Review, and Closure only.</i>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		
Can submit RNI submissions on behalf of the PI? <i>RNI can only be submitted by the person who created the RNI in ESTR.</i>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Modification required to add or update this role ?	<input checked="" type="checkbox"/> <i>Modification to "Other parts of the study".</i>		<i>PI Proxy must be a Study Team Member, but Proxy assignment does not require a Mod.</i>	<input checked="" type="checkbox"/> <i>Modification to "Study Team Members".</i>	
Has approval to conduct human subjects research activities /is listed on the personnel roster?	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Has view-only access to ESTR records?					<input checked="" type="checkbox"/>

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

Submission Workspace Overview

Initial/Main-study, Continuing Review, Modification/Update and Reportable New Information submission workspaces are formatted similarly. However, 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.
- Continuing Review, Modification/Update, and Reportable New Information workspaces (webpages) 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.

The screenshot shows the IRB workspace for study IRB17-0013, titled "Community Engagement and Pet Adoption Rates". The interface includes a breadcrumb bar (1), a status region (2) indicating the submission is "Approved" with dates from 1/19/2017 to 1/23/2017. A "Next Steps" sidebar (3) offers actions like "View Study" and "Modify Study". An "Activities" table (4) lists recent actions such as "Modification MOD17-0013-01 Opened" and "Letter Sent". A process flow diagram (5) illustrates the review process from Pre-Submission to Review Complete. A "History" tab (6) is active, displaying a detailed log of activities with columns for Activity, Author, and Activity Date.

Region	Information in this region
1	<p>Breadcrumb Available in all workspaces, click the double arrow [>>] to view the breadcrumb bar. This provides additional navigation links to the parent page for each view. Use links to navigate to the following information:</p> <ul style="list-style-type: none"> IRB for all submissions, Study name to navigate to the Initial/Main study workspace, or Submission name to navigate to the submission workspace.
2	<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.
3	<p>Next Steps Visible in all workspaces, this set of silver 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.
4	<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, and Manage Guest List are only visible on the Initial/Main study workspace.</p>

5	<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, and IRB office and coordinator (if one is assigned), • IRB determination letter (labeled “Letter”), if a determination has been made, • 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).
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>Project Contacts</u> List of study team members listed on the SmartForm, including current Human Subjects Training information on file. • <u>Documents</u> Draft and finalized documents submitted for review, with versioning information for each document • <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. • <u>Snapshots</u> View of the application at each change in state (for example, the appearance of the SmartForm between pre-review and changes submitted)

Responding to a Request for Clarifications or Modifications

At any stage during the review process, the IRB may request clarifications to the study. Similarly, the official IRB determination may be that the study requires changes (or additional modifications) before research can begin. Both situations require the study staff to take similar actions. In either case, the PI, any PI proxy, and the study's primary contact will receive a system notification requesting either clarifications or modifications. The study also appears in My Inbox for each member of the study team.

Important! Any study team member can 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 My Inbox, click the name of the study to open it.
2. Locate the details of the request, as described here:

For Clarification Requested: In the Activity column under Clarification Requested, read the request details. If applicable, click the **read more** link to display the remaining text.

History Funding Project Contacts Documents Reviews

Filter Activity [] Go + Add Filter x Clear All

Activity	Author	Activity Date
Clarification Requested	Calrissian, Lando	1/23/2017 7:31 PM

Dear Jon,
Thank you for your submission to the IRB! In reviewing this project, it appears that the following revisions are necessary. Please make the following changes to the documents, upload the revisions to the appropriate pages of the SmartForm (by clicking "Edit Study" and submit the response to proceed with IRB review:

1. On the Protocol: For question 1, additional information is needed to describe who what when why and how.
2. On the Consent Form: Please provide participants with an appropriate contact on the las... [read more](#)

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

IRB17-0013

Community Engagement and Pet Adoption Rates

Principal investigator: Kara Thrace
Submission type: Initial Study
Primary contact: Lee Adama
IRB coordinator: Laura Roslin

IRB office: HUA

Letter: [Correspondence_for_IRB17-0013.pdf\(0.01\)](#)

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

Edit Study

⋮

→ Submit Response

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:

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

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

History	Funding	Project Contacts	Documents	Follow-on Sub
Draft		Category		
CUHS Template Research Protocol.doc		IRB Protocol		
HRP-221_-_FORM_- Financial Interest Disclosure.doc		Financial Interest Disclosure Form		

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.
7. Navigate to the location of the current document within the SmartForm by clicking Continue on the right
8. Replace the original study document with the revised version by clicking "Update" beside the document on the SmartForm
9. 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:

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

My Inbox	IRB
Submissions	Meetings
Library	Help Center
Reports	

IRB
Create New Study
Report New Information
All Submissions
In-Review
Active
Archived
Filter ID
ID Name

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

Draft	Category	F
CUHS Template Research Protocol.doc	IRB Protocol	(
HRP-221_-_FORM_ Financial Interest Disclosure.doc	Financial Interest Disclosure Form	f

- 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 content 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 (and after), you can complete the **Add Comment** activity to:

- Post a note to the submission history that all individuals with access to the submission may view, and
- If selected, send a notice to:
 - PI/PI Proxy and Primary Contact
 - Study Team Members and/or
 - The assigned IRB Coordinator (If the IRB Coordinator box is selected and there is no assigned IRB Coordinator, a notice is sent to all members of the IRB office.)

Important!

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

Finding Determination Letters and Approved Documents

To find determination letters:

- Log in to irb.harvard.edu
- Navigate to an approved submission (see [Accessing a Submission](#) for more instructions).
- View the initial determination letter from the IRB/IRB Office at the top right of the workspace:

IRB office: HUA

Letter: [Correspondence_for_IRB15-2527.pdf\(0.01\)](#)

OR

1. Log in to irb.harvard.edu
2. Navigate to an approved submission (see [Accessing a Submission](#) for more instructions).
3. Click the Follow-on Submissions tab and click the “Correspondence Letter” link to see any/all Modification or Continuing Review letters. To **view** a letter, simply click on any Correspondence link and to **save** a letter, right click and select ‘Save Link As.’

Contacts	Documents	Follow-on Submissions	Reviews	Snapshots
<input type="text"/> <input type="button" value="Go"/> <input type="button" value="+ Add Filter"/> <input type="button" value="x Clear All"/>				
Date Entered IRB	Date Modified	State	IRB Coordinator	Correspondence Letter
ly IRB15-3624	7/22/2016 11:32 AM	7/25/2016 9:39 AM	Approved Peter Parker	Correspondence_for_MOD15-3624-04.pdf(0.01)
ly IRB15-3624	6/16/2016 2:18 PM	6/17/2016 9:34 AM	Approved Clark Kent	Correspondence_for_MOD15-3624-03.doc(0.01)
ly IRB15-3624	3/14/2016 3:13 PM	3/17/2016 9:48 AM	Approved Clark Kent	Correspondence_for_MOD15-3624-02.pdf(0.01)
ly IRB15-3624	3/10/2016 4:32 PM	3/11/2016 12:55 PM	Approved Clark Kent	Correspondence_for_MOD15-3624-01.pdf(0.01)

To find currently approved study documents:

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

History	Funding	Project Contacts	Documents	Reviews	Snapshots
Draft	Category	Final	Last Finalized	Document History	
Data_Collection_1.docx	Study Instrument/Tools	Data_Collection_1.pdf	1/23/2017 7:57 PM	History	
External site.docx	External Site Information	External site.pdf	1/23/2017 7:57 PM	History	
CUHS Adult Consent Form Template.doc	Consent Form	CUHS Adult Consent Form Template.pdf	1/23/2017 7:57 PM	History	
Device attachment1.docx	Device Attachment	Device attachment1.docx	1/23/2017 7:57 PM	History	

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

Managing Principal Investigator (PI) Proxy

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

The purpose of assigning a system-based proxy is to assist with the management of follow-on submissions (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 on an approved, non-ceded study. Any initial study application that has not yet been approved will need to be granted IRB approval before a proxy can be assigned. Any study for which the review has been ceded to an External IRB, assigning a PI Proxy is not permitted.

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.

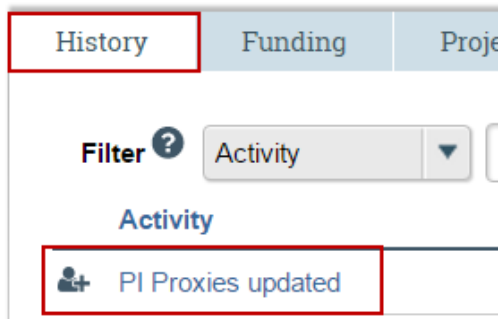
To assign a PI Proxy:

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**.

 [Assign PI Proxy](#)

4. A pop up will appear where you can select the individual(s) you would like to designate as PI Proxy. The list will show only approved study team members. If an individual you wish to assign as PI Proxy is not listed, they first must be added to the study via a Modification.
5. Check any/all of the individuals you wish to make PI Proxy, review the PI assurance statement
6. Click **OK**.

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:

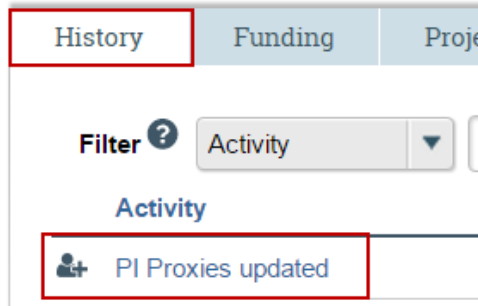
1. Log in to irb.harvard.edu
2. Navigate to an approved study (see [Accessing a Submission](#) for more instructions).
3. On the main study workspace (marked in the center as “Submission type: Initial Study”), under Next Steps, click **Assign PI Proxy**.

 [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

View Study



 Assign Primary Contact

A new window opens.

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

IRB16-1796

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
5. 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.
6. To **remove a guest** click Remove on the right, next to their name
7. 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. However, note that:

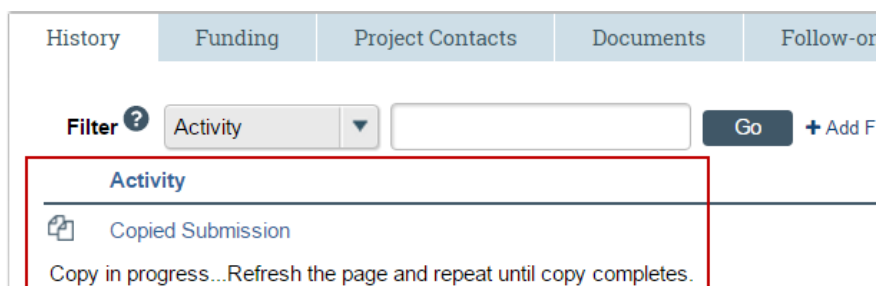
- The status of the copy is completely independent of the status and management of the original study;
- Only a Main/Initial Study (or Reportable New Information) can be copied. Modification/Update and Continuing review cannot be copied;
- Only the PI can copy a study; and
- The new copy must be edited and submitted by the PI for review by the IRB. 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**


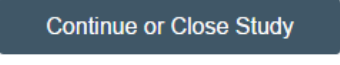
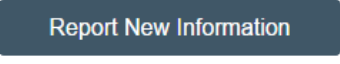
The copy activity will appear under the History tab of the study workspace. While the system is creating the copy, a progress note will appear.



6. Navigate to the new study by either:
 - Refreshing the page to view and click on a link to the new copy, or
 - Clicking My Inbox 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 determination is made are called “follow-on” submissions. These include submission types: Modification/Update, Continuing Review, and Reportable New Information.

To submit this type of information...	Start here...	Notes	
Modifications to an active study	From the Active tab, click the study name (see Accessing a Submission)	<p>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.</p> <p>To request study closure, submit a Continuing Review. Based on the research milestones completed, the study may be closed.</p> <p>To modify an External IRB project, see Updating External IRB Review,</p>	
Continuing review updates for an active study			
Request to close study			
New information or an adverse event report	<p>For new information about a particular study, start from the Active tab and click the study name (see Accessing a Submission)</p> <p>For information affecting multiple studies, start in one of the studies and add studies within the form.</p>	 <p>Report new information as soon as you become aware of it. The form identifies the types of information you must report.</p>	

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** (marked with a red arrow 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:
 - Change the Principal Investigator, the protocol or any Basic Information
 - 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.

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** (marked with a red arrow 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](#)

5. Select “Continue” and complete the Continuing Review / Study Closure Information SmartForm Page.
6. 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.
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.

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.

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 Inbox) 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 (marked with a red arrow 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
 - My Inbox 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
 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** (marked with a red arrow 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 My Inbox of the individual responsible for completing the required actions.

To view the Action Plan and respond to the IRB:

1. From My Inbox, click the name of the RNI submission to open it.
2. View the details of the RNI submission and the Action Plan, as described here:
 - Read the letter:** Click the letter link near the top of the page on the right side. The letter typically contains the Action Plan and a summary of the IRB's decisions.
 - Review the Action Plan:** Click the **Action Plan** tab and read the action plan listed there, plus any history of the action plan that might be helpful.
 - Review the RNI submission details:** If you aren't already familiar with the details of the information report, read it by clicking **View RNI** on the left side.
3. Take action inside or outside the system to complete the action plan. 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.
4. 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.
5. 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).

Finding More Information

Resource	Description	How to Access It
Help for a field or page	More information about a question or form.	Click  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 Medical Area only) at hsph.harvard.edu/ohra ▪ FAS, GSE, HKS, HBS, SEAS, HLS, GSD, HDS, and Radcliffe Institute (Studies in University Area only) at cuhs.harvard.edu

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*Published by Huron Technologies Inc.
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