

IRB Study Reviewer Guide

Electronic Submission Tracking and Reporting (ESTR)

December 8, 2023

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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 ESTRhhelp@harvard.edu

Locating the Reviewer To-Do List

IRB studies that are assigned to you **as an IRB reviewer** for action generally appear in the Dashboard with a link to the study. You may also receive an e-mail with a link to the study. An e-mail indicates that you must take action or informs you of important changes, such as an IRB decision about the study. To access a study that does not appear in the Dashboard, see [Accessing a Submission](#).

Note: A continuing review, modification, or RNI (reportable new information) submission can be handled similarly to a study.

To access studies or other submissions assigned to you:

1. Click the **Dashboard** link in the top right navigation header.



2. Identify the reason the study appears in the Dashboard by looking at the State column.

My Inbox My Reviews					
My Inbox					
Filter by ID Enter text to search for + Add Filter × Clear All					
ID	Name	Date Created	Date Modified	State	Coordinator
IRB20-0527	Perceptions of Sunny Spring Days	3/27/2020 9:31 AM	5/19/2020 1:13 PM	Non-Committee Review	Mary Little

The list called My Inbox contains all studies or other submissions that require you to take action in any capacity. As an IRB committee member or occasional reviewer, navigate to the My Reviews tab or look for the following states in the My Inbox State column to determine review actions:

Non-Committee Review: You have been designated as the reviewer for this not human subjects research, exempt or expedited study. You must submit your final review before the IRB decision can be communicated to the study team. If you request clarifications, the study comes back to you to finish the review after the clarifications are made.

Committee Review: You may be part of the committee that will review this study. If so, review the study details in advance. You can [request clarifications](#) or [record your notes and recommendations](#) in the system before the meeting.

- Open the submission by clicking the link in the Name column.
The submission workspace (webpage) opens.
- Click on **Review study** (or review submission) on the left to view the details of the submission.

Accessing a Submission

You may want to go to a specific submission workspace (webpage) to view or update its contents, submit it for review, review it, or take other actions. Note that your access to a submission is personalized based on your role in the system and the role you play in relation to the particular submission. In addition, the actions you can take on a submission are personalized.

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

To find a list that includes the submission name:

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



OR

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



Tips:

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

Managing Submission Permissions

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

Action	User Role(s)
Receives ESTR system notifications	Principal Investigator, Primary Contact, PI Proxy
Can create submissions on behalf of the PI <i>All types of submission</i>	Principal Investigator, Primary Contact, PI Proxy, Study Team Member
Can submit initial submissions	Principal Investigator Only
Can submit follow-on submissions on behalf of the PI <i>Modifications/updates, continuing review, and closures</i>	Principal Investigator, PI Proxy
Can complete the Copy Submission activity	Principal Investigator
Modification required to add or update this role	Principal Investigator (using modification to "Other Parts of the Study"), PI Proxy, Study Team Member (using modification to "Study Team Members"). Note: The PI Proxy must be a study team member, but Proxy assignment does not require a modification
Has approval to conduct human subjects research activities/is listed on the personnel roster	Principal Investigator, PI Proxy, Study Team Member
Has view-only access to the submission	Guest

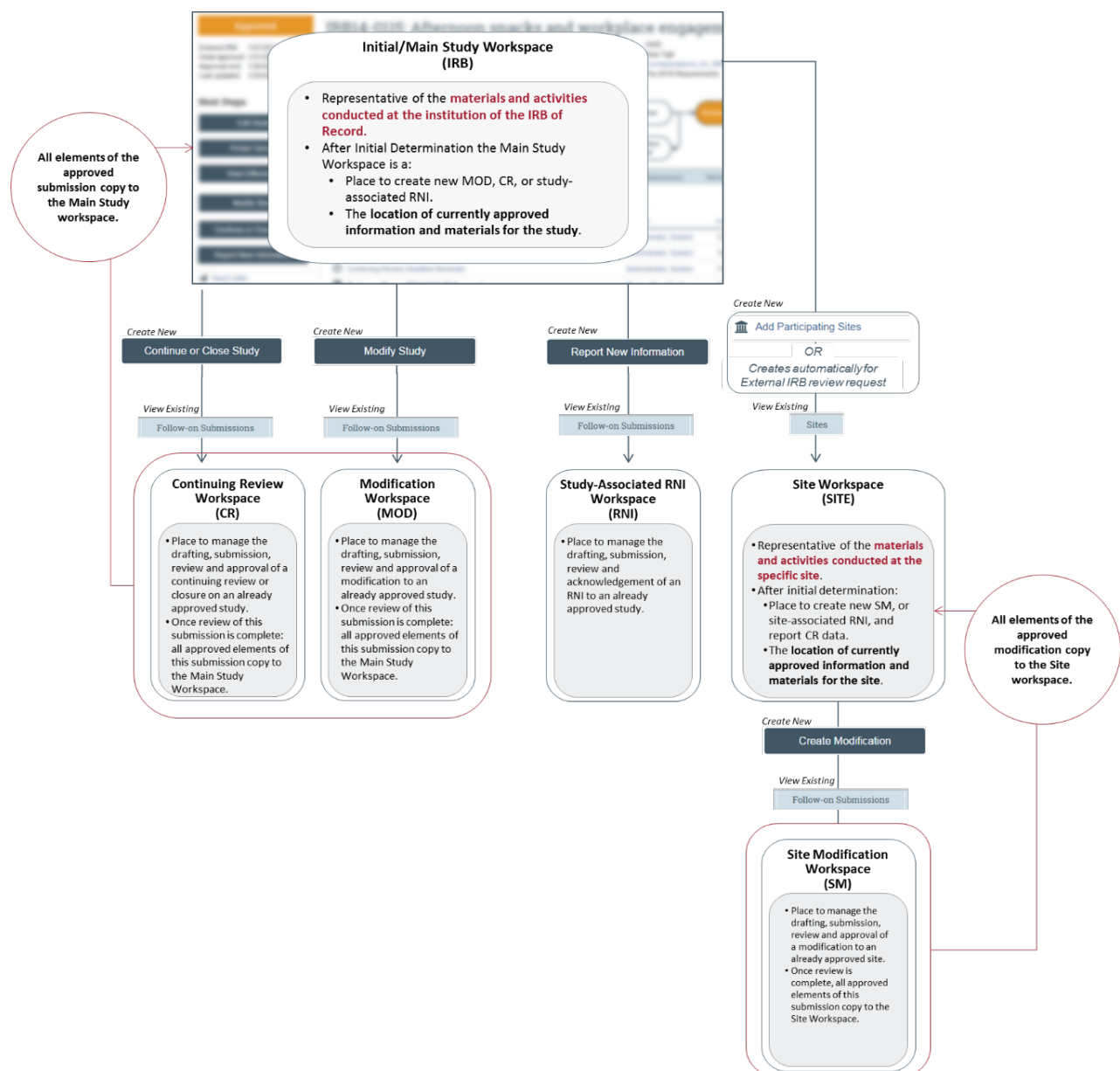
*To manage permissions per project, see sections for how to [change a primary contact](#), [assign proxies](#), [change study team members](#), [copying a study](#), and [add guests](#).

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

Submission Workspace Overview

Initial/Main-study, Continuing Review, Modification/Update and Reportable New Information submission workspaces are formatted similarly. 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.
- The Site workspace (labeled with numbers SITE##-####) is always associated with a main study and will have the most current reviewed information for that site.
- Continuing Review, Modification/Update, and Reportable New Information workspaces (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.

Dashboard | **Portal** | **Agreements** | **OAIR** | **IRB** | ...

Submissions | Meetings | Library | Institutional Profiles | Reports | ...

Pre-Submission

Created IRB: 11/30/2023 6:37 PM
Updated: 11/30/2023 6:39 PM

Next Steps

Edit Study
Printer Version
Submit

Assign Coordinator
Assign Primary Contact
Manage Ancillary Reviews
Manage Guest List
Add Comment
Add Private Comment
Copy Submission
Discard
Manage Related Projects

IRB23-0033: Effects of Corgi barks on cortisol levels in people who work from home

Principal investigator: Aston Martin (PI)
Submission type: Initial Study
Primary contact: Jason Molina (SS)
PI proxies:

IRB office: HMS
IRB coordinator: Nico Robin (IRBD)

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete
Clarification Requested → Clarification Requested → Modifications Required

Important! The submit activity must be completed for review to begin. Only the Principal Investigator or Proxy can see and complete the submit activity on the left.

History	Funding	Contacts	Documents	Reviews	Snapshots	Related Projects
Filter by: Activity	Enter text to search		+ Add Filter X Clear All			
Activity	Author	Activity Date				
Withdrawn	Robin (IRBD), Nico	11/30/2023 6:39 PM				

Region	Information in this region
1	Status Visible in all workspaces, the status region will show: <ul style="list-style-type: none"> The status of the submission once it is created and through the review process, Information about when a submission was sent to the IRB and updated, and Initial/Main study workspaces also display the initial and approval end (expiration) dates for reference, as applicable.
2	Next Steps Visible in all workspaces, this set of blue buttons allows for: <ul style="list-style-type: none"> Editing or viewing the current submission SmartForm, Displaying a printer version, Viewing changes over time, and On Initial/Main study workspaces only: Creating new Continuing Review, Modification, or Reportable New Information submissions for the study.
3	Activities Visible on all workspaces, activity buttons display depending on the type of submission, the status of the submission, and your role on the study. Mostly, activities displayed take action on the submission only. However, Assign PI Proxy, Assign Primary Contact, Manage Related Projects, and Manage Guest List are only visible on the Initial/Main study workspace.
4	Submission Overview This section displays the following submission-specific items for reference: <ul style="list-style-type: none"> Number and name of the submission/workspace being viewed

	<ul style="list-style-type: none"> PI, submission type, primary contact, PI Proxy/ies (if assigned), and IRB office and coordinator (if one is assigned) IRB determination letter (labeled “Letter”), if a determination has been made Regulatory Oversight to indicate if a submission is/was subject to review under pre-2018 Common Rule or 2018 Common Rule Image of the state of review for the submission. Note that when viewing an Initial/Main study workspace the image may indicate “review complete” while an associated submission (such as a Continuing Review or Modification” is under review).
5	Notification Area When the record has not yet been submitted for review, a reminder to complete the submit activity displays in this space.
6	<p>Submission Tabs On a submission, the Initial/Main study workspace shows all current approved details (including documents and study team members) while all follow on submission workspaces display information that was proposed at the time of review and determination. Click on tabs to view:</p> <ul style="list-style-type: none"> <u>History</u> Information about each action taken on a submission and in-brief view of comments. <u>Funding</u> List of all funding listed on the SmartForm, with a link to GMAS, if applicable. <u>Contacts</u> List of study team members listed on the SmartForm. The tab also includes their current Human Subjects Training information on file and their training expiry date. If no training is listed, they do not have current active training. Each team member is listed with a Date Modified, intended to show when any additions or revisions occur during review or modification. <u>Documents</u> Draft and finalized documents submitted for review, with versioning information for each document <u>Sites</u> Links to associated Site workspaces for a study (only visible on the <i>main study workspace</i> of collaborative projects where Harvard is the IRB of record for at least one site) <u>Follow-on Submissions</u> Links to Continuing Review, Modification/update, or Reportable New Information workspaces for a study (only visible on the <i>main study workspace</i>) with quick access to all determination letters <u>Reviews</u> View additional details about the review, including ancillary review details, data security level determinations, and completed checklists. <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) <u>Related Projects</u> Information about Agreements, Data Safety, and other IRB submissions which have been associated with the study via the Manage Related Projects activity (only visible on the main study workspace) including the current state of the related submission and a link to the related project workspace.

Locating Meeting Agenda Items

As a committee member, you can get a meeting agenda listing the studies and other submissions to be reviewed in an upcoming meeting. You can get the agenda in two forms:

- As a web page with links to the submissions

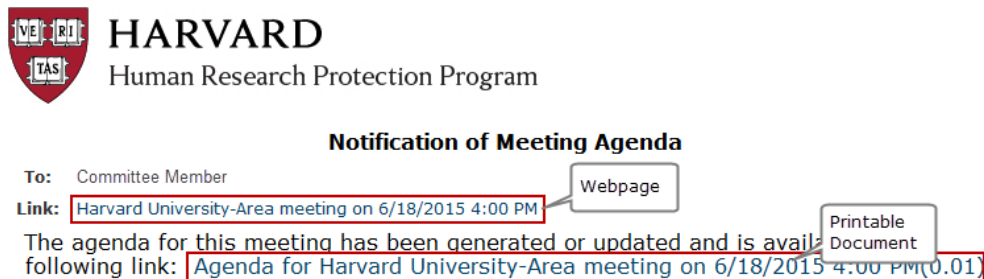
- As a printable document

The procedures below describe how to access both forms of the agenda in two alternative ways:

- From an agenda notification e-mail you receive
- By navigating to the agenda within the IRB system

To access the agenda from an e-mail you receive:

1. Open the e-mail informing you about an IRB meeting agenda.
The notification content should resemble this:



2. Click the appropriate link:
 - To access the meeting workspace web page containing links to the studies, click the link next to Link (shown above). The meeting workspace and its important links are shown below. **Note:** The most up-to-date agenda is in the web page format.
 - To open or save the printable document, click the link next to Description (shown above).
3. If prompted, log in to irb.harvard.edu.

For more details about opening the document or using the web page, see the procedure below about navigating to the agenda.

To access the agenda by navigating to it:

1. Click the **Meetings** link which appears in the secondary menu at the top of every other **Submissions** page.



2. From the list of meetings shown in the center of the page, click the name of the meeting to view.
The meeting workspace displays the list of agenda items in the center of the page, resembling this:

Harvard Faculty of Medicine

Meeting date & time: 1/24/2017 4:00 PM
Location: Gordon Hall
Agenda: [Agenda for Harvard Faculty of Medicine meeting on 1_24_2017 12_00 AM\(0.01\)](#)
Items on agenda: 2
Minutes: Not yet created. [Printable Document](#)
Report: [Expedited Submissions Approved in the Last 45 Days](#)

Agenda Items		Attendees	Links to submissions on agenda		
ID	Name	State	Coordinator	Record Decision	
IRB17-0002	Kittens and Rainbows	Committee Review	Kara Thrace		
RNI17-0003	Participant Complaint	Committee Review	Ira Stein (irbd)	Submit RNI Committee Rev	

2 items < page 1 of 1 >

3. Click the appropriate link:

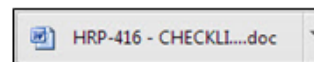
- To access a study directly from the agenda items list, click the link to the study (shown above).
- To open or save the printable document, click the link in the page header next to Agenda (shown above). The agenda is in Microsoft Word format.

About downloading Word documents: Microsoft® Word documents open differently in different web browsers. If the document does not open promptly:

Click the Word icon if it is flashing at the bottom of your screen, and then click one of your open Word documents.



Check the bottom of the browser window to see if the document icon and name is shown there. If so, click the name to open it.



Locating Checklists for Reviewers

Several worksheets and checklists are provided in the system to guide your review process and document your decisions. They are intended for pre-reviewers, designated reviewers, and committee reviewers.

- Worksheets** are for the reviewer's benefit only.
- Checklists** must be completed and attached when submitting your review comments to document your decisions.

When a submission is assigned to Non-Committee or Committee review, IRB staff may suggest Worksheets or Checklists pertinent to the review by including them with the Pre-Review activity.

To locate Worksheets or Checklists suggested for review of the submission:

1. Navigate to the appropriate submission. See sections: [Locating the Reviewer To-Do List](#) or [Locating Meeting Agenda Items](#).
2. Click the **Reviews** tab (near the middle of the screen).
3. View any supporting documents included with the Pre-Review information.

History **Funding** **Project Contacts** **Documents** **IRB Assignment Details** **Reviews** ***

Most Recent Pre-Review

Date submitted: 1/29/2017 6:46 PM -05:00
 Regulatory oversight: HHS (Department of Health and Human Services)
 Special determinations: Waiver of consent documentation
 Risk level: No greater than minimal risk
 Type of research: Social / behavioral / educational
 Missing materials:
 Notes:

Supporting documents: HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent.doc
 HRP-442 - CHECKLIST - Information Security Level Determination.doc

Ancillary Reviews

Review Type	Organization	Person	Reqd	Accepted	Comments
Faculty Sponsor		Mary Jones	yes	yes	I reviewed the project document and have no suggested changes or additions.

Committee Member Review Comments

Person	Role	Notes	Checklists	Supporting docs	Date
Ira Stein		Note for reviewers: The investigator provided some responses to questions, but did not have time to respond to all. The attached list remains pending.		Memo.txt	1/29/

4. Click a link to open or save the applicable document, which is in Microsoft Word format. See below for information about downloading Word documents.

To locate the full list of Worksheets and Checklists:

1. Click the **Library** link in the top sub-menu.

HARVARD UNIVERSITY | **ESR - IRB**

Dashboard **Agreements** **IRB**

Submissions Meetings **Library** Institutional Profiles Reports ***

Library

General Worksheets Checklists Templates and Forms Ancillary Review and Other

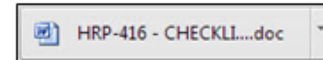
2. Click the **Worksheets** or **Checklists** tab, depending on the document you want to view. See [Key Checklists and Worksheets](#) for more information.
3. Click a link to open or save the applicable document, which is in Microsoft Word format.

About downloading Word documents: Microsoft® Word documents open differently in different web browsers. If the document does not open promptly:

Click the Word icon if it is flashing at the bottom of your screen, and then click one of your open Word documents.



Check the bottom of the browser window to see if the document icon and name is shown there. If so, click the name to open it.



Key Checklists and Worksheets

Many checklists and worksheets for reviewers are available in the IRB Library to provide reminders, guide decisions, and help document decision criteria.

Important! Checklist information is required by regulations to document the findings that justify your determinations. Fill out the pertinent checklists and attach them when you submit the review form. For committee reviews, attach your individual checklists as described in [Preparing Comments for a Meeting](#).

Worksheets also provide important guidance, but regulations do not require them to be retained.

The following table summarizes some of the key pertinent checklists and worksheets, organized by the types of review decisions you must make. Consult with your IRB policies and procedures for a complete list of Checklists, Worksheets and requirements.

Topic	Checklists (use and attach)	Worksheets (for reviewer's use)
Approval criteria		<ul style="list-style-type: none"> Criteria for Approval
Level of review		<ul style="list-style-type: none"> Engagement Exemption Expedited
Consent / recruitment	<ul style="list-style-type: none"> Waiver or Alteration of Consent Waiver of Written Documentation of Consent HIPAA Waiver of Authorization 	
Special populations	<ul style="list-style-type: none"> Pregnant Women Non-Viable Neonates Neonates of Uncertain Viability Use of Fresh Human Fetal Tissue in Research Prisoners Children Cognitively Impaired Adults 	
Devices / drugs	<ul style="list-style-type: none"> Non-Significant Risk Device (FDA) 	

Topic	Checklists (use and attach)	Worksheets (for reviewer's use)
Federal agencies / laws	<ul style="list-style-type: none"> HIPAA Waiver of Authorization 	<ul style="list-style-type: none"> NIH GDS Institutional Certification Additional Federal Agency Criteria

Reviewing a Submission

To view the details of a submission:

1. Log in to irb.harvard.edu
2. Navigate to the submission (see [Accessing a Submission](#) for more instructions).
3. Click on **View Study** or submission on the left to view the details of the submission. For a continuing review or modification/update, click **View Submission** instead.
4. Use the Continue and Back buttons to view all of the pages and click on document links to view detailed attachments. Note that clicking Continue from the Supporting Documents page (the last page of the form) exits the study.

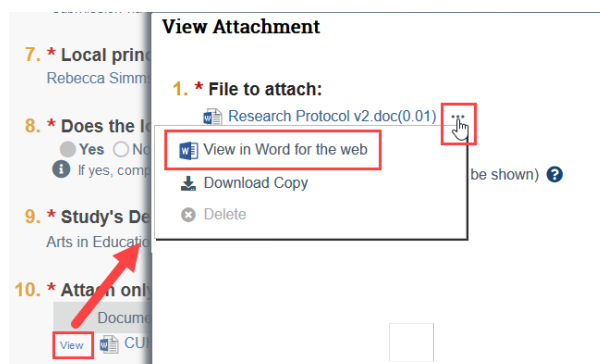
To view the details of a submission:

5. Log in to irb.harvard.edu
6. Navigate to the submission (see [Accessing a Submission](#) for more instructions).
7. Click on **View Study** or submission on the left to view the details of the submission. For a continuing review or modification, click **View Submission** instead.
8. Use the Continue button to view all the pages and click on document links to view detailed attachments. The left-hand navigation menu allows you to jump between different SmartForm pages. Note that clicking Continue from the Supporting Documents page (the last page of the form) exits the SmartForm.

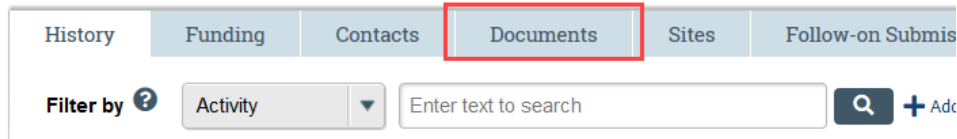
To view the documents included as part of the submission, there are two options:

- While viewing the details of the study (as instructed above), click the name of each document when you encounter it on the various forms to download. Documents are listed in tables throughout the forms.

Some documents in the SmartForm may also be viewed in the browser using Office 365 Online. To view a document in the browser, first click the "View" link to the left of the document name. Then, select the ellipsis next to the document name in the slide-in window and select "View in Word for the web."



- When you have opened the study workspace (as in step 2 above), you can view a list of all the attached documents in one place by clicking the Documents tab.



Tip: If the study team updated the documents, they may contain tracked changes. You can use the review features in Word to toggle between showing the original and final versions of the document. When the IRB approves the documents, all tracked changes will be accepted and comments removed in the final versions.

Requesting Clarifications to a Submission

If, during your review, you would like to request that the PI make changes to the study or provide additional information, you can do so via the Request Clarifications activity.

- In Non-Committee Review, requesting clarifications sends the submission back to the study team so they can edit it.
- In Committee Review, requesting clarifications allows the study team to provide a written response but not edit the SmartForm. This is explained in detail below.

To request clarifications on a study in Non-Committee Review:

- From the Dashboard, click the name of the submission to open it.
- Click **Request Clarification...** on the left.

Next Steps



- In the Request Clarification form, provide detailed questions or requests for changes.
Note: You can also attach documents that further explain and/or show suggestions for resolving the problems (e.g. a track changes Word document).
- Click **OK** to send the request to the study team and to open the SmartForm for edits. You will receive an e-mail notification when the study team submits their response to the clarification request.

Important! The following items on the SmartForm cannot be changed after a study is submitted (even when clarifications are requested).

- The department chosen on the first page of the SmartForm. If the incorrect department is indicated here, either (a) withdraw the submission, change the department and resubmit it; OR (b) copy the submission and discard the one with the incorrect department. Proceed with review of the copied, corrected and resubmitted study.

- The selected attachment category for items included on the last page of the SmartForm. Incorrectly categorized items must be deleted and re-added with the correct category selected.
- For Modifications: the type of modification (study team members only or other parts of the study) cannot be changed once selected. If the incorrect option is selected, the submission must be discarded and recreated with the correct type chosen.

To request clarifications on a study in Committee Review:

1. From the Dashboard, click the name of the study to open it.
2. Click **Request Clarification...** on the left.

Next Steps



3. In the Request Clarification form, provide detailed questions or requests for changes.
Note: You can also attach documents that further explain and/or show suggestions for resolving the problems (e.g. a track changes Word document).
4. Click **OK** to send the request to the study team. You will not receive an e-mail notification when the study team submits their response to the clarification request.

Important! Requests for clarifications are handled differently during committee review than during other types of review in that study team members are not solely in control of the submission:

- Study team members cannot edit the study when the clarifications requested are from committee review, but they can submit comments back to the committee.
- Committee members can continue to request clarifications after a request has been made.
- The committee cannot record a decision for the submission when it is in the Clarification Requested state. So, before the meeting, either:
 - The IRB coordinator can remove the submission from the agenda before the meeting and reassign it to a later meeting
 - OR
 - At the time of the meeting, the committee chair or administrator can use the Convene Meeting activity to return all submissions still in the Clarification Requested state to the Committee Review state so the reviews can be recorded.

Viewing Changes to a Submission

When a submission changes based on reviewer requests and a response is submitted, you can click **Review Study** or **Review Submission** in the workspace. This allows you to re-review the revised submission, or to look only at what has changed, you can:

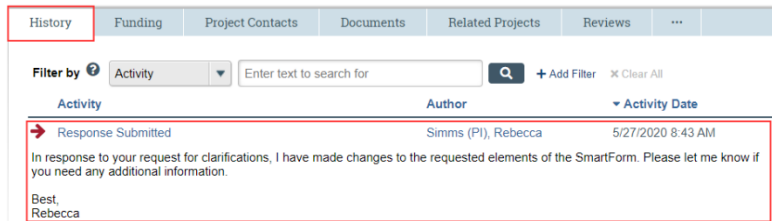
1. View the response submitted for a particular request

2. View the differences between two versions of a submission

SmartForm Compare

To view the response submitted for a clarification request:

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



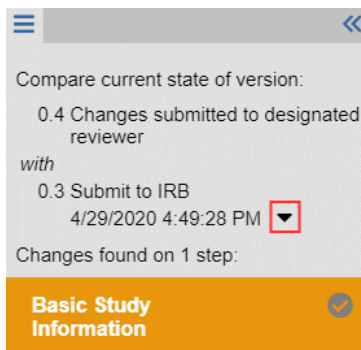
3. Click the **Changes Submitted** activity link to see any notes or documents added to the submission.

To view the differences between two versions of a submission:

1. From the Dashboard, click the name of the submission to open it.
2. Depending on the state of the submission, Click **View, Review, or Edit Study** (or Submission) on the left.
3. In the SmartForm, click the **Compare** tab on the left navigation.
Note: If you are in Review Mode (clicked “Review Study” to enter the SmartForm), SmartForm Compare will automatically be activated. You will not see the Validate or Compare buttons shown in the following screenshot, and may proceed to step 4.)




4. Click the dropdown arrow to select a version to compare the current SmartForm to.



5. Look for the pencil icon next to the page(s) where changes have been made.
Click the pencil to jump to the page with changes. The changes since the version you selected will appear with the old values highlighted in a gray box.

Study Scope

1. ★ Does the study involve the use of a **DRUG** in one or more persons other than use of an approved drug in the course of medical practice?
- ☐ Yes ☒ No


Rebecca Simms (PI) • modified 6 days ago • version 0.4 (Changes submitted to designated reviewer)

Old Value:
yes

Tip: If the team updated the documents, they may contain tracked changes. You can use the review features in Word to toggle between showing the original and final versions of the document.

Document Compare

If a revised document is uploaded as a revision, each version of the document is stored on the document history. For Microsoft Office documents which support tracked-changes (such as Word), Two versions may be selected to generate a tracked version for review.

To access document history and create a tracked-changes version:

- From the Dashboard, click the name of the study to open it.
- Click **Printer Version** on the left or the Documents tab on the center of the page
- Navigate to the document
- Click the History link

History	Funding	Project Contacts	Documents	Sites	Follow-on Submissions	...	
Study Related Documents							
Draft	Category	Final	Last Finalized	Document History			
CUHS_Protocol_2018-6-8.docx	IRB Protocol	CUHS_Protocol_2018-6-8.docx	6/12/2018 8:51 AM	History			

- In the pop up, choose two versions to compare
- Click the Compare button

Compare	Date	Version	Person	Action	Notes	Uploaded File
<input checked="" type="checkbox"/>	6/8/2018 3:29 PM	0.14	Yanhua Bird	File Uploaded & Edited		CUHS_Protocol_2018-6-8.docx
<input checked="" type="checkbox"/>	2/13/2018 10:45 AM	0.13	Yanhua Bird	File Uploaded & Edited		CUHS_Protocol_2018-2-13.docx
<input type="checkbox"/>	2/12/2018 4:59 PM	0.12	Yanhua Bird	File Uploaded & Edited		CUHS_Protocol_2018-2-12.docx
Compare						

- A pop up will appear to save the tracked version to your compute
- Save the document and view the changes

Snapshots

A snapshot is a record of a submission at a particular point in history. The snapshot includes all SmartForm fields, along with attachments. Snapshots can be used to see what was previously reviewed or approved.

Snapshots (noted with camera icon here) are **taken at specific points during the review** of each submission:



Snapshots are taken at minor (ex. 0.1, 0.2, 0.3...) and major increments (ex. 1.0, 2.0, 3.0...). **When viewing snapshots:**

History	Funding	Contacts	Documents	Sites	Follow-on Submissions	Reviews	Snapshots	Related Projects
History of submission contents								
Version		State During Snapshot					Snapshot Taken	
	Snapshot: 1.0(0.01)	... Approved					8/27/2018 3:48 PM	
	Snapshot: 0.3(0.01)	... Clarification Requested (Pre-Review)					8/6/2018 4:34 PM	
	Snapshot: 0.2(0.01)	... Pre-Submission					8/6/2018 3:23 PM	

Snapshot created when in this state and just before the submission moved to the next state because of an activity.



Other Notes about Snapshots

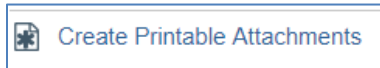
- Snapshots are also added on the main study workspace each time the study is approved via a Modification and will appear as a major increment in the Approved state.
- Snapshots are not taken when a continuing review is approved because nothing changes about the SmartForm when a continuing review is approved.
- When ESTR was upgraded in October 2015, pre- and post- migration snapshots for existing submissions were captured to verify data elements affected by data migration. These snapshots were recorded for tracking purposes and do not represent a change in the study.
- Historically, when a printable packet was created, an additional link would appear here. It is labeled "Smartform Pages as of..." This snapshot is recorded for tracking purposes and does not represent a change in the study. Note that the current "Create Printable Attachments" activity does not record an additional snapshot.

Creating a Printable Attachments

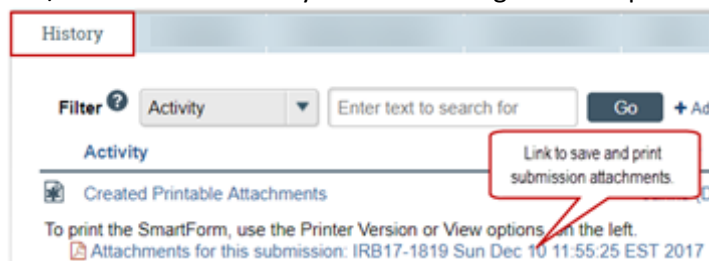
The Create Printable Attachment activity (available on all workspaces except Site or Site Modification) assists IRB staff with organizing materials for review. Completing this activity will generate one file pdf file of all submission attachments, for further formatting (if needed). **This activity can only be conducted by IRB staff and Committee Members.**

To create a printable attachments:

1. Click **Create Printable Attachments** on the left



2. A pop up window will appear during processing and will close automatically
3. View the "History" tab on the workspace to find the created file. Note that projects which include IND/IDE attachments may not be able to generate a printable attachment file.



4. Click on the file to view and/or save to a separate space for further formatting.
Note: The file available on the history represents the submission at a single point in time and are not updated when the SmartForm is updated.
5. To View or Print the submission SmartForm, click the Printer Version or View options on the left side of the workspace, as available.

Attachments File Contents

When clicking on the file entitled "Attachments for..." attachments appear in the following order (as applicable):

- Reports of New Information attachments: Only RNI attachments in the order they are attached
- Initial Submission, Continuing Review, and Modification/Update attachments:
 1. Protocol Attachments
 2. External Site Attachments
 3. Drug Attachments
 - 3.1. Attachments for each Drug
 - 3.2. IND Attachments
 - 3.3. Other Drug Attachments
 4. Device Attachments
 - 4.1. Attachments for each Device
 - 4.2. Other Device Attachments
 5. Consent Forms, Assent Forms, HIPAA Authorization Materials
 6. Supporting Documents, by category:
 - 6.1. Ancillary Approvals/Permissions
 - 6.2. Data use agreements or other Agreements
 - 6.3. Debriefing Materials
 - 6.4. External Site Information
 - 6.5. Federal Department Requirements Checklists
 - 6.6. Financial Interest Disclosure Form
 - 6.7. Foreign Language Documents
 - 6.8. Funding Source Attachments
 - 6.9. Individual Investigator Agreement (IIA)

- | | |
|---|--|
| 6.10. IRB Authorization Agreement (IAA) Request | 6.14. Radiation Safety Form |
| 6.11. Other | 6.15. Recruitment Materials/Advertisements |
| 6.12. PI's Current CV (ICH-GCP E6 Only) | 6.16. Sponsor Protocol including DHHS-approved protocol |
| 6.13. Protocol Attachment (<i>if attached to the Supporting Documents page of the SmartForm, rather than the Study Scope page of the SmartForm</i>) | 6.17. Study Instruments/Tools |
| | 7. Study Personnel Forms (including any attached CITI documents) |

Preparing Comments for a Meeting

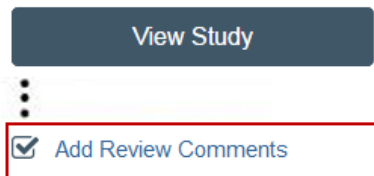
While reviewing a study, you can record your review comments within the IRB system. You can also upload required checklists and any review-related documents. This lets committee members view each other's comments before and during the meeting.

To record your review comments:

Important! By following these steps, all your comments and the files you attach will be purged from the system when the approval letter is sent. Your comments are never visible to the study team members.

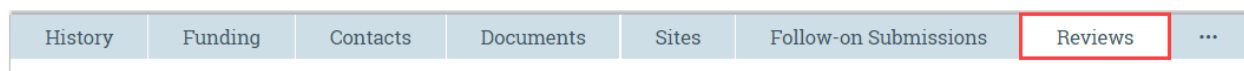
1. Open the study. For details, see [Accessing a Submission](#) or [Locating Meeting Agenda Items](#).
2. Click **Add Review Comments** on the left.

Next Steps



3. Type in notes and upload any relevant reviewer checklists and other related documents.
4. Click **OK**.

Note: Before and during the committee meeting, you can go to the study's Reviews tab as shown below to view your comments and comments from other reviewers.



Submitting a Review Decision

Important! The information provided here is meant for IRB staff member reviewers only.

Note for committee members: An IRB staff member must submit the decision on behalf of the committee. If you are a reviewer of the study, record your comments and attach relevant files (such as reviewer checklists) as described in [Preparing Comments for a Meeting](#).

After reviewing a study or other submission, you must record the decision in the system. Recording the decision completes the review and moves the study forward in the IRB process.

Tip: You can include comments when you record your decision. It is best to phrase your comments as questions or requests for information. If you need the study team to answer a question before you can complete the review, request clarifications as described in [Requesting Clarifications to a Submission](#).

There are several types of review, with key procedures for are identified below:

- [Ancillary review](#)
- [Pre-review](#)
- [Designated \(Non-Committee\) review](#)
- [Committee review](#)

Notes:

- The procedures below assume that the study team has completed any requested clarifications.
- Specific steps to complete activities in other states of review (including External IRB and study closure) are noted in the IRB Staff Administration Guide.

To open the study:

1. From the Dashboard, click the name of the study to open it.
2. Choose the appropriate procedure below.

To add or complete an ancillary review (IRB staff only):

1. Click the Manage Ancillary Review activity in the appropriate submission where the ancillary review must be recorded. A pop up will appear.



2. Click "Add" at the left side of the table. Another pop up will appear.
If updating an ancillary review status on behalf of the reviewer, click "Update" beside the review type and fill in the form.
3. On the Add pop up:
 - Question 1** Enter information in either Organization (aka Department) or Person. Only organizations with assigned reviewers will be available for selection. Selecting an organization may send a notice to multiple possible reviewers. Only one needs to complete the review. Any person can be selected.
 - Question 2** Select the review type (This question is required).
 - Question 3** Indicate if response is required (per guidance/best practice).
 - Question 4** Add a public comment for the reviewer (visible on the Reviews tab).
Click **OK**, the additional pop up will close.
4. See the newly added or revised item display on the table in the pop up.
5. Click **OK**.

Any added review comments are shown in the study and are visible to the study team.

To complete a pre-review (IRB staff only):

1. Click **Submit Pre-Review** on the left.

 [Submit Pre-Review](#)

2. If the PI is restricted, red indicator text will appear at the top of this activity form. To change PI status, view Updating a Person Profile in the IRB Staff Administration Guide.
3. Answer the relevant questions, paying special attention to each required question marked with a red asterisk (*). Note:
 - Practice at this time is to never mark “Broad Consent”.
 - It is important to indicate additional study features when applicable. Specifically, if the SmartForm indicates that a study is multisite/collaborative, either multi-site or collaborative must be marked on this activity. Consult your IRB Definitions for information on the appropriate selection.
4. (Optional) Attach documents related to the review, such as checklists.
5. If you are ready to move the study to the next stage of IRB review, answer Yes when asked if you are ready to submit this pre-review.

Otherwise, answer No, which enables you to return and perform Submit Pre-Review again to update the information.
6. Click **OK**.

Important! If you moved the review to the next state (pre-review complete):

- Now you must assign the study to a committee meeting **or** a designated reviewer.
- If any sites were added via the Manage Participating Sites activity and are pending, associated site workspaces will now be created, and the site submissions will be available for revision and review.

Tip: If the information entered for pre-review is inaccurate, contact the study's IRB coordinator to request a change. The coordinator can change the pre-review information (by completing the **Edit Pre-Review** activity) until the decision from designated or committee review is submitted. Make sure it is corrected before you submit your review decision.

To complete a designated (or non-committee) review (IRB staff only):

1. Click **Submit Designated Review** on the left.

 [Submit Designated Review](#)

2. Answer the relevant questions, paying special attention to each required question marked with a red asterisk (*). Note when completing form elements on this activity:
 - Determination:
 - Not Research: For review of studies not meeting the definition of research under 46.102(d), choose “Not Human Research”. When generating the determination letter, be careful to edit the text to match the specific decision.

- .118 Determination: For studies meeting criteria for documented review under 46.118, mark the “Not Human Research” determination. When generating the determination letter, the appropriate templates will appear for selection.
- Minor Modification: For review of minor modifications meeting Expedited criteria 46.110(b)(2), use the category “(mm) minor modification”.
- Modifications Required: When determining that Modifications are Required to Secure Approval on a Continuing Review, later in this form, indicate the anticipated approval date. To retain study approval while response is pending, visit the main study workspace AFTER sending the letter to complete the “Update Expiration Date” activity and confirm the newly updated expiration date.

Important! Use of Approval as an Exempt or Expedited category “other” for reasons other than study closure requires approval by leadership in the IRB office.

▪ **Dates:**

- Complete the approval, effective and expiration dates per IRB office practice for approval intervals and accounting for study anniversary dates, where appropriate. If these items auto-populate, be sure to verify that they are correct.
- For studies that do not require continuing review, such as those determined to meet the definition of Not Research, Not Human Subjects Research, or studies which meet Exemption criteria; remove the expiration date if it is pre-populated.

3. (Optional) Add comments and attach documents related to the review.
4. If true, check the box to indicate that you do not have a conflicting interest. (For more details about conflicting interests, click the blue question mark icon.)
5. If you have entered all the relevant information and are ready to submit the final IRB decision, answer Yes when asked if you are ready to submit this review. Otherwise, answer No, which enables you to return and perform Submit Designated Review again to update the information.
6. Click **OK**.

If you submitted the final decision, the IRB can now officially communicate the decision to the study team. If needed, this activity form can be edited after it is completed. However, re-completing the form may update the noted effective date.

To complete a committee review (IRB staff only):

Important! An IRB staff member must submit the decision on behalf of the committee. If you are a reviewer of the study, record your comments and attach relevant files (such as reviewer checklists) as described in [Preparing Comments for a Meeting](#).

1. Click **Submit Committee Review** on the left.



 [Submit Committee Review](#)

2. Answer the relevant questions, paying special attention to each required question marked with a red asterisk (*). See the section of this guide detailing non-committee (designated) review for additional notes about review elements on this activity.
3. (Optional) Add notes and attach documents related to the committee's review.

4. If you have entered all the relevant information and are ready to submit the final IRB decision, answer Yes when asked if you are ready to submit this review. Otherwise, answer No, which enables you to return and perform Submit Committee Review again to update the information.
5. Click **OK**.

If you submitted the final decision, the IRB can now officially communicate the decision to the study team. If needed, this activity form can be edited after it is completed. However, re-completing the form may update the noted effective date.

Finding More Information

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

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