IRB Ancillary Reviewer Guide

Electronic Submission Tracking and Reporting (ESTR)

November 5, 2021

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Ancillary Review Overview

Ancillary reviews allow individuals, departments, offices, and other additional reviewers to give feedback, approval, and/or provide documentation on the submission in parallel with the IRB review. During IRB review, staff of the IRB office will manually select the reviewer or reviewing organization/department each time a review is needed or required. IRB staff can add ancillary reviewers to a study, modification, or continuing review.

When assigned by IRB staff, Ancillary reviewers will receive a notification of requested review.

Ancillary review determinations can be recorded in ESTR at any time from the Pre-Review to Post-Review states (and before the IRB determination is issued), as illustrated here.

The system does not prevent a submission from being reviewed or approved by the IRB with ancillary reviews outstanding. Decisions about how, when, and whether to interrupt the IRB review process to wait for ancillary reviews are typically based on Harvard policies, but may be made on a case by case basis by the IRB. If an Ancillary review determination is delayed, please contact the IRB Coordinator assigned to the study (named at the center of the submission workspace).

All investigators must comply with any policy that requires an ancillary review in order to proceed with IRB review and approval (e.g. per the Harvard Research Data Security Policy, any project classified with an information security level 4 or 5 requires a signed worksheet/documentation of approval from HUIT before IRB approval may be issued).

Types of Ancillary Review

The following are current types of Ancillary review which may be recorded in ESTR by the IRB office or the assigned non-IRB reviewer (as applicable to the submission under review). When assigned by IRB staff, Ancillary reviewers will receive a notification of requested review.

- Committee on Microbiological Safety (COMS)
- Dean
- Department Chair Review
- Embryonic Stem Cell Research Oversight Committee (ESCRO)
- Faculty Sponsor Review
- Financial Interest
- GDPR-Based Evaluation
- Genomic Data Sharing Institutional Certification
- Institutional Official
- IT Security Review
- Office of Technology Development (OTD)
- Other Scientific
- Provostial Review

- QA/QI
- Radiation Safety Committee (RSC)
- The Academy (HMS-based)

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

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.

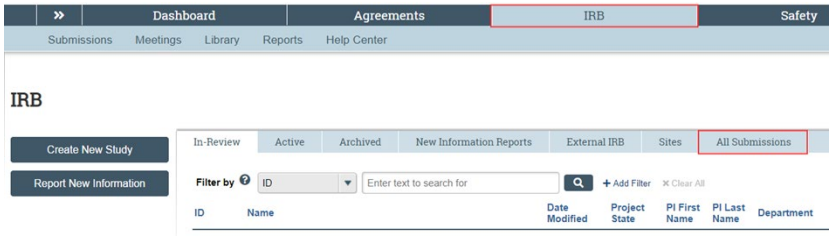
To view a submission workspace (webpage)**,** click the submission name when you find it in a list of studies.

To find a list that includes the submission name:

Dashboard (only items that require attention): Click the **Dashboard** link in the top navigation header. The Dashboard is composed of two tabs: My Inbox and My Reviews. **My Inbox** contains all studies or other submissions that require you (or your team members) to take action. **My Reviews** contains only studies for which you are an Ancillary or Designated IRB Reviewer.

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:

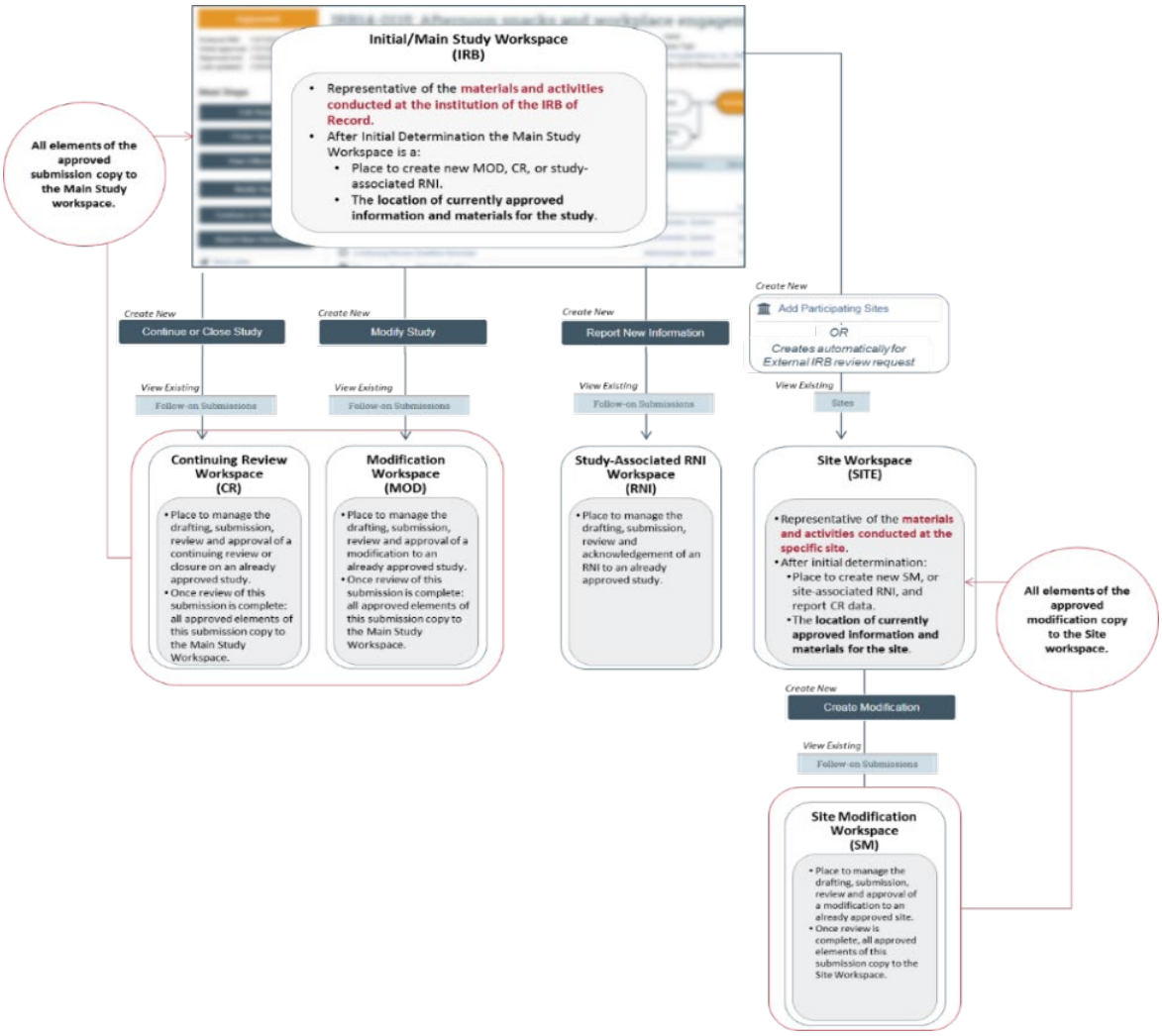
Action	User Role(s)
Receives ESTR system notifications	Principal Investigator, Primary Contact, PI Proxy
Can **create** submissions on behalf of the PI *All types of submission*	Principal Investigator, Primary Contact, PI Proxy, Study Team Member
Can **submit initial submissions**	Principal Investigator Only
Can **submit follow-on submissions** on behalf of the PI *Modifications/updates, continuing review, and closures*	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, contact estrhelp@harvard.edu for expanded guest access.

Submission Workspace Overview

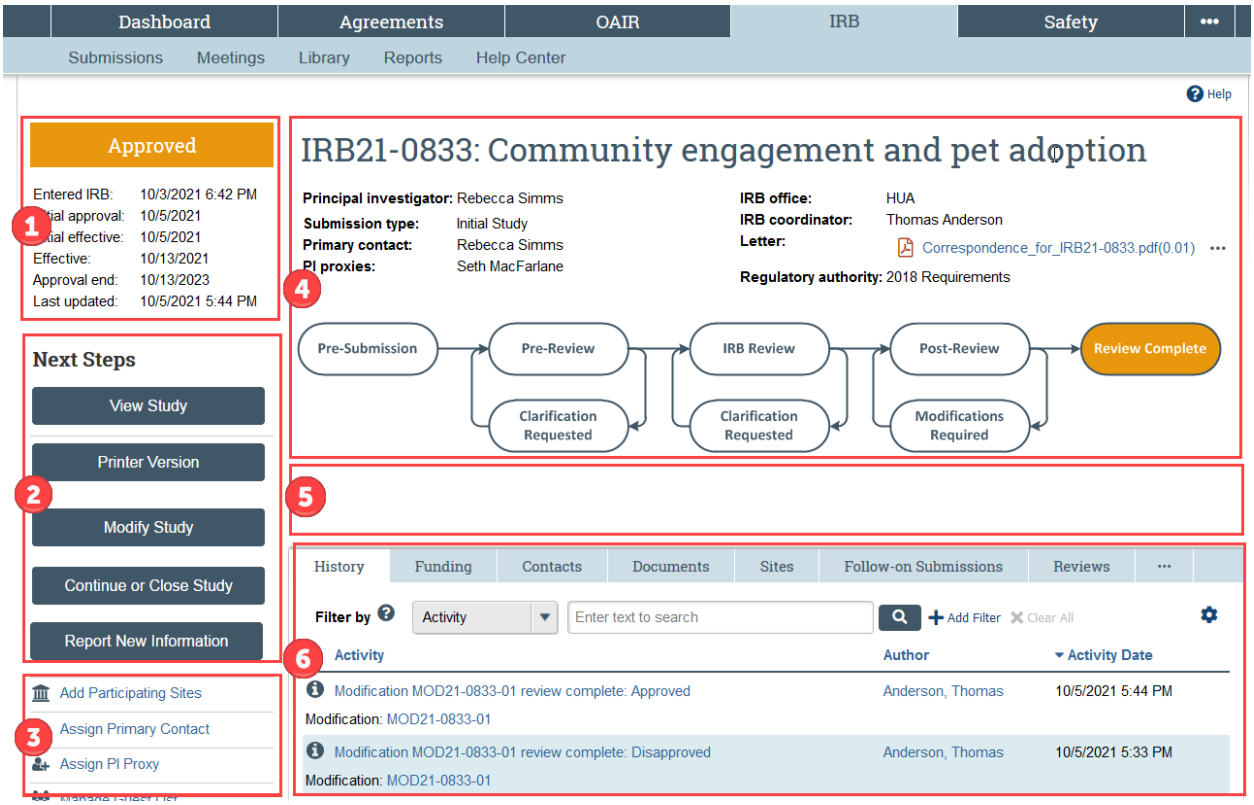
Initial/Main-study, Continuing Review, Modification/Update and Reportable New Information submission workspaces are formatted similarly. However, the following general concepts apply to navigation:

- 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.



Region	Information in this region
1	**Status** Visible in all workspaces, the status region will show: • 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: • 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: • Number and name of the submission/workspace being viewed • PI, submission type, primary contact, PI Proxy/ies (if assigned), and IRB office and coordinator (if one is assigned)

	• IRB determination letter (labeled "Letter"), if a determination has been made • Regulatory Oversight to indicate if a submission is/was subject to review under pre-2018 Common Rule or 2018 Common Rule • Image of the state of review for the submission. Note that when viewing an Initial/Main study workspace the image may indicate "review complete" while an associated submission (such as a Continuing Review or Modification" is under review).
5	**Notification Area** When the record has not yet been submitted for review, a reminder to complete the submit activity displays in this space. *Content blank in example image above.*
6	**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: • History Information about each action taken on a submission and in-brief view of comments. • Funding List of all funding listed on the SmartForm, with a link to GMAS, if applicable. • Contacts List of study team members listed on the SmartForm, including current Human Subjects Training information on file. • Documents Draft and finalized documents submitted for review, with versioning information for each document • Sites Links to associated Site workspaces for a study (only visible on the *main study workspace* of collaborative projects where Harvard is the IRB of record for at least one site) • Follow-on Submissions Links to Continuing Review, Modification/update, or Reportable New Information workspaces for a study (only visible on the *main study workspace*) with quick access to all determination letters • Reviews View additional details about the review, including ancillary review details, data security level determinations, and completed checklists. • Snapshots View of the application at each change in state (for example, the appearance of the SmartForm between pre-review and changes submitted) • Related Projects Information about Agreements, Data Safety, and other IRB submissions which have been associated with the study via the Manage Related Projects activity (only visible on the main study workspace) including the current state of the related submission and a link to the related project workspace.

Locating the To-Do List

If you are a member of an ancillary office which is not required to complete review but must view elements of submissions or studies, you may not see items in the Dashboard.

Submissions that are assigned to you for action generally appear 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.

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

If IRB approval is issued before Ancillary Review is completed, the study may not appear in the Dashboard. To access a study that does not appear in the Dashboard because of this or for another reason, see Accessing a Submission.

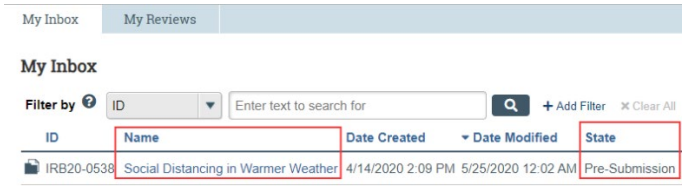
To access studies or other submissions assigned to you:

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

   The **Dashboard** is composed of two tabs: My Inbox and My Reviews. **My Inbox** contains all studies or other submissions that require you (or your team members) to take action. **My Reviews** contains only studies for which you are an Ancillary or Designated IRB Reviewer.

   As an ancillary reviewer (either by name or representing a specific organization), it is important to note that the IRB: a) can begin its review before you submit your review and; b) may or may not wait for your input before completing its review of the study.

2. Identify the reason the study appears in My Inbox by looking at the State column. Items in states other than "Pre-Submission" may be in IRB review states that require your review.



3. Open the submission by clicking the link in the Name column.

   The submission workspace (webpage) opens.

4. Click on **view study** or submission on the left to view the details of the submission.

Reviewing a Submission

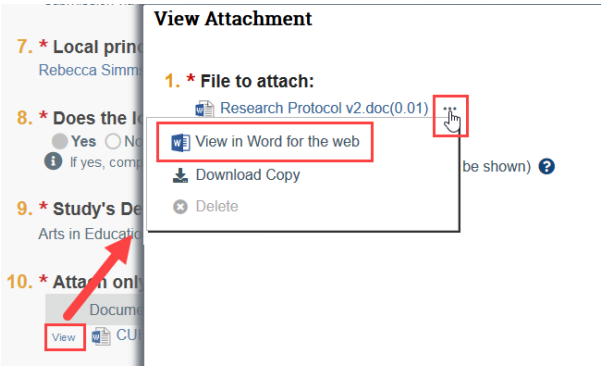
To view the details of a submission:

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, click **View Submission** instead.
4. 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.

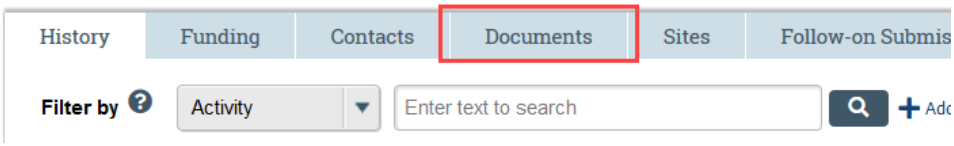
To view the documents included as part of the submission, there are two options:

- 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."



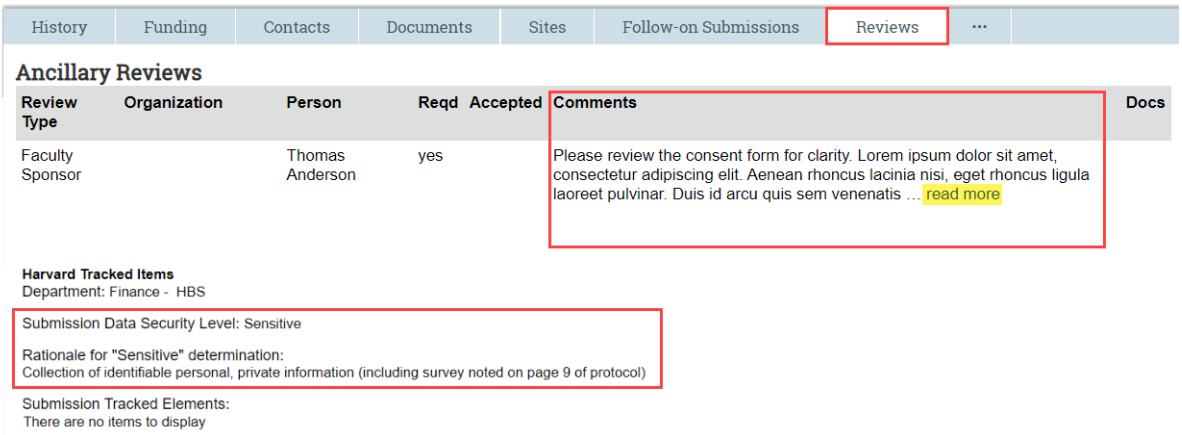
- When you have opened the study workspace (as in step 2 above), you can view a list of all the attached documents in one place by clicking the Documents tab.



  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.

To view review context (shared by the IRB staff member)

When you have opened the study workspace (as in step 2 above), you can view context notes for your consideration on the Reviews tab.



Requesting Additional Information on a Submission

During your ancillary review, if you would like to request changes to the study or to provide additional information, you can do so via the **Add Comment** activity.

1. Log in to irb.harvard.edu
2. Navigate to the submission (see Accessing a Submission for more instructions).
3. From the submission, click **Add Comment**.
4. Use the comment box space to request changes to the study or ask the PI to provide additional information.
5. (Optional) Upload any documentation to support your request (e.g. a tracked changes version of study documents to convey the changes you are requesting).
6. Select the appropriate comment recipients so that the PI/Study Team and IRB Coordinator will know that you've requested clarifications. It is recommended that all three are selected.
   - All individuals with access to the submission can view the comment, even if they are not marked as recipients of the comment notice.
   - If no recipients are selected for the comment notice, the comment will only appear on the History tab of the submission workspace.
7. When you are done, click **OK**.

Submitting an Ancillary Review Decision

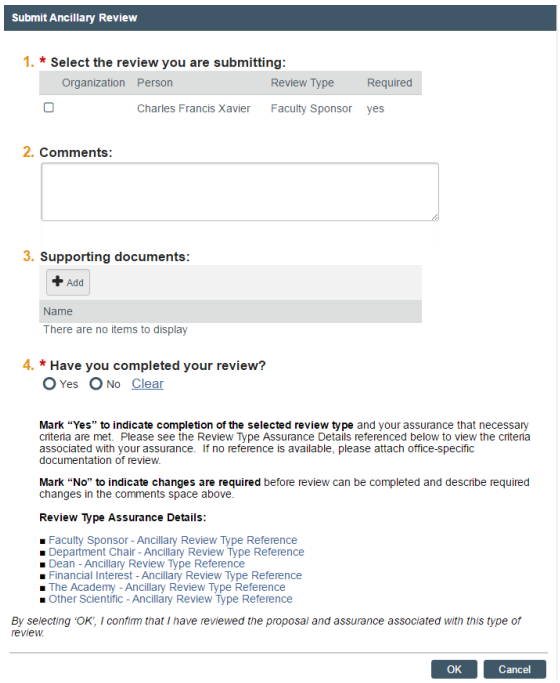
The procedures below assume that the study team has completed any needed revisions and review is complete.

To complete an ancillary review:

1. Log in to irb.harvard.edu
2. Navigate to the submission (see Accessing a Submission for more instructions).
3. From the submission, Click **Submit Ancillary Review** on the left. A pop up window will open with questions.

- If you have received a notification that Ancillary review is required, but you are unable to locate the above activity, add indication of your review via public comment via the steps described in the section: Requesting Additional Information on a Submission. IRB Staff will ensure the review is otherwise appropriately recorded on the study.
- If IRB staff are recording an ancillary determination on behalf of the reviewer, the Manage Ancillary Approvals activity will be used to update the review type.
- If IRB Staff included a note for the reviewer, it will appear in the Submit Ancillary Review pop-up for view/edit.

4. Complete the questions in the activity form:



Question 1: Select the review you are completing from the list.

Question 2: (Optional) Add comments related to the review. Note that comments made in this space do not send an email (see Requesting Changes for more instructions)

Question 3: (Optional) Attach documents related to this review. Documents can be attached by: a. clicking "Add" and browsing to the location of the document on your computer; or b. dragging one or more documents from the location on to your computer and dropping it on the Supporting Documents space provided.

Question 4: Indicate whether you have completed your review and criteria are met based on the on-screen instructions.

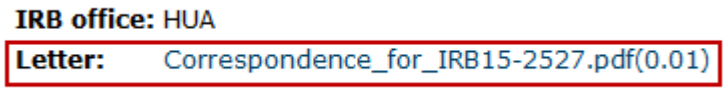
5. Click **OK**.

Upon completion of this activity, the system sends a notification of review update to the PI/Proxy, Primary Contact and the IRB Contact. Additionally, the review and comments completed here are shown on the History and Reviews tab and are visible to everyone who can access the submission.

Finding Determination Letters and Approved Documents

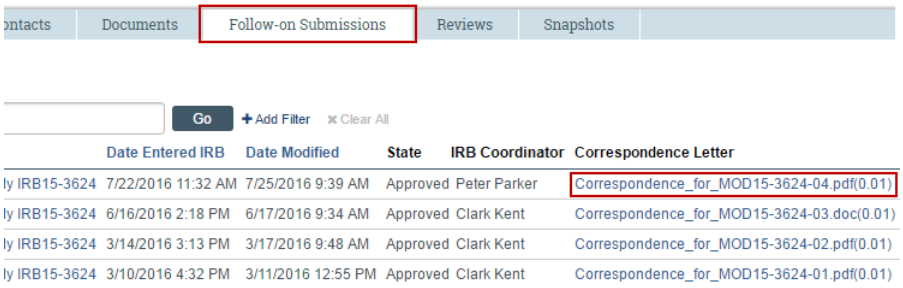
To find determination letters:

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



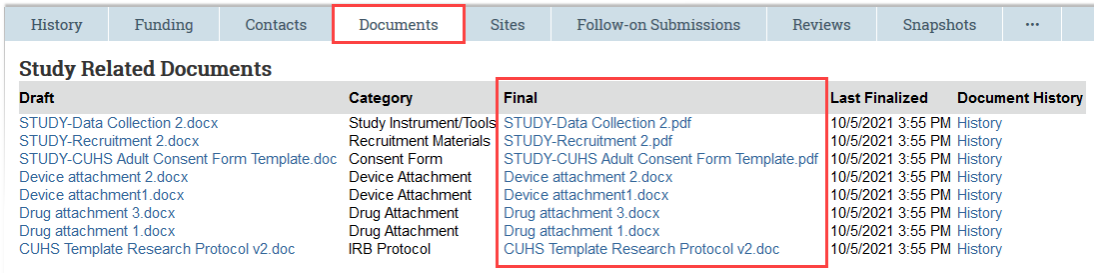
OR

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



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.'



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.

Generating Standard Reports

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

The reports provide links to the individual submissions, as well as sorting and filtering options.

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

To generate a standard report:

1. Log in to irb.harvard.edu
2. Click **IRB** in the top navigator.
3. Click **Reports** in the IRB sub-menu.

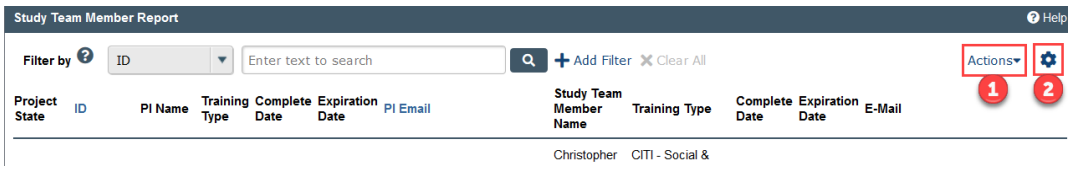
   The list of standard reports appears. To find a custom report, click the **Custom Reports** tab.
4. Identify the report to generate and click the link. The report appears, listing the relevant submissions.

Tips: Try filtering the list by status. Next to Filter by, select **Status**. Then type the state to view, such as **Approved** for a study report or **Acknowledged** for an RNI report and click **Go**.

If you or members of your office **require special access** to multiple studies or reports for a department or school, please contact your IRB office or estrhelp@harvard.edu for special access.

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

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



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

browser settings) it will save the file to your default folder or a pop up will appear for you to choose the location to save the file.

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

Finding More Information

Resource	Description	How to Access It
Help for a field or page	More information about a question or form.	Click 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	▪ 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.