



HARVARD

Human Research Protection Program

Electronic Submission Tracking and Reporting (ESTR)

Ancillary Reviewer's Guide

November 9, 2018

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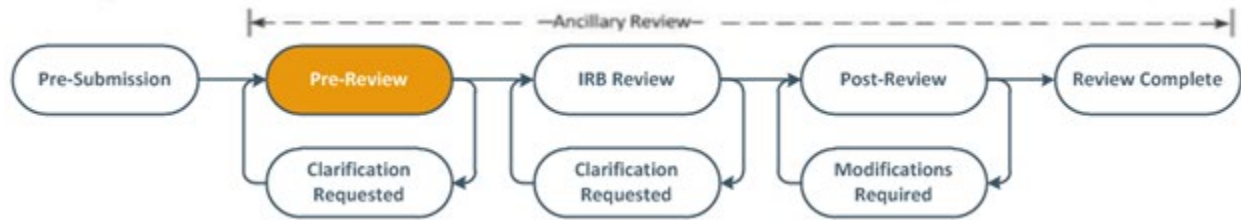
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Ancillary Review Overview

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
- 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

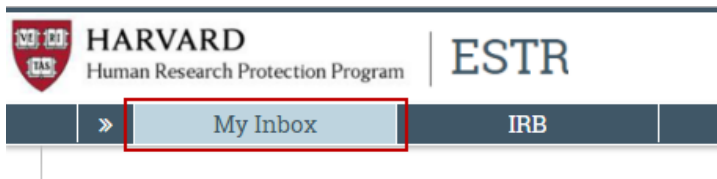
Accessing a Submission

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.

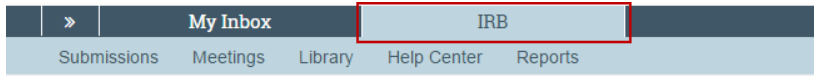
To find a list that includes the submission name:

- **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

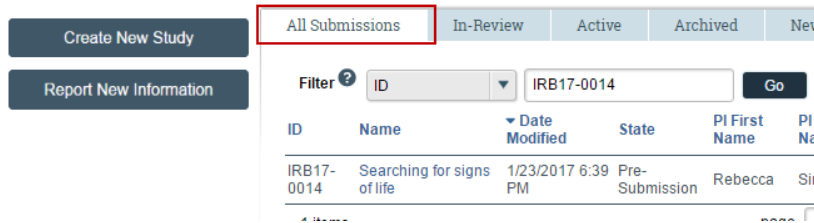


OR

- **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"/>

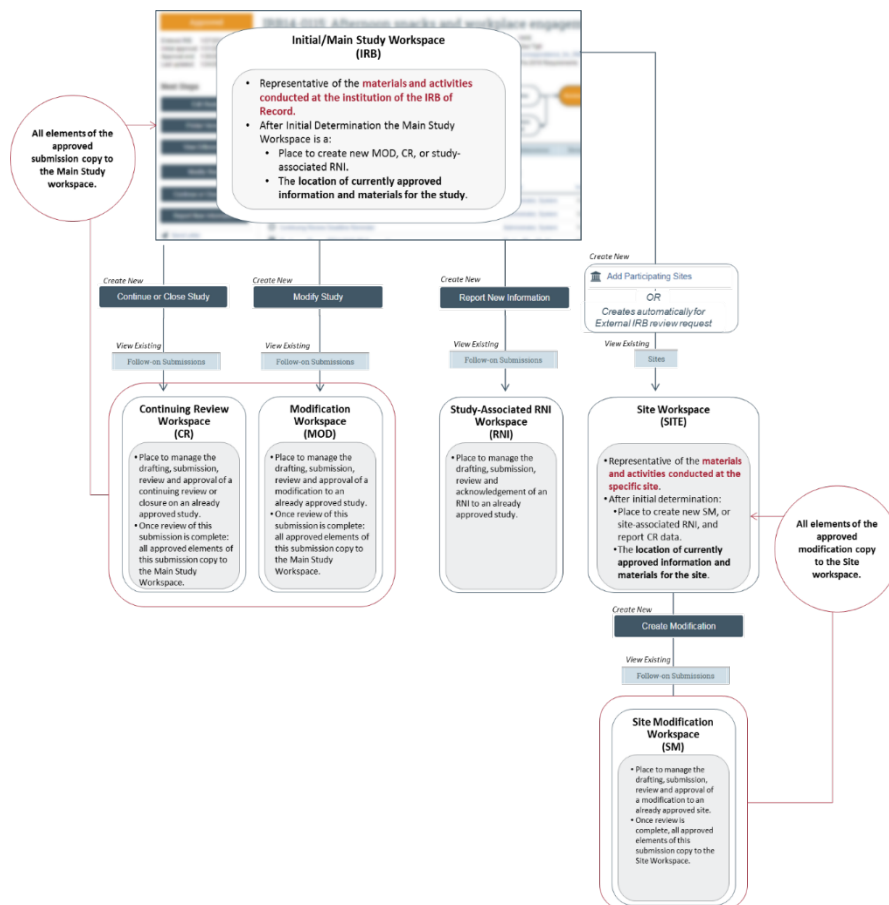
*To manage permissions per project, see sections for how to [change a primary contact](#), [assign proxies](#), [change study team members](#), and [add guests](#).

**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.

Approved
 Entered IRB: 1/19/2017 11:24 AM
 Initial approval: 1/19/2017
 Initial effective: 1/19/2017
 Effective: 1/19/2017
 Approval end: 1/18/2018
 Last updated: 1/23/2017 6:30 PM

Next Steps
 View Study
 Printer Version
 View Differences
 Modify Study
 Continue or Close Study
 Report New Information
 Assign PI Proxy
 Assign Primary Contact
 Manage Guest List
 Copy Submission
 Add Comment

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)

History
 Filter: Activity
 Activity Author Activity Date
 Modification MOD17-0013-01 Opened Simms (pi), Rebecca 1/23/2017 6:30 PM
 Modification: MOD17-0013-01
 Letter Sent Jahns (DEV), Alisa 1/19/2017 11:25 AM
 Correspondence_for_IRB17-0013.pdf
 Pre-Review Submitted Jahns (DEV), Alisa 1/19/2017 11:24 AM
 Submitted Jahns (DEV), Alisa 1/19/2017 11:24 AM
 Copied Submission Simms (pi), Rebecca 1/17/2017 6:43 PM
 New Copy: IRB17-0014 AJ Regression Testing #7 011717
 Created Study Simms (pi), Rebecca 1/17/2017 6:41 PM
 Copied from IRB17-0012 AJ Regression Testing #5 011717

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, 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).
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>Site</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, Sites, 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)

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 your Inbox (also referred to here as your Inbox).

Submissions that are assigned to you for action generally appear in My Inbox 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 My Inbox. To access a study that does not appear in My Inbox because of this or for another reason, see [Accessing a Submission](#).

To access studies or other submissions assigned to you:

1. Click the **My Inbox** link in the top navigation header.



The list called My Inbox contains studies or other submissions that require you to take action. 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.

My Inbox

Filter ? ID 3

ID	Name	Date Created	Date Modified	State	Cc
IRB18-1240	Searching for Signs of Life	9/25/2018 5:04 PM	11/5/2018 12:02 AM	Pre-Submission	

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.

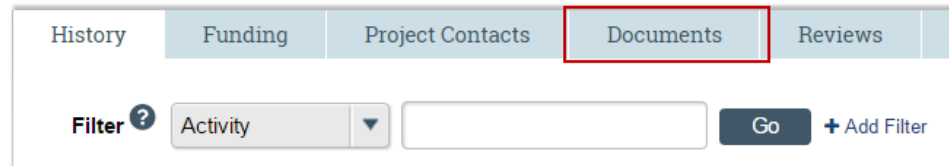
Reviewing a Submission

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 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 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. Documents are listed in tables throughout the forms.
- 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 Additional Information on a Submission

During the course of 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.

4. Complete the questions in the activity form:

Submit Ancillary Review

1. * Select the review you are submitting:

Organization	Person	Review Type	Required
<input type="checkbox"/>	Charles Francis Xavier	Faculty Sponsor	yes

2. Comments:

3. Supporting documents:

+ Add

Name
There are no items to display

4. * Have you completed your review?

Yes No [Clear](#)

Mark "Yes" to indicate completion of the selected review type and your assurance that necessary criteria are met. Please see the Review Type Assurance Details referenced below to view the criteria associated with your assurance. If no reference is available, please attach office-specific documentation of review.

Mark "No" to indicate changes are required before review can be completed and describe required changes in the comments space above.

Review Type Assurance Details:

- Faculty Sponsor - Ancillary Review Type Reference
- Department Chair - Ancillary Review Type Reference
- Dean - Ancillary Review Type Reference
- Financial Interest - Ancillary Review Type Reference
- The Academy - Ancillary Review Type Reference
- Other Scientific - Ancillary Review Type Reference

By selecting 'OK', I confirm that I have reviewed the proposal and assurance associated with this type of review.

OK
Cancel

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:

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.

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 is allowed to 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.

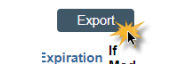

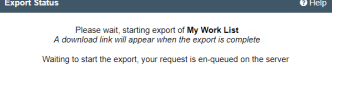
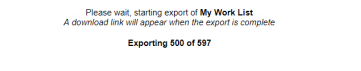

To generate a standard report:

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.


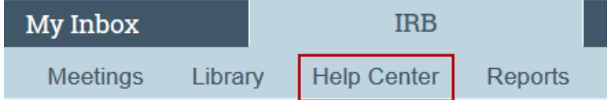
Tips: Try filtering the list by status. Next to Filter by, select **Status**. Then type the state to view, such as **Approved** for a study report or **Acknowledged** for an RNI report and click **Go**.

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 estrhel@harvard.edu for special access.

Report results can be exported to Excel from the results pop up window.

Important notes about using EXPORT in ESTR	
	<p>1. Click the Export button only ONCE. The system will take a moment to display a pop-up window.</p>
	<p>2. Double check that the pop up isn't blocked before clicking again. <i>Unblock the pop up by always allowing if it is blocked.</i></p>
	<p>3. If the pop-up displays: <i>Waiting to start the export, your request is en-queued on the server</i>, leave it open. The export will begin once the one ahead of it is done. <i>Closing this window will not cancel your export, it will only limit your access to the export link.</i></p>
	<p>4. If there are no other exports pending, the pop up will begin counting items in the anticipated file.</p>
	<p>5. Once the export is done, a link will appear. Click on the link to download the exported complete list.</p>

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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