Safety Reviewer / Specialist Guide

Data Safety and Security System

December 8, 2023

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Logging In

The Data Safety 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.

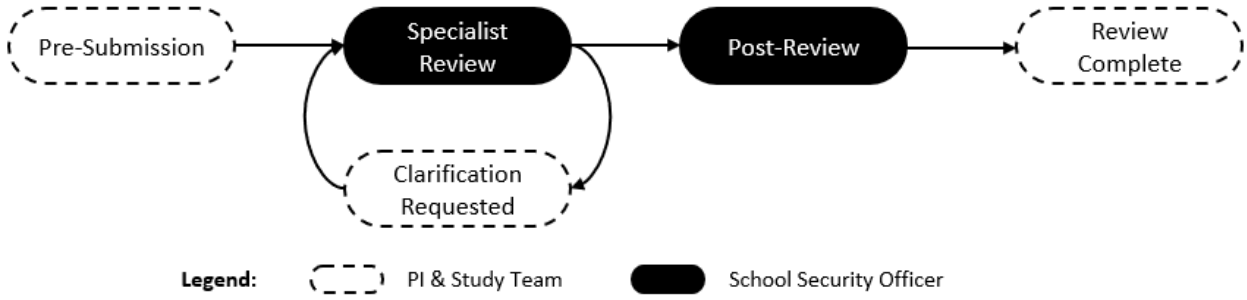
To log in:

1. Locate your HarvardKey and password
2. Navigate to researchsafety.harvard.edu
3. Ensure the correct login 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 the Data Safety system, to your personal workspace.

If you are unable to log in, contact the Research Safety Help Desk at rshelp@harvard.edu.

Review Process Overview

The basic process for a study/protocol (or initial submission) is shown in the following diagram.



The legend indicates who can take major actions during each state within the process.

Specialist Review

Upon submission, the study is automatically assigned to a School Security Officer (SSO), determined by the PI's department. The SSO should conduct the data security review, including review of all uploaded documents, in this state.

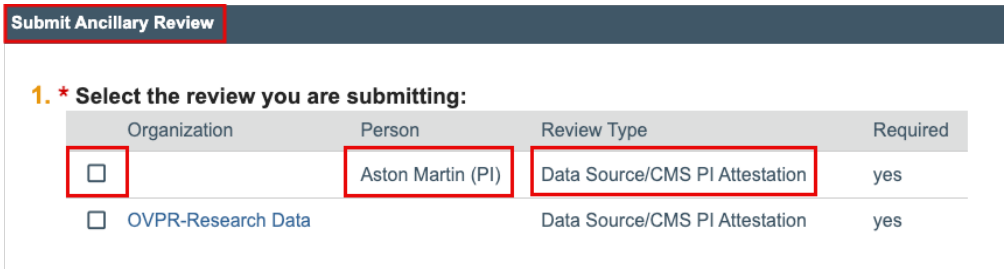
While the submission is in the Specialist Review state, you can take the following activities:

1. **Assign Specialist** – If you need to reassign the submission to a different SSO (for example, reassigning to HUIT after determining the submission involves DSL 4-5), you can do so using the "Assign Specialist" activity.
2. **Manage Ancillary Reviews (optional)** – In some circumstances, you may want another person or department/organization to review the submission before completing your review. You can assign ancillary reviewers using this activity. Ancillary reviewers can provide feedback, approval, and/or provide documentation on the submission in parallel with the Safety review.

   Important! Ancillary reviews may be marked "required" or "optional." Only required ancillary reviews will appear in the reviewer's inbox. Optional ancillary reviewers will

may only access the assigned submission via the “In Review” or “All Submissions” tabs. Both types of ancillary reviews, “required” or “optional” will trigger system notifications to the reviewer.

If the PI has selected a **CMS institution** as the provider for externally provided data, the Safety Specialist must request ancillary reviews by OVPR (organization) and PI (person) as part of safety review. The PI will then be prompted to attest to use of CMS data as part of the safety review process.



3. **Request Clarifications (optional)** – If you have questions for the study team or need them to revise the submission prior to completing your review, select the “Request Clarifications” activity. When you do, you will be prompted to record your comments to the lab in a pop-up window.
4. **Approve Submission (Admin) (required step)** – If you have completed your review and have no further questions for the research team, select the “Approve Submission (Admin)” activity. This will transition the submission to the “Post-Review” state, which will give you access to additional activities to prepare and send the determination letter.

Post-Review

The Post-Review state gives the SSO the opportunity to complete the following activities:

1. **Manage Ancillary Reviews (optional)** – Review the status of ancillary approvals on the Reviews tab and make any necessary updates.
2. **Prepare Letter (required step)** – To inform the study team that the Safety review has been completed, you must first prepare the determination letter using this activity.

   Notes:

   - The Prepare Letter activity and the letter draft will not appear on the workspace until the Send Letter activity is completed (by clicking “OK” on the pop up). To view draft versions of a determination letter before the letter is sent, complete the Prepare Letter activity again.
   - Clicking the generated letter from the activity will attempt to open Office 365. If the file format extension reads .doc rather than .docx, the document may not open. If the document does not open, please choose the download option to edit and then upload to this activity.

3. **Send Letter (required step)** – Completion of this activity triggers the submission to transition to the Approved state and sends a notification letter to the PI, PI Proxy, and Primary Contact to alert them that the review is complete.

Other Optional Activities

The following activities are available in the Specialist Review and Clarifications Requested states:

1. **Withdraw –** Withdrawing a submission will return it to the pre-submission state for edits and resubmission by the study team. The study team can Withdraw a submission at any time until the Post-Review state.
2. **Discard** – The Discard activity removes a submission from any further consideration. Like the Withdraw activity, the study can be discarded at any time after submission until the Post-Review state. The PI, Primary Contact, and proxies will be notified when a record is discarded.
3. **Add Comment & Add Private Comment** – This activity allows you to record notes on your review. "Add Comment" creates a comment visible to all with read access to the study, whereas "Add Private Comment" creates a comment that is visible only to the study team and other specialists.
4. **Track Safety Elements** – This activity allows you to record elements of data management that require Harvard tracking and reporting. This activity can only be completed by reviewers. It can be initiated during the approval process, and can be edited anytime. Information entered here displays to all individuals with access to the record.

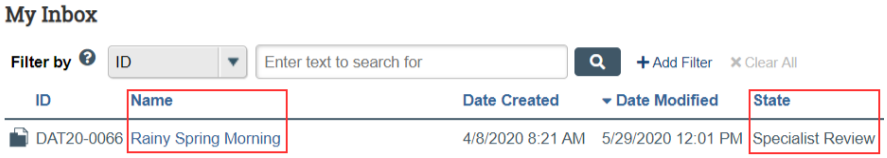
Locating the Reviewer To-Do List

Submissions that are assigned to you for review generally appear in the **Dashboard** with a link to the study. You will also receive an email with a link directly to the submission. An email indicates that you must take action or informs you of important changes, such as a determination about the submission. To access a submission that does not appear in My Inbox, see Accessing a Submission.

To access submissions assigned to you:

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

2. Open the submission by clicking the link in the Name column. This will open the submission workspace.



3. Click on the **View Protocol** button on the left to view the details of the submission.

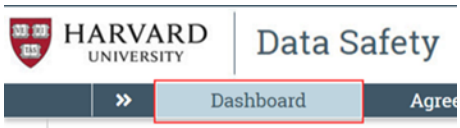
Accessing a Submission

You may want to go to a specific submission workspace 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 submission. In addition, the actions you can take on a submission are personalized.

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

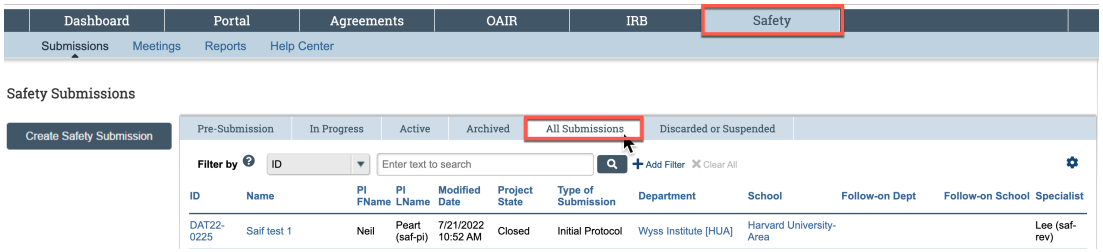
To find a list that includes the submission name:

- **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 submissions that require a response to a requested clarification.



OR

- **Safety** (all items to which you have access): Click **Safety** in the top navigation header and select the **All Submissions** tab. This list displays links to the workspaces for all studies, continuing reviews, and modifications entered into the system that you have permission 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 a 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 School Security Officers and ancillary reviewers. See below for a list of system actions and permissions:

Action	User Role(s)
Receives 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 **edit** submissions in the "pre-submission" and "clarifications requested" states *All types of submission*	Principal Investigator, PI Proxy, Study Team Member
Can **edit** submissions on behalf of the PI/Team in all review states (until approval) *All types of submission*	Assigned review specialist
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"), 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 access data**/is listed on the personnel roster	Principal Investigator, PI Proxy, Study Team Member
Has **view-only** access to the submission	Guest

Instructions for managing permissions per project are described in the Study Submission Guide.

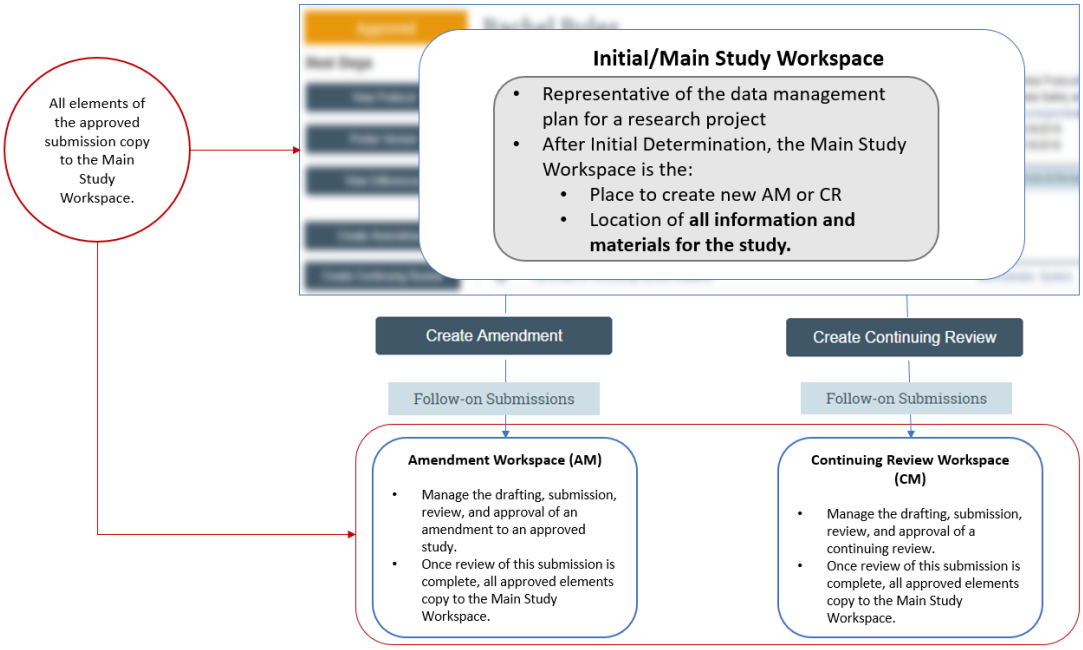
For view access to many records in a department or school, see Requesting Viewer Access to ESTR-IRB, Agreements-DUA, or Data Safety for expanded guest access.

Submission Workspace Overview

The Initial/Main Study, Continuing Review, and Modification/Update workspaces are formatted similarly. The following general concepts apply to navigation:

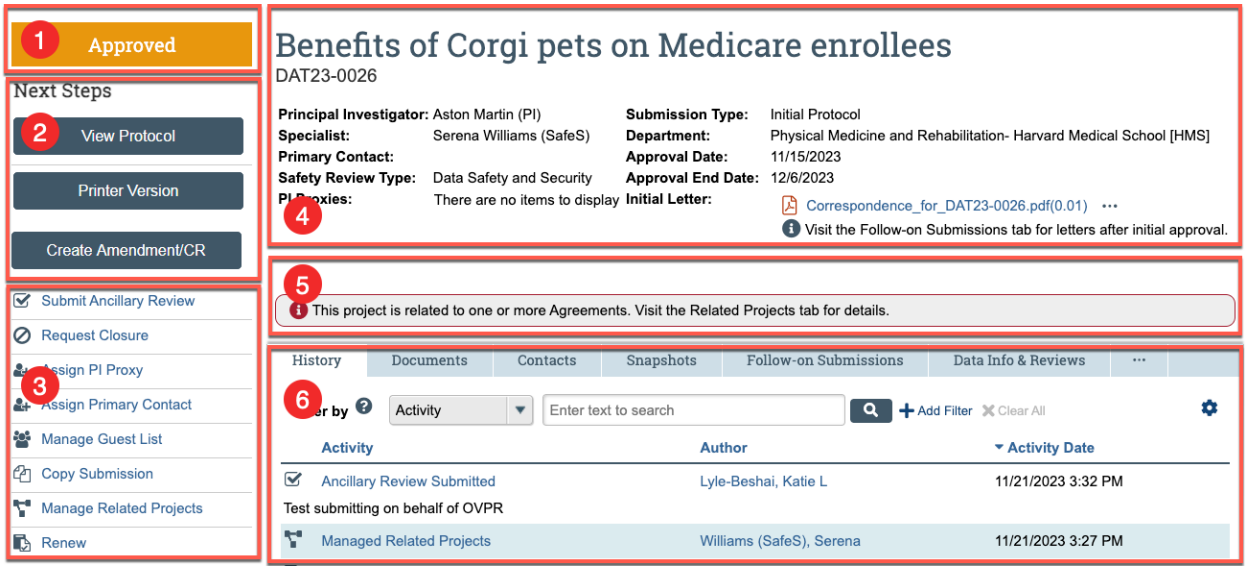
- The Initial/Main Study workspace (labeled DAT##-####) always has the most current approved information and materials for a protocol.

- Continuing Review, Amendment, and Amendment/CR (not depicted in the image below) workspaces are used actively during the review of that submission only. Once a determination is made (or the submission is discarded), the Initial/Main Study workspace is updated with any revised elements and these workspaces are used for reference only and should not be the go-to location for protocol 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 current review status of the submission.
2	**Next Steps** Visible in all workspaces, this set of blue buttons allows for: • Editing or viewing the current submission SmartForm, • Displaying a printer-friendly version, • Viewing changes over time, and • On Initial/Main study workspaces only: Creating new Continuing Review or Amendment submissions for the study by choosing Amendment/CR.
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, 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 review specialist (if assigned) • Review determination letter (labeled "Letter") if a determination has been made. • On Continuing Review, Amendment, or Amendment with CR workspaces only: a link to the Initial/Main study will appear at the top of this section.
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	**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 the tabs to view: • History Information about each action taken on a submission and in-brief view of comments. • Documents All documents submitted for review, with versioning information for each document. • Contacts List of study team members listed on the SmartForm, including current training information on file. • Snapshots View of the application at each change in state (for example, the appearance of the SmartForm between Specialist Review and changes submitted). • Follow-on Submissions Links to Continuing Review, Amendment, or Amendment/CR workspaces for a study (only visible on the *main study workspace*). For easy reference, the tab also displays the name of the assigned specialist for each of the follow-on submissions. • Data Info & Reviews Displays each data set described within the submission, its Harvard Data Safety Level, and all corresponding data storage locations. Also displays the information that is relevant for external reviewers who need to access basic information about the record.

- Related Projects Quick links to any submissions in the ESTR-IRB and Agreement-DUA system that are related to the submission you are viewing. Related projects should be added or removed by using the **Manage Related Projects** activity.

Assigning Ownership of a Submission

Before a reviewer takes action on a submission, the submission must be assigned to them. Any user with Safety Reviewer permissions can take ownership of the submission or assign it to another reviewer. The submission can be reassigned at any point.

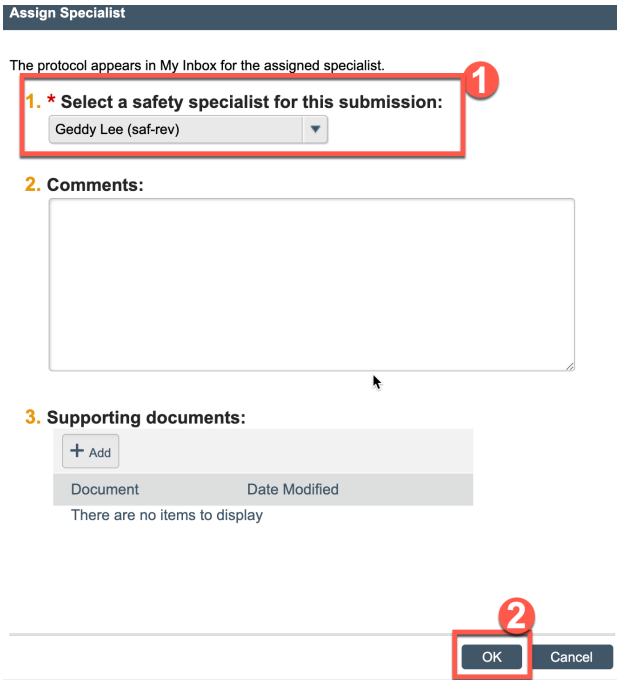
When an item is submitted, it will automatically be assigned to the reviewer responsible for a department or school and a notice is sent to that reviewer/review team.

Important! Submissions involving data that is determined to be DSL 4 or 5 must be reviewed by HUIT Information Security. Be sure to reassign the submission appropriately as described below.

To assign a Reviewer / Specialist:

1. Open the submission (See Accessing a Submission for more instructions).
2. Click **Assign Specialist** on the left.

3. Select (1) yourself or another reviewer and (2) click **OK**.



Reviewing a Submission

To begin your data security review, you will first need to review the details of the submission and related documents.

To view the details of a submission:

1. From **My Inbox**, click the name of the submission to open it.
   Note: If the submission does not
2. View the SmartForm:
   a. Page by page, with linked documents:
      Note: Choose the Compare option (at the top of the left navigation panel) for a single, scrollable view after choosing these options to access SmartForm pages.
      - For an Initial Submission, click **View** or **Edit Protocol**
      - For an Amendment, click **View** or **Edit Amendment**
      - For a Continuing Review, click **View** or **Edit Continuing Review**
      - For an Amendment with Continuing Review, click **View** or **Edit Amendment/CR**

   OR

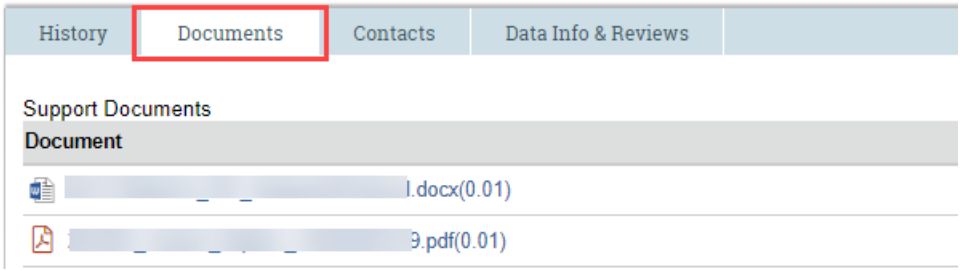
   b. As one page with linked documents, click **Printer Version** and then choose "Default" in the slide out.

To view documents associated with a submission:

1. While viewing the details of the submission (as instructed above), click the name of each document when you encounter it on the SmartForm

OR

2. Select the **Documents** tab on the submission workspace.



Looking Up Study Team Training

Per the HRDSP, all individuals using sensitive data must complete Research Data Security Training. However, the policy leaves the determination of appropriate training up to the reviewing School Security Officer.

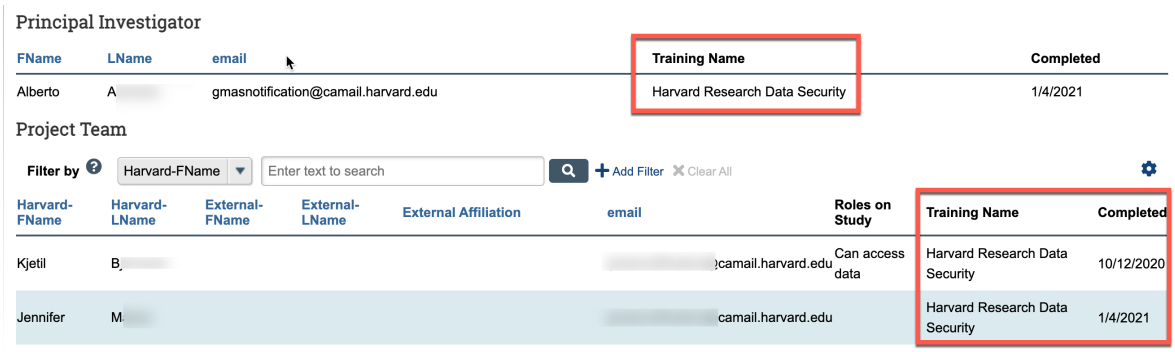
The two most frequently assigned trainings are:

- Harvard Research Data Security Training Course in the Harvard Training Portal
  This training, developed by the Office of the Vice Provost for Research, explains the requirements of the HRDSP and the various reviews (IRB, Agreements, and Data Safety) that might be required depending on the research.
- Information Security Training in CITI
  This training covers the basics of information security and secure data management for research. It is not Harvard-specific.

When users complete either of the above trainings, their completion will be recorded in the system within one week of completion. If you opt to assign a different training, you can email rshelp@harvard.edu to request that the completion of other training be documented on a person profile the Safety system.

Finding Training Records on the Submission Workspace

The first place to look for completion of required training is on the Project Contacts tab of the study workspace. If the study team is listed in the protocol SmartForm, completed trainings will be listed beside each individual's name:



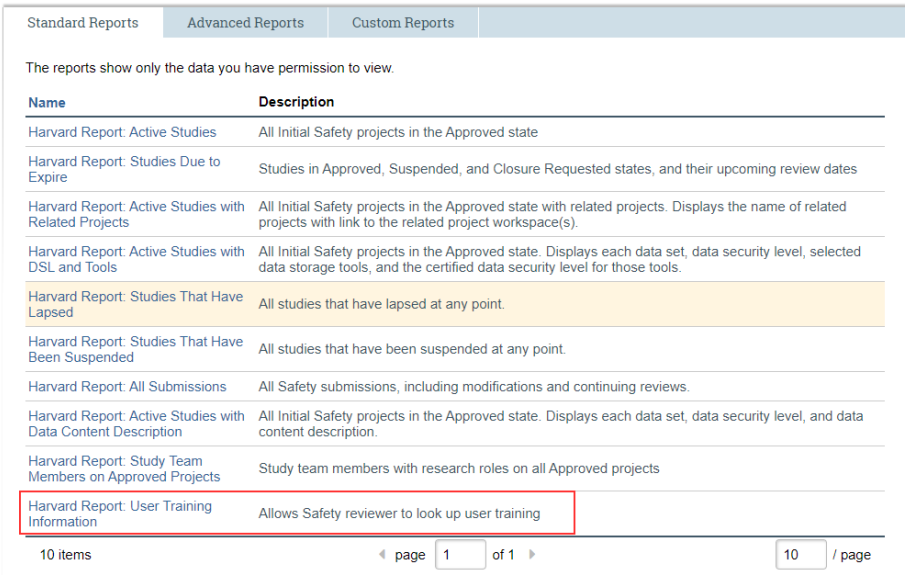
Finding Training Records on a User Profile

If you have agreed to refer to a related IRB submission for a Safety study team, the study team members will not be listed on the Project Contacts tab of the study workspace. Instead, you will need to look up each user's profile to view their training records.

To do so,

1. Navigate to the Safety tab and click **Reports**

2. On the Standard Reports tab, select **Harvard Report: User Training Information**



3. The report will display all active users in the Safety system, along with the names and dates of any completed training. You can use the **Filter by:** section at the top of the report to search for a user by first name, last name, and/or e-mail address.

Requesting Clarifications on a Submission

During your review, you can request that the study team provide additional information or make changes to the submission.

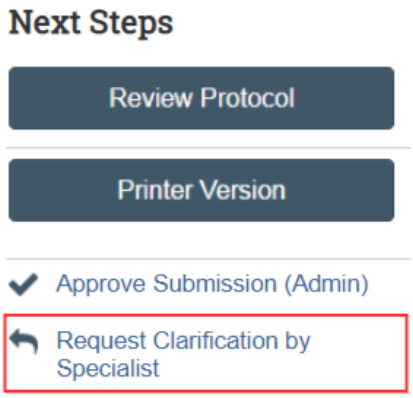
Requesting clarifications returns the submission to the study team so they can edit it and respond to your questions. This step should occur after a Specialist has been assigned. Requesting clarifications can be useful when:

- **Required details are missing** from the SmartForm or on the record.
- There is **inconsistent information** between elements of the SmartForm which need clarification.
- A new item was discovered during review that **needs to be added to the SmartForm**.

The Data Safety System is the system of record for data management plans, so it is important to use this opportunity to ensure the submission is correct and complete during review.

To request clarifications:

1. Navigate to the study workspace (see Accessing a Submission for further instructions).
2. Click **Request Clarification by Specialist** on the left.



3. In the Request Clarification activity 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.
4. Click **OK** to send the request to the study team for edits.
   You will receive an email notification when the study team submits a response to your clarification request.

Completing Your Review

Once all your questions and clarification requests have been answered, you will need to complete the review process and approve the Safety submission. At this point, the submission should be in the "Specialist Review" state.

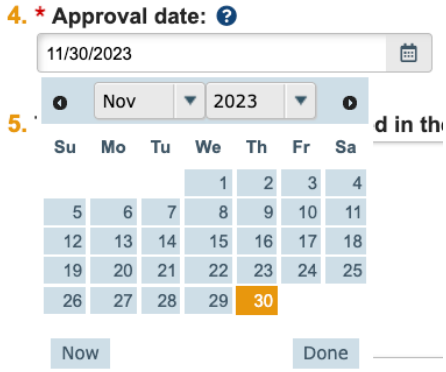
1. Confirm that any Ancillary Reviews have been completed and that any ancillary feedback has been incorporated into the submission, as appropriate.
2. Click on the **Approve Submission (Admin)** activity and complete the activity SmartForm. You will need to fill in or confirm the following:
   a. **Assigned Specialist** – This should be pre-populated with the name of the currently assigned specialist.

Note: If you are completing the approval for a submission and someone else's name is listed here, close the activity window without saving and use the **Assign Specialist** activity to reassign the submission (see: Assigning Ownership of a Submission for more information).

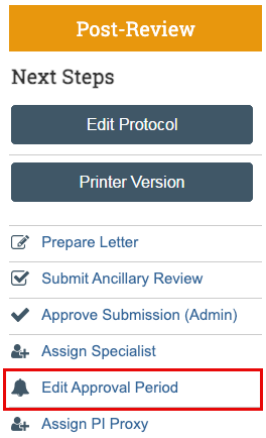
b. **Select committee for acknowledgment** – Select "Data Safety and Security."

c. **Approval End Date** –
   - For Initial, Continuing, and Amendment/CR review, this assumes a one-year approval period and defaults to one year from today's date, minus one day. If no expiry should be applied, choose: 01/01/3000.
   - For Amendment review, this defaults to the existing expiry date for the protocol.

d. **Approval date** – This value defaults to today's date and is editable by hovering over the calendar icon to the right of the date.



Note: The approval period can be updated after a safety submission has been approved by clicking on the **Edit Approval Period** activity. This option is only available for safety submissions that are not already in lapsed status.

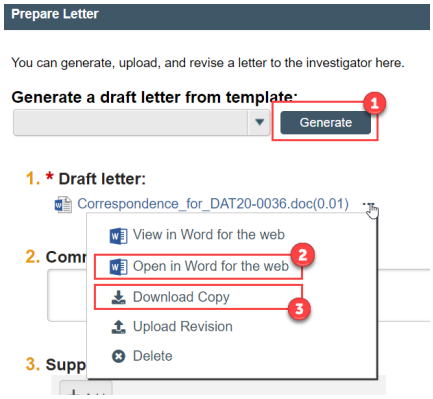


e. **Explanation** (optional) – Text included here will be populated in the determination letter when completing Prepare Letter. Include any additional notes about the scope of approval for this submission. For example, as a reviewer you can include a note to the researcher to submit an amendment to add updated terms and ensure security review is completed for updated terms of the DUA when the draft terms are available for review.

f. **Supporting Documents** (optional) – If you have any additional documents relating to the approval, you can upload them in this section.

g. Click **OK** to complete the Approve Submission (Admin) activity. This will transition the submission to the Post-Review State.

3. Click on the **Prepare Letter** activity and complete the activity form.
   a. Choose the template appropriate template type of submission to ensure information is correctly populated. If an Explanation was added in the Approve Submission (Admin) activity, it will appear on the letter for review and any needed edits before sending.
   b. Generate a determination letter by clicking the **Generate** button (1).



Tip: You can edit the approval letter by clicking on the ellipsis followed by **Open in Word for the web** (2) or by downloading a copy of the determination letter to your computer and clicking **Upload Revision** (3) to upload your revised version. Be aware that clicking "Generate" again will overwrite your uploaded document.

> **Note:** Clicking the generated letter from the activity will attempt to open Office 365. If the file format extension reads .doc rather than .docx, the document may not open. If the document does not open, please choose the download option to edit and then upload to this activity.

Click **OK** when you are finished.

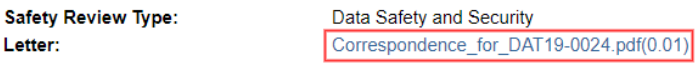
4. Click on the **Send Letter** activity and complete the activity form. You will be given another opportunity to review the determination letter at this point. Click **OK** to complete your review and activate the submission.

Important! Completing the Send Letter activity will transition the submission to the "Approved" state, activate the submission, and send notifications to the PI, PI Proxy, and Primary Contact, as well as to individuals responsible for any Harvard data storage tools indicated on the Submission.

Finding Determination Letters and Documents

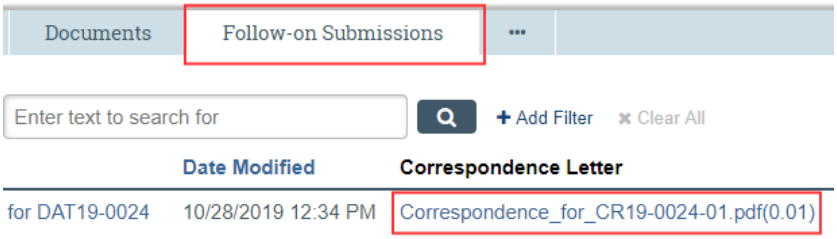
To find determination letters

1. Log in to researchsafety.harvard.edu.
2. Navigate to an approved submission (See Accessing a Submission for more instructions).
3. View the determination letter at the top right of the workspace.



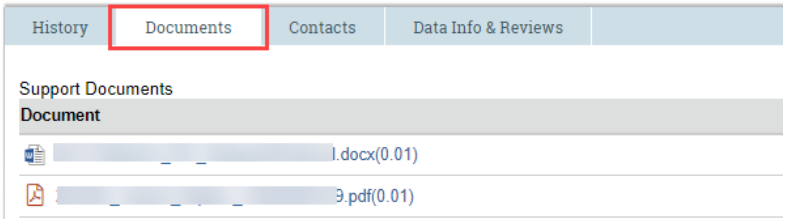
OR

1. Log in to researchsafety.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. To **save** a letter, right click and select "Save Link As."



To find current protocol documents

1. Log in to researchsafety.harvard.edu.
2. Navigate to an approved submission (See Accessing a Submission for more instructions).
3. Click on 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."

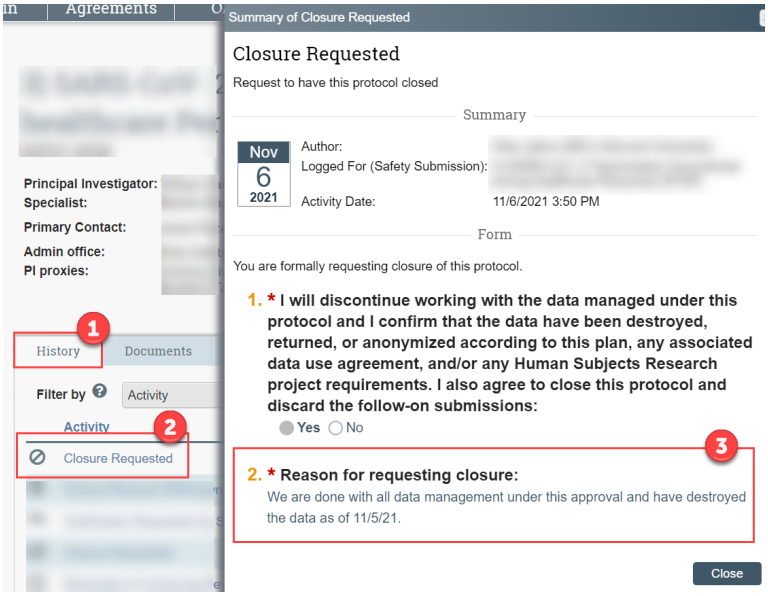
Reviewing a Closure Request

The study team may request closure for a study at any time after it has been approved. This action will transition the study to the "Closure Requested" state and a system notification of the request for review will be sent to the assigned specialist.

The study team must indicate their reason for requesting closure. To view the complete request and rationale.

1. Navigate to the study workspace (see Accessing a Submission for more instructions).

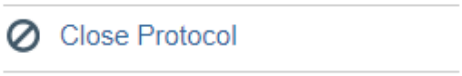
2. Click on the entry in the History tab (1) listing “Closure Requested” (2)
3. In the pop-up panel, look at question 2, “Reason for Requesting Closure” (3)



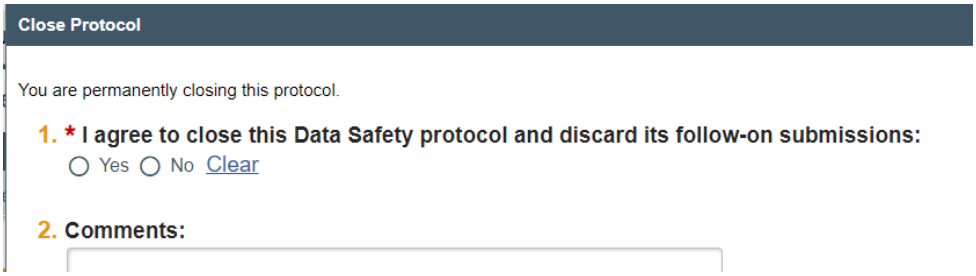
Important! If the rationale provided is unclear or inadequate, the specialist can Request Clarifications. If the protocol should not be closed, the closure can be rejected by a) completing the Request Clarifications activity and then 2) asking the project team to complete the Withdraw Closure Request activity or by completing it on their behalf.

To close a study:

1. On the main study workspace (marked in the center as “Submission Type: Initial Study), under Next Steps, click **Close Protocol**.



2. Complete the required questions on the Activity Form and click **OK**. The Principal Investigator, PI Proxy, and Primary Contact will receive a system notification when the study is closed.



Important! Closed studies cannot be reactivated. However, if the study team wishes to continue the work described in a closed study, they can use the **Copy Submission** activity to create a copy of the study that may be submitted for review.

Known Bug! Requesting Clarifications closure request fora submission that already had a follow-on corrupts the submission. Please withdraw the Closure Request and contact rshelp@harvard.edu for an Administrator to close out the submission.

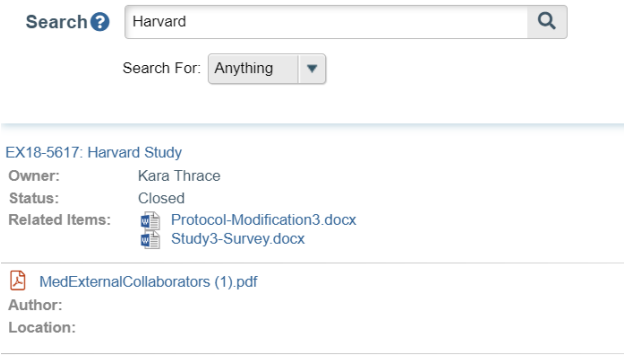
Using Site Search

Reviewers can see the option to conduct a keyword search of information on submission records and within record attachments.

To search:

1. Log in to researchsafety.harvard.edu.
2. Click **Safety** in the top navigator.
3. In the search bar (at the right, just above the tabbed area), type the keyword(s) then click the **magnifying glass** icon. A pop up will appear and results may take a moment to display.

4. In the pop up of results, identify the items of interest and click to those items, as needed.
   - Results may be records, records and attachments to the SmartForm, or records and attachments on activities. Attachments are listed as Related Items and do not represent all the attachments on that record.
   - If a result displays without an author or record, it means the document was removed from a record but still exists in the system database.



Generating Standard Reports

The Safety system includes many standard reports to help you find relevant submissions and understand the overall data safety and security program.

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 report generated by a PI will only include 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. School Security Officers and other administrators may have access to all report data.

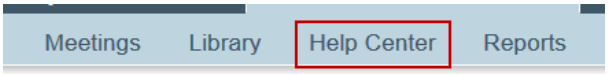
To generate a standard report:

1. Log in to researchsafety.harvard.edu.
2. Click **Safety** in the top navigator.
3. Click **Reports** in the Safety sub-menu.
4. The list of standard reports appears. Identify the report you want to generate and click the title. The report will appear, listing the relevant submissions.
5. Report results can be exported to Excel from the results pop-up window by clicking the **Export** button.

Important! Notes on Exporting Reports

- Click the Export option once. The system will take a moment to indicate the download has occurred.
- If the download does not appear automatically, check to confirm that your browser is not saving files to a default folder.
- If no other exports are pending, the progress with display on the button and a download option will appear when the export file is ready for download.

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. 
Safety Submission Guide	Instructions for submitting a protocol 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.
Safety Reviewer / Specialist Guide	Instructions for reviewing a submission.	
Data Safety Support	External website with additional information about using the Safety system	https://ras.fss.harvard.edu/data-safety
Data Safety Help Desk	Contact for help with access and use	rshelp@harvard.edu
OVPR, HUIT and Support Websites	Information about the review process and requirements	▪ Office of the Vice Provost for Research: https://research.harvard.edu/2020/06/26/research-data-management/ ▪ Harvard University Information Technology: https://security.harvard.edu/ ▪ Research Data Management at Harvard: https://researchdatamanagement.harvard.edu/

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

Appendix I: Ancillary Reviews

Type*	Trigger(s)	Assignment
Department	A department contact needs to be engaged or consulted during the review due to funding, technical or contract concerns.	Person = Appropriate department contact
Export Control Consultation	There is an export control concern identified and there is no sponsored funding, IRB or DUA review otherwise indicated (these other reviews would ordinarily trigger an export control-related review).	• HMS/HSDM: Organization = Office of Research Administration [ORA-HMS] / Person = Melissa Korf • HSPH: Organization = TBD / Person = Pat O'Neill (temporarily) • University Area: *School specific:* FAS = Kristen Harding, GSE = Tiffany Blackman, HKS = Carrie Kachoria, Wyss = Katrin Duevel
GDPR-Based Evaluation	There is a GDPR concern identified and there is no DUA review otherwise indicated and the request to manage related projects has already been made but remains incomplete / unclear. Note: GDPR review may have already occurred in ESTR (if human subjects research)	Person = Rachel Talentino
IRB Consultation	There is no IRB review but there should be, or the related IRB review appears unclear or incorrect and the request to manage related projects has already been made but remains incomplete / unclear. *The IRB teams prefer that the reviewer email with these questions, where possible.*	• HMS/HSDM: Organization = IRB Office [HMS] • HSPH: Organization = IRB Office [SPH] • University Area: TBD
Strategic Procurement	There is a contract or arrangement with a vendor for services, which involves DSL 3+ information	TBD
OGC Consultation	TBD	
OSP/ORAs Consultation	• There is no DUA but there should be, or the related DUA appears unclear or incorrect and the request to manage related projects has already been made but remains incomplete / unclear.	• HMS/HSDM: Organization = Office of Research Administration [ORA-HMS] • HSPH: Person = named reviewer on existing or Pat O'Neill (temporarily, if there is no other contact)

Type*	Trigger(s)	Assignment
	• There is no DUA but a collaboration agreement may be needed (for example, identifying the bounds of the safety review) • There is no DUA already in place or in review (known via manage related projects) and if you are sharing Harvard confidential data, a written agreement is needed.	• University Area: Organization = Person = named reviewer on existing or Carolina Harvey (temporarily, if there is no other contact)
Provost Consultation	There is a concern identified related to required Provostial review and there is no sponsored funding, IRB or DUA review otherwise indicated (these other reviews would ordinarily trigger an export control-related review).	Organization: Office of the President and Provost / Person = Rachel Talentino
Resource Consultation	A resource is appropriate for use (selected or not yet selected) and active acknowledgement, consultation, or review is needed.	**For discussion: May be optional, requested use by FASRC for more real time awareness.** TBD: some resources are set up as organizations and others are individual contacts.
OTD Consultation	Materials are being transferred as part of the project, and there is no IRB or DUA review otherwise indicated (these other reviews would ordinarily trigger an OTD review). There is an industry-collaboration involving proprietary information, and there is no DUA covering the relationship.	For other groups that would assign OTD review, the reviewer puts this on the researcher to connect with OTD. The OTD process is not as transparent to the security reviewers. Connection with OTD seems rare and responses are even rarer. Rich might be the contact.
Other	Another party must complete review or provide consultation on the submission.	Person = Appropriate contact
Data Source / CMS PI Attestation	When externally provided data comes from a CMS institution, PI and OVPR are added as required ancillary reviewers.	PI (person) and OVPR (organization) must each provide ancillary review for this data source.

***Based on policy/process, if all necessary information has been received, a completed ancillary review is not also required prior to completing safety review.**