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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 who 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 trigger system notifications to the reviewer and will appear in the reviewer’s inbox. Optional ancillary reviewers will not receive notifications and may only access the assigned submission via the “In Review” or “All Submissions” tabs.

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 lab, 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.

   **Note:** The Prepare Letter activity and the letter draft will not appear on the workspace until the Send Letter activity is completed. To view draft versions of a determination letter before the letter is sent, complete the Prepare Letter activity again.

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.

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.

**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.

   ![Dashboard Link](image)

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

   ![Submission Workspace](image)

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

   ![View Protocol Button](image)

**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.

   ![Dashboard List](image)

   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.

![Safety tab in the top navigation header](image)

**Submissions**

![Submissions filter by Name](image)

**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:

<table>
<thead>
<tr>
<th>Action</th>
<th>User Role(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receives system notifications</td>
<td>Principal Investigator, Primary Contact, PI Proxy</td>
</tr>
<tr>
<td>Can <em>create</em> submissions on behalf of the PI</td>
<td>Principal Investigator, Primary Contact, PI Proxy, Study Team Member</td>
</tr>
<tr>
<td>All types of submission</td>
<td></td>
</tr>
<tr>
<td>Can <em>submit</em> initial submissions</td>
<td>Principal Investigator Only</td>
</tr>
<tr>
<td>Can <em>submit</em> follow-on submissions on behalf of the PI</td>
<td>Principal Investigator, PI Proxy</td>
</tr>
<tr>
<td>Modifications/updates, continuing review, and closures</td>
<td></td>
</tr>
<tr>
<td>Can complete the <strong>Copy Submission</strong> activity</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>Modification required to add or update this role</td>
<td>Principal Investigator (using modification to “Other Parts of the Study”), Study Team Member (using modification to “Study Team Members”).</td>
</tr>
</tbody>
</table>

**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

Has **view-only** access to the submission

Principal Investigator, PI Proxy, Study Team Member

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 and Amendment workspaces are used actively during the review of that submission only. Once a determination is made (or the submission is discarded), Continuing Review and Amendment 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*

<table>
<thead>
<tr>
<th>Region</th>
<th>Information in this region</th>
</tr>
</thead>
</table>
| 1      | **Breadcrumb** Available in all workspaces, click the double arrow [⋙] to view the breadcrumb bar. This provides additional links to the parent page for each view. Use links to navigate to the following information:  
  - Safety listing workspace for all submissions  
  - Study name to navigate to the Initial/Main study workspace, or  
  - Submission name to navigate to the submission workspace. |
| 2      | **Status** Visible in all workspaces, the status region will show the current review status of the submission. |
| 3      | **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 Modification submissions for the study. |
| 4      | **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. |
| 5      | **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. |
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.
- **Project Contacts** List of study team members listed on the SmartForm, including current training information on file.
- **Documents** All documents submitted for review, with versioning information for each document.
- **Follow-on Submissions** Links to Continuing Review or Modification/Update workspaces for a study (only visible on the main study workspace) with quick access to all determination letters.
- **Related Projects** Quick links to any submissions in the ESTR-IRB and DUA-Agreements system that are related to the submission you are viewing. Related projects should be added or removed by using the Manage Related Projects activity.
- **Data Info & Reviews** Displays each data set described within the submission, its Harvard Data Safety Level, and all corresponding data storage locations.
- **Snapshots** View of the application at each change in state (for example, the appearance of the SmartForm between Specialist Review and changes submitted).

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:
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 assignment of appropriate training up to the reviewing School Security Officer.

The two most frequently assigned trainings are:

  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 in 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:

<table>
<thead>
<tr>
<th>Team Member Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter by Harvard-Fname</td>
</tr>
<tr>
<td>John Smith</td>
</tr>
<tr>
<td>Jane Doe</td>
</tr>
</tbody>
</table>

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**


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. Last day of continuing review period – 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.

d. Approval date – This value does not default and must be manually entered. Select the approval date or date review completed.

Tip: To quickly select today’s date, click the calendar icon (1) on the right side of the date field, then click Now (2):

e. Explanation (optional) – Include any additional notes about the approval of this submission here.

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. Generate a determination letter by clicking the **Generate** button (1).

   ![Prepare Letter](image)

   You can generate, upload, and revise a letter to the investigator here.

   **Generate a draft letter from template:**

   ![Generate a draft letter from template](image)

   **1. Draft letter:**

   ![Draft letter](image)

   **2. Commands:**

   ![Commands](image)

   **Tip:** You can edit the approval letter by clicking on the ellipsis followed by “Open in Word Online” (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.

   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.

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**Finding Determination Letters and Documents**

**To find determination letters**

1. Log in to [researchsafety.harvard.edu](http://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. Under the Activity Form tab (1), look at question 2, “Reason for Requesting Closure” (2)

**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.**

   ![Close Protocol button]

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.

**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 button only ONCE. The system will take a moment to display a pop-up window.
- If the pop-up window doesn’t appear automatically, check to confirm that your browser isn’t blocking pop-ups.
- If the pop-up displays a message that says, “Waiting to start the export. Your request is enqueued on the server,” leave the window open. Your export will begin once the report ahead of it is finished. Closing this window will not cancel your export, it will only limit your access to the export link.
- If no other exports are pending, the pop-up will begin counting items in the anticipated file.
- Once the export is done, a link will appear. Click the link to download the exported list.
Finding More Information

<table>
<thead>
<tr>
<th>Resource</th>
<th>Description</th>
<th>How to Access It</th>
</tr>
</thead>
<tbody>
<tr>
<td>Help for a field or page</td>
<td>More information about a question or form.</td>
<td>Click 📝 next to the question or at the top of the form.</td>
</tr>
<tr>
<td>Help system</td>
<td>The full online help system, with search and table of contents. The online help contains procedures and information for all users.</td>
<td>Click the Help Center sub-menu link at the top of the screen.</td>
</tr>
<tr>
<td>Safety Submission Guide</td>
<td>Instructions for submitting a protocol for review.</td>
<td>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.</td>
</tr>
<tr>
<td>Safety Reviewer / Specialist Guide</td>
<td>Instructions for reviewing a submission.</td>
<td></td>
</tr>
<tr>
<td>Data Safety Support</td>
<td>External website with additional information about using the Safety system</td>
<td><a href="https://ras.fss.harvard.edu/data-safety">https://ras.fss.harvard.edu/data-safety</a></td>
</tr>
<tr>
<td>Data Safety Help Desk</td>
<td>Contact for help with access and use</td>
<td><a href="mailto:rshelp@harvard.edu">rshelp@harvard.edu</a></td>
</tr>
</tbody>
</table>
| OVPR, HUIT and Support Websites | Information about the review process and requirements                     | • Office of the Vice Provost for Research: [https://vpr.harvard.edu/pages/harvard-research-data-security-policy](https://vpr.harvard.edu/pages/harvard-research-data-security-policy)  
• Harvard University Information Technology: [https://security.harvard.edu/](https://security.harvard.edu/)  
• Research Data Management at Harvard: [https://researchdatamanagement.harvard.edu/](https://researchdatamanagement.harvard.edu/) |