Table of Contents
Logging In ...................................................................................................................................................... 3
Accessing a Submission .................................................................................................................................... 3
Communicating with Staff and/or Study Team ............................................................................................ 6
Finding Determination Letters and Documents .......................................................................................... 6
Generating Standard Reports ....................................................................................................................... 8
Find More Information ................................................................................................................................. 9
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.

Accessing a Submission

You may want to go to a specific submission. 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. As a viewer, the actions you can take will be very limited.

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, 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 protocol 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.
Submission Workspace Overview

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

- The Initial/Main Protocol 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.

**Important!** Guest access is managed separately for each protocol, amendment, and continuing review. View access to the protocol does not automatically grant access to any related amendments or continuing reviews.
## Workspace Regions

*Image displays the Initial/Main Protocol 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  
  • Protocol name to navigate to the Initial/Main protocol 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 protocol workspaces only: Creating new Continuing Review or Modification submissions for the protocol. |
| 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 protocol. |
| 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 protocol workspace shows all current approved details (including documents and protocol 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 protocol 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 protocol (only visible on the main protocol 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 can 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).

### Communicating with Staff and/or Study Team

You can complete the **Add Comment** activity to post a note to the submission history that all individuals with access to the submission may view.

**Important!**

- Completion of this activity DOES NOT send an email or notice; it only records a note on the submission history.
- The information in these activities is visible to all individuals with access to the submission, even if they are not selected as notice recipients.
- Do not attach items which are part of the review.

### 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](http://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. There are two ways to view study documents:
   a. Download documents from the Study Workspace
      i. Click on the Documents tab on the main protocol workspace.

      ii. 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.”

   b. View documents in Office Online
      i. Click “View Protocol” to enter the protocol SmartForm and navigate to the page where documents are uploaded.

      ii. Click the ellipsis to the right of the document name, then select “View in Word Online.”
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 protocol 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.
Find 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/) |
This guide is a site-specific, edited version of materials originally produced by Huron Technologies, Inc.

© 2012-2015 Huron Technologies Inc. All rights reserved. Use and distribution prohibited except through written agreement with Huron.

Click is a registered service mark of Huron Consulting Group, Inc. All other trademarks, registered trademarks, service marks, and trade names are the property of their respective owners.

Information in this document is subject to change without notice.

Published by Huron Technologies Inc.
1925 NW AmberGlen Pkwy
Suite 400
Beaverton, OR 97006