

Data Safety Viewer Guide

Data Safety and Security System

December 8, 2023

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.....	7
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.

Dashboard	Portal	Agreements	OAIR	IRB	Safety
Submissions	Meetings	Reports	Help Center		

Safety Submissions											
Create Safety Submission											
Pre-Submission		In Progress		Active		Archived		All Submissions		Discarded or Suspended	
Filter by ID Enter text to search + Add Filter × Clear All											
ID	Name	PI FName	PI LName	Modified Date	Project State	Type of Submission	Department	School	Follow-on Dept	Follow-on School	Specialist
DAT22-0225	Saif test 1	Neil	Pearl (saf-pi)	7/21/2022 10:52 AM	Closed	Initial Protocol	Wyss Institute [HUA]	Harvard University-Area			Lee (saf-rev)

Tips:

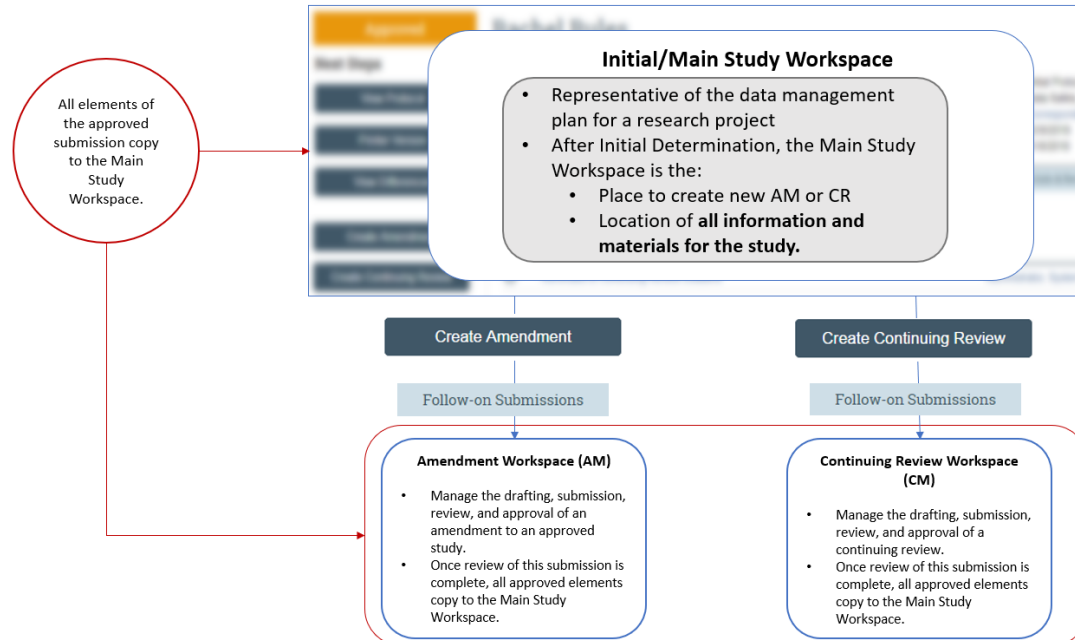
- Try filtering this list by the protocol name or Principal Investigator. Next to **Filter By**, select **Name** or **Investigator**. Then type the beginning of the name and click **Go**.
- View the **State** column to see where a submission is in the review process.

Submission Workspace Overview

The Initial/Main 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

1 Approved

Next Steps

2 View Protocol

Printer Version

Create Amendment/CR

3

4

5

6

Benefits of Corgi pets on Medicare enrollees
DAT23-0026

Principal Investigator: Aston Martin (PI) **Submission Type:** Initial Protocol
Specialist: Serena Williams (SafeS) **Department:** Physical Medicine and Rehabilitation- Harvard Medical School [HMS]
Primary Contact: **Approval Date:** 11/15/2023
Safety Review Type: Data Safety and Security **Approval End Date:** 12/6/2023
PI Proxies: There are no items to display **Initial Letter:** [Correspondence_for_DAT23-0026.pdf\(0.01\)](#) ...
 Visit the Follow-on Submissions tab for letters after initial approval.

This project is related to one or more Agreements. Visit the Related Projects tab for details.

Activity	Author	Activity Date
Ancillary Review Submitted Test submitting on behalf of OVPR	Lyle-Beshai, Katie L	11/21/2023 3:32 PM
Managed Related Projects	Williams (SafeS), Serena	11/21/2023 3:27 PM

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: • <u>History</u> Information about each action taken on a submission and in-brief view of comments. • <u>Documents</u> All documents submitted for review, with versioning information for each document. • <u>Contacts</u> List of study team members listed on the SmartForm, including current training information on file. • <u>Snapshots</u> View of the application at each change in state (for example, the appearance of the SmartForm between Specialist Review and changes submitted). • <u>Follow-on Submissions</u> Links to Continuing Review, Amendment, or Amendment/CR workspaces for a study (only visible on the <i>main study workspace</i>). For easy reference, the tab also displays the name of the assigned specialist for each of the follow-on submissions. • <u>Data Info & Reviews</u> 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. • <u>Related Projects</u> 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.

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.

In the activity, pop up: Choose notice recipient(s) to also notify individuals of the comment.

3. Who would receive an e-mail notification:

Only choose 'safety specialist' if a person is assigned to this review.

Role Name
☐ PI/PI Proxies/Primary Contact
☐ Protocol Team Members
☐ Safety Specialist

Important!

- 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.
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.

Safety Review Type: Data Safety and Security
Letter: [Correspondence_for_DAT19-0024.pdf\(0.01\)](#)

OR

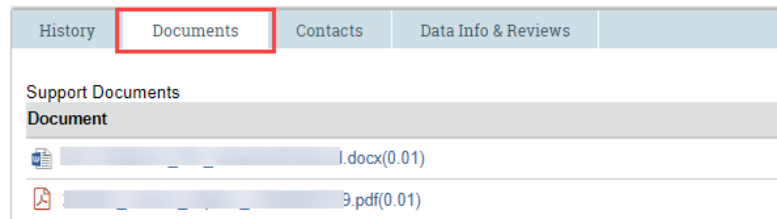
1. Log in to researchsafety.harvard.edu.
2. Navigate to an approved submission (See [Accessing a Submission](#) for more instructions).
3. Click the Follow-on Submissions tab and click the Correspondence Letter link to see any/all Modification or Continuing Review letters. To **view** a letter, simply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

Documents	Follow-on Submissions	...
Enter text to search for Q + Add Filter x Clear All		
Date Modified	Correspondence Letter	
for DAT19-0024 10/28/2019 12:34 PM	Correspondence_for_CR19-0024-01.pdf(0.01)	

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.

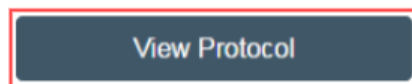


- ii. Click on the appropriate document link to view the version you're looking for. To save a document, right click and select "Save Link As."

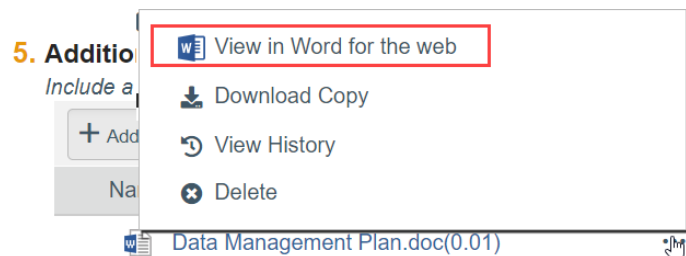
Document	Date Modified
Generic Text Doc.txt	10/28/2019 11:58 AM

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

Next Steps



- ii. Click the ellipsis to the right of the document name, then select **View in Word for the web**.



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.

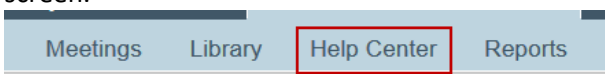
To generate a standard report:

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.

Find 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.