Cross-Suite Mini-Guide

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Viewing Agreement Details

Depending on your role or the actions required, you may need to view detailed information provided as part of the submission.

- To view the details of a submission
 - Navigate to the submission (see <u>Finding Submissions</u> for more instructions).
 - Read through the submission details (see <u>Viewing Submission Details</u> for more instructions).
- View activity history
 - View the history tab on the submission workspace for information regarding each action taken on a submission and in-brief view of comments or activity attachments.
 Information under the history tab can be useful in reviewing activity and notes regarding ancillary reviews.
- View agreement documents, information regarding review, negotiations, and tracked elements
 - From the submission workspace, you can view a list of all the attached documents in one place by clicking on the Agreement Documents tab. Click on the ellipsis next to each document for options to view the document within the browser or download a copy to your computer. Under this tab, you will also find information entered during review, negotiations, as part of ancillary or tracked elements.

Viewing Safety Protocol Details

Depending on your role or the actions required, you may need to view detailed information provided as part of the submission.

- To view the details of a submission
 - Navigate to the submission (see Accessing a Submission for more instructions).
 - Read through the submission details (see <u>Reviewing a Submission</u> for detailed instructions).
- View documents associated with a submission.
 - From the submission workspace, you can view a list of all the attached documents that
 were included in the submission by selecting the **Documents** tab. Click on the ellipsis
 next to each document for options to view the document within the browser, download
 a copy to your computer or view its history.
- View study team members training details
 - o From the submission workspace, you can view a list of all individuals with completed data security training under the **Contacts** tab. 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. If the study team is listed in the protocol SmartForm, completed trainings will be listed beside each individual's name.

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Note: 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. Please navigate to reports (see Finding Training Records on a User Profile).

View data details and reviews

 From the submission workspace, click on the **Data Info & Reviews** tab to view information on each data set described within the submission, including its Harvard Data Safety Level, and all corresponding data storage locations.

Viewing IRB Submission Details

To begin reviewing a submission, log in to irb.harvard.edu and navigate to the submission.

- To view the details of a submission
 - See <u>Accessing a Submission</u> for detailed instructions on navigating through a submission.
- View documents associated with a submission
 - From the submission workspace, click on the **Documents** tab to view a list of all
 attached documents that were included as part of the submission. Click on the ellipsis
 next to each document for options to view the document within the browser, download
 a copy to your computer or view its history.
- View worksheets and checklists for reviewers
 - When a submission is assigned to Non-Committee or Committee review, IRB staff may suggest Worksheets or Checklists pertinent to the review by including them with the Pre-Review activity. From the submission workspace click on the **Reviews** tab to quickly view the latest pre-review, committee review, and data security level details. Further down, there are additional sections for Harvard Tracked Items which includes the Data Security Level.

Note: Please review the section on <u>Locating the Reviewer To-Do List</u> and <u>Navigating</u> <u>through Meeting Agenda</u> section of the IRB Reviewers guide for a more detailed step-by-step guide.

- View study team and current active training
 - From the submission workspace, click on the Contacts tab for current active training information, training expiry dates and date modified information for everyone.

Note: If the Current Active Training is blank, it means the individual does not have current active training.

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Finding More Information

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Resource	Description	How to Access It
Help for a field or page	More information about a question or form.	Click the question mark icon ② 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 in each of the respective applications covered above. Dashboard Portal Agreements Submissions Meetings Library Institutional Profiles Reports Help Center
Submission Guides	Instructions for submitting IRB Submission, Safety Protocol or DUA 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.
Reviewers' Guides	Instructions for reviewing an IRB, Safety or DUA submission.	
Additional Support	External website with additional information about using the different systems.	https://ras.fss.harvard.edu/agreements https://ras.fss.harvard.edu/data-safety https://ras.fss.harvard.edu/estr
Help Desk	Contact for help with access and use	duahelp@harvard.edu rshelp@harvard.edu estrhelp@harvard.edu
Reviewing Office Websites for Agreements	Information about the DUA review process and requirements	 Harvard T.H. Chan School of Public Health: Sponsored Programs Administration (SPA) Harvard Medical and Dental Schools: Office of Research Administration (ORA) – Research Data Management University Area, all other Harvard schools: Office for Sponsored Programs (OSP)
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/
IRB Websites	Information about the IRB review process and requirements	 HMS, HSDM, and HSPH (Studies in Longwood Area only) at hsph.harvard.edu/orarc/irb FAS, GSE, HKS, HBS, SEAS, HLS, GSD, HDS, and Radcliffe Institute (Studies in University Area only) at cuhs.harvard.edu

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