

DUA Ancillary Reviewer Guide

Agreements System

December 8, 2023

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Ancillary Review Overview

Ancillary reviews allow individuals, departments, offices, and other additional reviewers to give feedback, approval, and/or provide documentation on the submission in parallel with the agreement review. During review, the owner/reviewer will manually select the reviewer or reviewing organization/department each time a review is needed or required. Ancillary reviewers can be added to an initial agreement or an amendment.

Ancillary review can be assigned from pre-submission through internal/external review. An ancillary reviewer can only complete their approval activity during this time (between pre-submission and internal/external review). If an ancillary review is left incomplete upon approval/activation, it can no longer be completed on that submission.

Assigning ancillary review is a useful tool for identifying the following necessary reviews on a submission which either a) must be recorded and tracked as a separate and specific review type; or b) if the ancillary reviewer must access the submission to complete their review.

Important! Ancillary Reviews should be submitted before the Agreement submission is activated. Ancillary Reviews cannot be completed once the Agreement is active.

Types of Ancillary Review

Ancillary review can be used to track the following consultations or approvals during review of the agreement. In some cases, the DUA reviewer will use the Log Correspondence activity for unofficial recommendations.

Review Type	Ordinarily required, if applicable
Information Security Consultation	Yes
Local SSO Review	Yes
Local IT Review (such as for resources/ provisioning)	No
IRB Consultation	No
Export Control Consultation	Yes
COMS Consultation	No (could be Yes, if DURC)
Provost Consultation	Yes
OGC Consultation	Yes (in some cases – it is sought but not required)
OTD Consultation	Yes (in some cases – it is sought but not required)
Department / School Consultation	No (unless there are unusual risks or substantial charge)
GDPR-Based Evaluation	No
Radiation	No
Safety	No

Review Type	Ordinarily required, if applicable
Scientific	No

While the management of ancillary review can be completed by the DUA team, the best practice is for only the reviewing/submitting office to complete these activities. The owner/reviewer can assign an ancillary review for the reviewer to complete approval or they can record an ancillary review on behalf of the reviewer.

Logging In

The Agreements 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 dua.harvard.edu.
3. Ensure the correct log in 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 Agreements system, to your personal workspace.

If you are unable to log in, contact the DUA Help Desk at duahelp@harvard.edu.

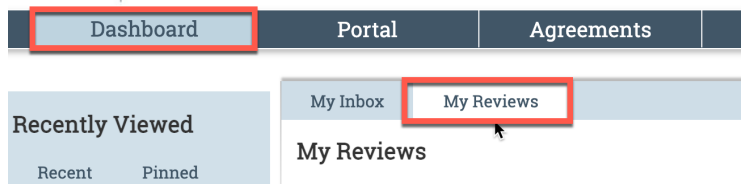
Accessing a Submission

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

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

To find a list that includes the submission name:

- **My Reviews** (only items that require review): Click the **Dashboard** link in the top navigation header and the **My Reviews** tab on the Dashboard. (The **My Inbox** list displays submissions assigned to you for action, such as submissions you are preparing to submit or items where you need to submit response to a requested clarification.)



OR

- **Agreements** (all items to which you have access in the Agreement System): Click **Agreements** in the top navigation header and select the **All Agreements** tab. The lists display workspaces for all

agreements and amendments entered into the agreements system that you have permissions to view.

Agreements

Create Agreement

Pre-Submission In Progress Active Archived All Submissions

Filter by [?] ID Enter text to search + Add Filter ✕ Clear All

ID	Name	Agreement	Agreement Type	PI (First)	PI (Last)	Contracting Party
DUA19-0812AM1	Amendment for Decision-making impairments in OCD 1	Data Use Agreements		Jennifer	Lerner	Massachusetts General Hospital

Tips:

- Try filtering this list by the submission name or Principal Investigator (PI) last name. 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 the submission is in the review process.

Submission Workspace Overview

Initial/Main Agreement and Amendment submission workspaces are formatted similarly. However, the following general concepts apply to navigation:

- The Initial/Main Agreement workspace (labeled with numbers DUA##-####) always has the most current approved information and materials for an agreement.
- The Amendment workspace (webpage) is used actively during the review of that submission only. Once a determination is made (or the submission is discarded), Amendment workspaces are used for reference only and should not be the go-to location for DUA information.

Workspace Regions

Image displays the Initial/Main Agreement workspace for reference.

The screenshot displays the Initial/Main Agreement workspace with the following regions and components:

- Top Navigation Bar:** Dashboard, Portal, Agreements, OAIR, IRB, Safety.
- Sub-navigation Bar:** Agreements, Help Center, Reports.
- Pre-Submission Region (1):**
 - Primary Contact: Aston Martin (PI)
 - Principal Investigator: Aston Martin (PI)
 - Owner:
 - Created: 11/28/2023 5:55 PM
 - Received:
 - Modified: 11/28/2023 6:23 PM
 - Effective:
 - Expires:
- Next Steps Region (2):**
 - Edit Agreement
 - Printer Version
 - View All Correspondence
- Test Data Use Agreement Region (4):**
 - Submission ID: DUA23-0054
 - Office: OSP
 - Submission Type: Initial Agreement
 - Department: Architecture- Graduate School of Design [GSD]
 - Agreement Type: Data Use Agreements
 - Contracting Party: NIH/NIMH
 - Flowchart: Pre-Submission → Unassigned → In Review → Signing → Active. Clarification Requested loops back from Unassigned and In Review.
- Important! Region (5):**

Important! The submit activity must be completed for review to begin. Only the Principal Investigator, Proxy, or Primary Contact can see and complete the submit activity on the left.
- Activities Region (3):**
 - Submit
 - Manage Ancillary Reviews
 - Manage Admin Contacts
 - Assign PI Proxies
 - Discard
 - Copy Agreement
 - Manage Related Projects
 - Add Comment
- History Region (6):**
 - Filter by: Activity
 - Enter text to search
 - Clear All
 - Activity Log:

Activity	Author	Activity Date
Changes Made	Martin (PI), Aston	11/28/2023 6:23 PM
Managed Related Projects	Martin (PI), Aston	11/28/2023 6:12 PM
Managed Related Projects	Martin (PI), Aston	11/28/2023 6:12 PM
Managed Related Projects	Martin (PI), Aston	11/28/2023 6:10 PM

Region	Information in this region
1	Status Visible in all workspaces, the status region will show: - The status of the submission once it is created and through the review process, - Information about when a submission was sent to the ORA/SPA/OSP and updated, - The name of the Primary Contact/Creator, Principal Investigator, and Owner/Reviewer, - Effective and expiration dates for reference, as applicable.
2	Next Steps Visible in all workspaces, this set of blue buttons allows for: - Editing or viewing the current submission SmartForm, - Displaying a printer version, and - On Initial/Main Agreement workspaces only: Creating new Amendment submission for the agreement.
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 agreement. Mostly, activities displayed take action on the submission only. Some activities, including Assign PI Proxy is only visible on the Initial/Main Agreement workspace.
4	Submission Overview This section displays the following submission-specific items for reference: - Number and name of the submission/workspace being viewed - Submission and agreement type

Region	Information in this region
	• Agreement office, school, Department and Contracting party • Image of the state of review for the submission. Note that when viewing an Initial/Main Agreement workspace the image may indicate “Active” while an associated amendment submission is under review. • Amendment workspaces only: A link to the Initial/Main Agreement will show at the top of this section.
5	Notification Area • When the record has not yet been submitted for review, reminder to complete the submit activity displays in this space. • ORA/SPA/OSP and ancillary reviewers see a section summarizing ancillary review status.
6	Submission Tabs On a submission, the Initial/Main Agreement workspace shows all current approved details (including documents and contacts) while all amendment submission workspaces display information that was proposed at the time of review. Click on tabs to view: • <u>History</u> Information about each action taken on a submission and in-brief view of comments or activity attachments. • <u>Contacts</u> List of all individuals associated with this agreement: The Owner/Reviewer, Contracting Party, PI/Agreement Manager, Creator, team members as listed on the SmartForm, and guests who have access. • <u>Snapshots</u> View of the application at each change in state (for example, the appearance of the SmartForm between internal review and changes submitted). • <u>Amendments</u> Only if there are any amendments associated with the Initial/Main Agreement, links to all associated amendments are listed. • <u>Related Projects</u> A list of Agreement, Data Safety or ESTR-IRB items associated with this request. This list is managed via the “Manage Related Projects” activity. • <u>Agreement Documents</u> A list of all drafted and signed documents. Review details, including Highlighted Terms, the Data Security Level and specific regulatory elements are also listed here, as identified and as applicable. Additionally, information about the party that is providing the data, the number of years data access is requested, and whether data is stored or managed at/by Harvard. • <u>Communication</u> Summary information about any correspondence logged. Visibility into correspondence (and the ability to manage correspondence status) is based on your role on the submission or how you are associated with the correspondence.

Reviewing a Submission

To view the details of a submission:

1. Navigate to the submission (see DUA Reviewer Guide section on [Finding Submissions](#) for more instructions).
2. Read through the submission details (see DUA Reviewer Guide section on [Viewing Submission Details](#) for more instructions).

Viewing Submission 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:

1. From Dashboard, click the name of the submission to open it.
Note: If the submission does not appear in your inbox, see the DUA Reviewer Guide section on [Finding Submissions](#).
2. View the SmartForm.
 - a. Page by page, with linked documents:

For an initial submission, click **View or Edit Agreement**.

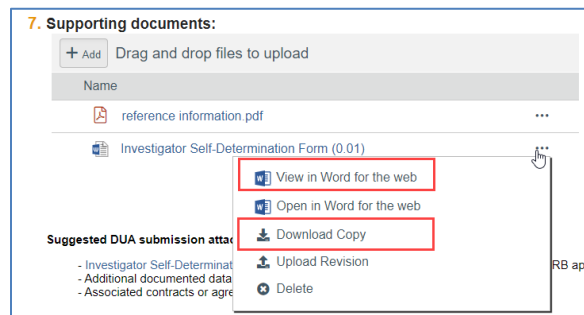
For an amendment, click **View or Edit Amendment**.

Use the Continue and Back buttons to view all of the pages and attachments.

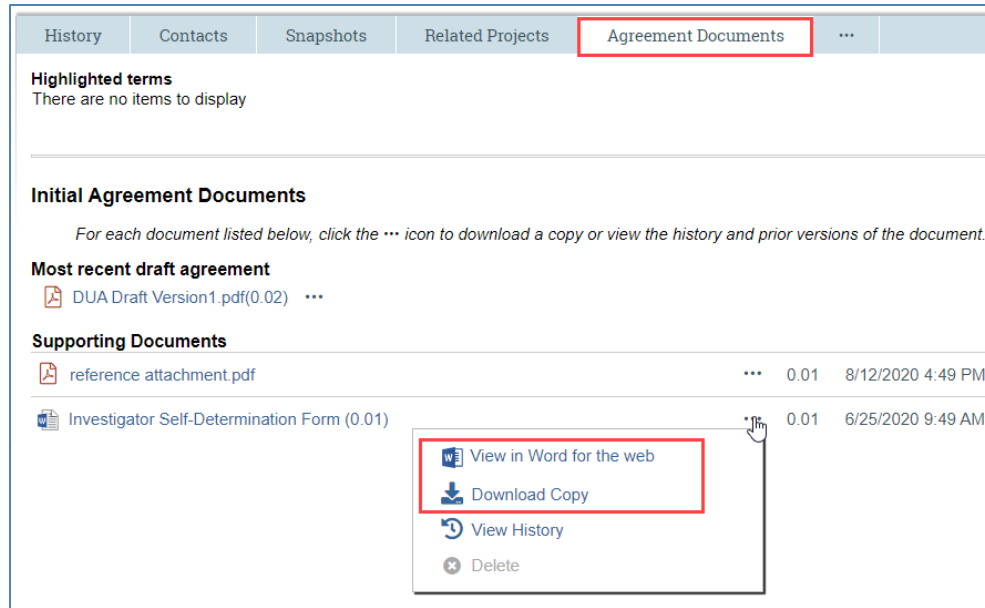
OR
 - b. As one page with linked documents, click **Printer Version**.

To view the documents included as part of the submission, you have these options:

1. While viewing the details of the agreement submission (as instructed above), click the **ellipsis** next to each document when you encounter it on the various forms. Select the **View in Word for the web** option to view the document within the browser or the **Download Copy** option to save a copy to your computer. Documents are listed on page(s) of the SmartForm.



2. When you have opened the submission workspace (as in step 1 above), you can view a list of all the attached documents in one place by clicking the Agreement Documents tab. Clicking the **ellipsis** next to each document will give you the option to view the document within the browser or to download a copy to your computer.



Note: The **View in Word for the web** option is only available for Microsoft XML documents (file extensions .docx, .xlsx, .pptx, and .vsdx). Documents in other formats must be downloaded for review.

To view the information entered during review, negotiations, as part of ancillary or tracked elements:

1. Open the submission as instructed in step 1 above.
2. View Ancillary notes on the workspace, under the workflow diagram.
3. View any review activity and notes on the History tab.
4. View tracked elements on the Agreement Documents tab.

Requesting Additional Information on a Submission

During the course of your ancillary review, if you would like to request changes to the agreement or to provide additional information, you can:

- Communicate via separate email messaging, outside of the system and until information is received.

OR

Communicate via the comment space in the **Submit Ancillary Review** activity. (see [Submitting an Ancillary Review Decision](#) for more instructions).

Additionally, you have the option to complete the **Add Comment** activity to:

- Post a comment on the agreement history that all individuals with access to the agreement may view.

 **Add Comment**

Note: Adding comments on the agreement will NOT send notifications to any other collaborators involved in the agreement.

Submitting an Ancillary Review Decision

The procedures below assume that the DUA team has completed any needed revisions and review is complete.

Important! Ancillary Reviews should be submitted before the Agreement submission is activated. Ancillary Reviews cannot be completed once the Agreement is active

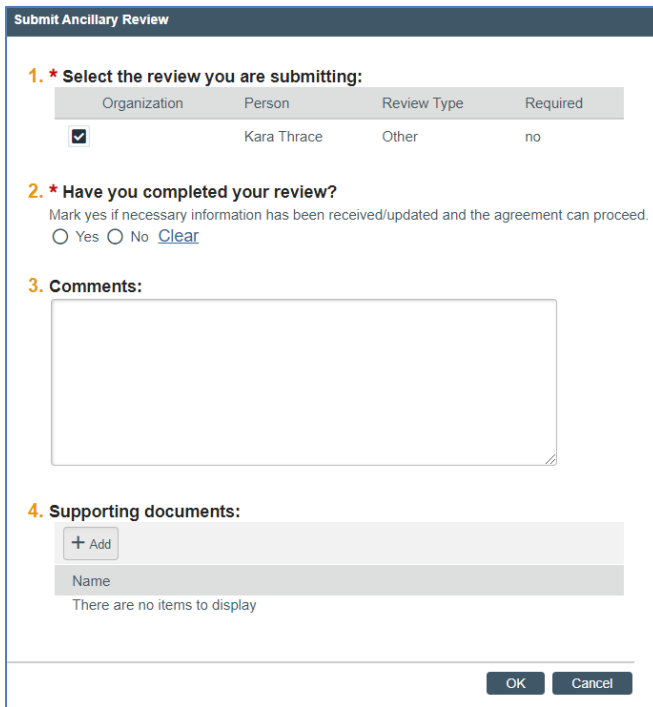
Important! If you do not complete the ancillary review and refer it to another person or group instead, you should contact the Owner of the Agreement so that they can manage the ancillary reviews as appropriate.

To complete an ancillary review:

1. Navigate to the submission (see [Accessing a Submission](#) for more instructions).
2. From the submission, Click **Submit Ancillary Review** on the left. A pop up window will open with questions.

 [Submit Ancillary Review](#)

- If you have received a notification that Ancillary review is required, but you are unable to locate the above activity contact the Owner/Reviewer for more information about what documentation or approval may be required.
 - If the Owner/Reviewer is recording an ancillary determination on behalf of the reviewer, the Manage Ancillary Approvals activity will be used to update the review type.
3. Complete the questions in the activity form:



1. * Select the review you are submitting:

Organization	Person	Review Type	Required
☒	Kara Thrace	Other	no

2. * Have you completed your review?
Mark yes if necessary information has been received/updated and the agreement can proceed.
☐ Yes ☐ No [Clear](#)

3. Comments:

4. Supporting documents:

[+ Add](#)

Name
There are no items to display

OK Cancel

Question 1: Select the review you are completing from the list.

Important! For review types indicated as required (Required column reads: yes), your approval is required before DUA review can be completed.

Question 2:

Mark "Yes" if your review is complete and the agreement or amendment may be activated/approved.

Mark “No” only if you must communicate information to the DUA team or Owner/Reviewer and the information is mandatory before your review can be completed. Marking “No” on a required review will still block the agreement from activation/approval.

Question 3: Fill in a comment, if one is available.

Question 4: Attach any relevant information or documentation.

4. Click **OK**.

Upon completion of this activity, the system sends a notification of review update to the submission creator and Owner/Reviewer. Additionally, the review and comments completed here are shown on the History to everyone who can access the submission.

Generating Standard Reports

The Agreements system includes standard reports to help you find relevant submissions and understand the overall operation of the Agreement offices.

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 submissions visible to the individual because of their role in the system or on a submission.

To generate a standard report:

1. Click **Agreements** in the top navigator.
2. Click **Reports** on the left.

The list of standard reports appears.

3. Identify the report to generate and click the link.

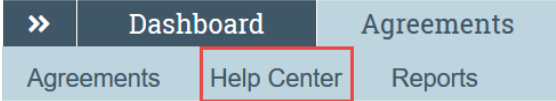
The report appears, listing the relevant submissions.

Tips:

- Try filtering the list by status. Next to Filter by, select **Status**. Then type the state to view, such as **Active** for an agreement and click **Go**.
- When using the **Export** option, it is very important to only click this button once. The pop up takes a moment to appear. Clicking Export multiple times may cause many requests to queue, block your actual export request. If you receive a “your request is in queue...” message, it means that someone else is running an export also. Leave that pop up window open and the export will begin via that window as soon as the previous request is complete.

If you or members of your office **require special access** to multiple studies or reports for a department or school, please contact your reviewing office or duahelp@harvard.edu for special access.

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. 
DUA Agreement Submission Guide	Instructions for submitting an agreement 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.
DUA Agreement Reviewer's Guide	Instructions for reviewing an agreement submission.	
Agreement Support	External website with additional information about using the Agreements system	https://ras.fss.harvard.edu/agreements
DUA Help Desk	Contact for help with DUA access and use	duahelp@harvard.edu
Reviewing Office Websites	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)

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