

# DUA Reviewer- Owner Guide

Agreements System

December 8, 2023

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## Agreements System Overview

### Submission Types

The agreements system treats both types of submissions—initial submissions and amendments—very similarly. You perform the similar types of activities and follow the same process for each, with small exceptions. The questions asked are different for each type of submission, but the workflow follows a similar path.

At the highest level, agreement submissions use the following general process workflow:



The system shows the appropriate diagram above when you view an individual submission and shows the current state of the submission in orange.

Agreements accepts these types of submissions:

- Initial submissions (new requests for DUA review)
- Amendments:
  - Revisions to documents that may require additional/updated signature.
  - Changes to the previously reviewed SmartForm contents that may not require additional DUA draft/signature but do require record update or review (such as changes to agreement contacts or in some cases, term extensions).

All submission types include possible ancillary reviews that can be conducted concurrently with the main review. The status of ancillary review is not reflected in the workflow image.

When an amendment is proposed, the review is managed in the agreement workspace. When the amendment review is complete, all approved changes on the amendment record are updated to the initial/main agreement workspace.

### DUA Review Process

The basic steps for an agreement (both initial submission and amendments) is listed in the following table. Required (Req.) steps are indicated in blue.

Step	Req.	Activity	Completed by	Resulting state	Step typically used for
1	*	Create Agreement or Create Amendment	PI/ DUA Team	Pre-Submission	Creation of a request for an agreement (DUA) or amendment to an existing agreement (DUA)
2	*	Submit	PI/ Creator/ Proxy	Unassigned	Official submission to the reviewing office to kick off the process after initial information is gathered.

Step	Req.	Activity	Completed by	Resulting state	Step typically used for
3	*	Assign Owner	Reviewer	Internal Review	<b>Assignment of reviewer among the reviewing office team(s)</b>
4		Request Clarifications	Reviewer	Clarifications Requested	To allow for the PI/DUA team to make revision and submit changes to the SmartForm or response to questions for further review. Note that the system will not allow completion of this activity if the Owner is not assigned.
5		Track Agreement Elements	Reviewer	No state change	Record of Harvard-required elements of an agreement. Can be completed in many phases of review, as needed.
6		Submit Changes	PI/ Creator/ Proxy	Internal Review	Re-initiate the review process with a response to requested changes or clarifications.
7		Generate Agreement	Reviewer	Internal Review	Only if an agreement draft is not included in the SmartForm. Generates an agreement pulling SmartForm data to a standard template format.
8		Revise Agreement	Reviewer	No state change	Update the draft (edit version) of the agreement as many times as needed. Can be completed in many phases of review, as needed.
9		Log Correspondence	Reviewer	No state change	Activity used to log communications or review To Do items of any type. Can be completed in many phases of review, as needed.
10		Manage Ancillary Review	Reviewer	No state change	Indication that an additional review is requested (may or may not be required to complete review). Can be completed in many phases of review, as needed. Note that PI/Creator can complete this activity also but only reviewer is expected to complete this step.
11		Email Agreement	Reviewer	No state change	Indication the agreement was email to another party (internal or external). Can be completed in many phases of review, as needed.
12	*	Move to External Review	Reviewer	External Review	<b>Point in time measurement of when an item is sent to an external</b>

Step	Req.	Activity	Completed by	Resulting state	Step typically used for
					<b>reviewing office for review/response.</b>
13	*	<b>Approve Language</b>	<b>Reviewer</b>	<b>Language Finalized</b>	<b>Indication agreement language has been finalized so the signing process can begin.</b>
14		Route for Signature	Reviewer	Routing for Signature	Indication agreement is in the process of being signed by various parties (intended to be used for internal signatures).
15	*	<b>Send out for Signature</b>	<b>Reviewer</b>	<b>Out for Signature</b>	<b>Indication agreement has been sent out to various parties for signature (intended to be used for external signatures).</b>
16	*	<b>Convert to PDF</b>	<b>Reviewer</b>	<b>Routing for Signature</b>	<b>Uploading of the official signed agreement converted to PDF format. Step required even if document is already PDF. Each time this activity is completed, a final version is added to the signed documents list.</b>
17	*	<b>Activate or Approve</b>	<b>Reviewer</b>	<b>Active</b>	<b>Indication the agreement is active and in force.</b>

**Note:** For a revision to the agreement record where a new signature is not required:

- The **Expedite Approval** activity may be completed by the reviewer on the amendment record. This activity only appears when there is no draft uploaded and on draft requested.
- The **Administrative Change** activity may be completed by the reviewer on the main agreement record (rather than completing a full amendment).

### Access to Submissions by Role

Access to a submission is personalized based on role in the system and the role one plays in relation to the particular submission. The following table summarizes the policies controlling the visibility of submissions (both Initial/Main Submissions and their Amendments):

System user role	Information visibility
Study staff	<p>Access to submissions that include you as the Principal Investigator/Agreement Manager, Creator, or Collaborator.</p> <p>Individuals with existing access to a submission can manage adding/removing access for other team members via an Amendment. The Amendment must be approved before permission are updated on the agreement.</p>

System user role	Information visibility
Agreement reviewing office staff	<p>Access to all submissions.</p> <p>Agreement staff and the site manager manage this access. Following official request sent to the <a href="mailto:duahelp@harvard.edu">duahelp@harvard.edu</a>, the site manager adds a system role to the individual person profile.</p>
Ancillary reviewers	<p>Full access to submissions assigned to you for review.</p> <p>Agreement reviewers manage this access by assigning or removing assignment via the Manage Ancillary Review activity.</p> <p>If a department requires group access, the site manager will manage this access. Following official request sent to the <a href="mailto:duahelp@harvard.edu">duahelp@harvard.edu</a>, the site manager adds reviewers to the appropriate department.</p>
Administrative office viewers, those with read-only access to all submissions reviewed by the reviewing office or which are associated with a particular department	<p>Read only access to all submissions associated with the reviewing office or department.</p> <p>Agreement staff and the site manager manage this access. Following official request sent to the <a href="mailto:duahelp@harvard.edu">duahelp@harvard.edu</a>, the site manager the individual to the department or school profile.</p>
Site manager	<p>Full access to all submissions.</p> <p>Current site manager manages this access on the person profile.</p>

## DUA Activity-Based Notices

Summary of activities that send notifications.

Activity Name	Description	Notice Recipients			
		PI	Creator/Proxy	Owner/Reviewer	Chosen on activity
Pre-Submission Reminder	Notice sent by the system when a submission is in pre-submission for one, five, and 10 days.	✓	✓		
Assign Owner	Notice sent when an Owner/Reviewer is assigned to the submission.	✓	✓	✓	
Request Clarifications	Notice sent when the Owner/Reviewer requests clarifications or revisions by DUA team.	✓	✓		
Response Time Exceeded	Notification sent by the system indicating that a response is pending. This is sent every seven days until changes are submitted.	✓	✓*		
Activate	Notice that an initial agreement is activated.	✓	✓		

Activity Name	Description	PI	Notice Recipients		Chosen on activity
			Creator/ Proxy	Owner/ Reviewer	
Approve <i>(and Expedite Approval, previously for Bypass Signatures)</i>	Notice that an agreement amendment is approved.	✓	✓		
Expiration Reminder	Notice sent by the system indicating if an expiration date is approaching. This notice is sent 30, 60, or 90 days prior to expiry.	✓	✓		
Notification of Expiry	Notice sent by the system indicating that the Agreement is past its expiration date.	✓	✓		
Submit Ancillary Review	Notice sent when an ancillary reviewer completes their review		✓	✓	
Submit Changes	Notice sent when the DUA team submits changes back for continued review			✓	
Contact Owner	Notice sent when a person with access to the submission wants to communicate with the assigned Owner/Reviewer			✓	
Email Agreement	Notice sent to the person selected in the activity.	✓			✓
Manage Ancillary Review	Notice sent to the assigned reviewer (or reviewer set for a chosen organization) for required ancillary reviews if “notify reviewers” is chosen on assignment.				✓
Log Correspondence or Edit Correspondence	Notice sent to a selected person only if “notify” is chosen on the activity.				✓

\*This notice is also sent to each person listed as an Agreement Collaborator.

### My Inbox Overview

The list called My Inbox, which appears on the Dashboard tab, contains submissions that require you (or your team members) to take action. See the examples below to understand what you should and should not expect to appear in My Inbox.

**Tip:** Look at the State column in My Inbox and see the explanation for that state in the table below.

Your role	In My Inbox		Not in My Inbox
	State	Explanation	
<b>Research team</b>			
PI/Agreement Manager, Creator or Collaborators	Pre-Submission	Complete the submission forms. The PI or Creator must complete the submit activity to let the review begin.	Submissions already in review
	Clarification Requested	Change the submission or clarification is needed. Opportunity to also provide summary notes to the reviewer when submitting the changes.	Approved submissions

Your role	In My Inbox		Not in My Inbox
	State	Explanation	
<b>Ancillary</b>			
Ancillary reviewer	One of several	You have been selected as a reviewer (either by name or representing a specific organization). In some cases, the reviewing office can begin its review before you submit your review. These submissions can also be accessed on the My Reviews tab on the Dashboard.	Submissions not yet submitted for review
<b>Reviewing office/Administrative staff</b>			
Agreement office staff	Internal Review	Newly submitted submissions appear in the Unassigned tab of the Submissions page. Once assigned to a reviewer, items will appear in that person's Inbox.	Items submitted but not yet assigned
	External Review, Language Finalized, Out for Signature, Route for Signature	Review and negotiation are in progress. You must proceed with coordinating party responses, obtaining signatures and complete activation/approval.	Submissions not yet submitted or assigned; and submissions where review is complete.

## Finding Submissions

To find submissions which are both assigned to you and others:

1. Click **Agreements** in the top left navigation area.



2. Click the tabs to view different types of filtered lists.

The image shows a table of filtered submissions under the 'My Office's Agreements' tab. The table has columns for ID, Name, Type, Office, Status, PI (First/Last), Department, School, Contracting Party, Owner Last Name, Modified Date, Date Submitted, and Expiration Date. Two rows of data are visible, both for PI Rebecca Simms.

ID	Name	Type	Office	Status	PI (First)	PI (Last)	Department	School	Contracting Party	Owner Last Name	Modified Date	Date Submitted	Expiration Date
DUA20-0343	Sports Injury Data - Golf	DSP	OSP	Terminated	Rebecca	Simms (PI)	Anthropology	Faculty of Arts and Sciences [FAS]	A.C. Ratschesky Foundation	Lemon (agrev)	4/22/2020 10:21 AM	4/21/2020 10:40 AM	4/25/2020
DUA20-0348	Sports Injury Data - Frisbee Golf	DSP	OSP	External Review	Rebecca	Simms (PI)	Korea Institute	Faculty of Arts and Sciences [FAS]	Kailon, Inc.	Lemon (agrev)	5/13/2020 12:33 PM	5/4/2020 1:50 PM	

Lists will only display the items to which you already have access, based on your role or office.

- **My Work List:** Submissions assigned to you as reviewer/owner which are in any state of review and where review is not yet complete. Only reviewing office staff can see this tab.
- **Unassigned:** Items submitted to your office that are not yet assigned to a reviewer/owner. Items can be assigned directly from this list by clicking the “Assign Owner” link. Only reviewing office staff can see this tab.

- **My Office's Agreements:** Submissions associated with your office in any state. Only reviewing office staff can see this tab.
  - **In-Review:** All submissions in any in-review state (such as unassigned, internal review, or out for signatures). Items listed here are associated with any reviewing office across the University. Any person accessing the agreements application can view this tab.
  - **Active:** All agreements in the Active state. Items listed here are associated with any reviewing office across the University. Any person accessing the agreements application can view this tab.
  - **Archived:** All submissions in the expired, terminated or discarded states. Items listed here are associated with any reviewing office across the University. Any person accessing the agreements application can view this tab.
  - **All Submissions:** All submissions in any state. This is a good tab to use if search is needed and the state of a submission is unknown. Items listed here are associated with any reviewing office across the University. Any person accessing the agreements application can view this tab.
3. Click on the ID or name of the submission to access submission details.

**Tips:**

- The tabbed lists can be filtered by some column heading, including by the submission name or principal investigator (PI). Next to Filter by, select Name or PI(Last). Then type the beginning of the name and click Go.
- Use the “%” symbol to replace portions of a name which are unclear or possibly not spelled correctly. This is called a “wildcard” character.
- View the **State** column to see where the submission is in the review process.

## Navigating Submissions

Once you open a submission, you see the webpage for this submission; also referred to as a “workspace”. The workspace is your access point for:

- Viewing the submission contents and details, including all actions performed on it
- Performing actions on the submission

The figure below identifies the key workspace elements that help you find your way around the agreements system and perform actions on the submission.

- 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 (labeled with numbers DUA##-####AM##). 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 shows the workspace for a 'Test Data Use Agreement'. It includes a navigation bar with 'Dashboard', 'Portal', 'Agreements', 'OAIR', 'IRB', and 'Safety'. Below the navigation bar are 'Agreements', 'Help Center', and 'Reports' tabs. The main content area is divided into several regions:

- 1 Pre-Submission:** A summary box containing submission details like Primary Contact (Aston Martin), Principal Investigator (Aston Martin), Owner, Created (11/28/2023 5:55 PM), Received, Modified (11/28/2023 6:23 PM), Effective, and Expires.
- 2 Next Steps:** A set of blue buttons for 'Edit Agreement', 'Printer Version', and 'View All Correspondence'.
- 3 Activities:** A list of actions such as 'Submit', 'Manage Ancillary Reviews', 'Manage Admin Contacts', 'Assign PI Proxies', 'Discard', 'Copy Agreement', 'Manage Related Projects', and 'Add Comment'.
- 4 Submission Overview:** A flowchart showing the submission process: Pre-Submission (highlighted in orange) → Unassigned → In Review → Signing → Active. There are also 'Clarification Requested' boxes between Unassigned and In Review, and between In Review and Signing.
- 5 Important:** A warning box stating: '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.'
- 6 Activity Table:** A table with columns for Activity, Author, and Activity Date. The activities listed are 'Changes Made', 'Managed Related Projects', and 'Managed Related Projects'.

Region	Information in this region
1	<p><b>Status</b> Visible in all workspaces, the status region will show:</p> <ul style="list-style-type: none"> <li>The status of the submission once it is created and through the review process,</li> <li>Information about when a submission was sent to the ORA/SPA/OSP and updated,</li> <li>The name of the Primary Contact/Creator, Principal Investigator, and Owner/Reviewer</li> <li>Effective and expiration dates for reference, as applicable.</li> </ul>
2	<p><b>Next Steps</b> Visible in all workspaces, this set of blue buttons allows for:</p> <ul style="list-style-type: none"> <li>Editing or viewing the current submission SmartForm,</li> <li>Displaying a printer version, and</li> <li>On Initial/Main Agreement workspaces only: Creating new Amendment submission for the agreement.</li> </ul>
3	<p><b>Activities</b> 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.</p>
4	<p><b>Submission Overview</b> This section displays the following submission-specific items for reference:</p> <ul style="list-style-type: none"> <li>Number and name of the submission/workspace being viewed</li> <li>Submission and agreement type</li> <li>Agreement office, school, Department and Contracting party</li> </ul>

Region	Information in this region
	<ul style="list-style-type: none"> <li>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.</li> <li>Amendment workspaces only: A link to the Initial/Main Agreement will show at the top of this section.</li> </ul>
5	<p><b>Notification Area</b></p> <ul style="list-style-type: none"> <li>When the record has not yet been submitted for review, reminder to complete the submit activity displays in this space.</li> <li>ORA/SPA/OSP and ancillary reviewers see a section summarizing ancillary review status.</li> </ul>
6	<p><b>Submission Tabs</b> 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:</p> <ul style="list-style-type: none"> <li><u>History</u> Information about each action taken on a submission and in-brief view of comments or activity attachments.</li> <li><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.</li> <li><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).</li> <li><u>Amendments</u> Only if there are any amendments associated with the Initial/Main Agreement, links to all associated amendments are listed.</li> <li><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.</li> <li><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.</li> <li><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.</li> </ul>

Once a determination is made on an initial submission, two things change about the initial submission workspace, also referred to as the “main agreement workspace”:

- The main agreement workspace is the webpage where all current information about the agreement is located, including the most current approved / signed documents and the current expiration date, as applicable.
- Amendment submissions that follow initial activation may be created from the main submission workspace.

## 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 **My Inbox**, click the name of the submission to open it.

**Note:** If the submission does not appear in your inbox, see [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**

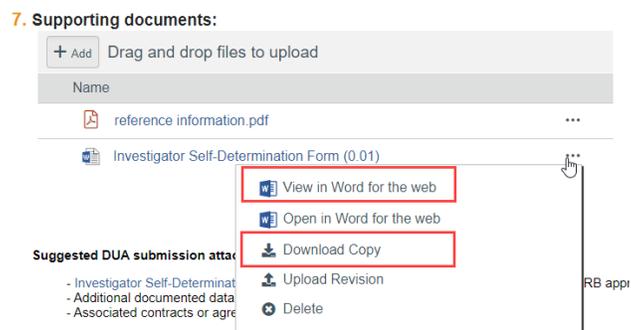
Use the Continue and Back buttons to view all of the pages and attachments.

OR

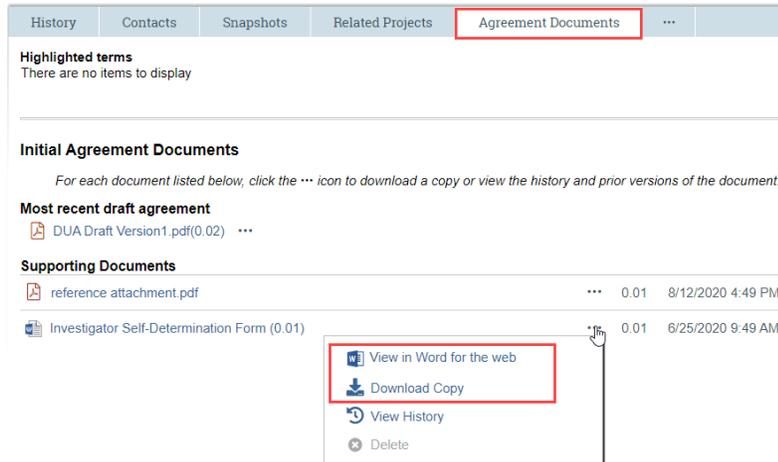
- b. As one page with linked documents, click **Printer Version**

### 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
3. View any review activity and notes on the History tab
4. View tracked elements on the Agreement Documents tab

## Assigning Ownership of a Submission

Before a reviewer takes action on a submission, the submission must be assigned to them. Any staff user with agreement reviewer permissions or higher can take ownership of the submission or assign it to another staff member. The submission can be reassigned at any point OR unassigned to return to the queue of submissions, as needed.

When an item is first submitted, it will appear on the Unassigned tab on the Submissions page (see [Finding Submissions](#) for information about navigating the Submissions page). The Unassigned tab is only visible to staff. After an owner/reviewer is assigned, only this assigned reviewer sees the submission in My Inbox as the submission is reviewed. The submission will move to and from the owner/reviewer in box as actions are taken in the review process.

**To assign an Owner/Reviewer:**

1. Open the submission.
2. Click **Assign Owner** on the left.
3. Select yourself or another staff member.
4. Click **OK**.

The reviewer gains access to activities that are reserved for the assigned reviewer and can move the submission through the process.

**To un-assign an Owner/Reviewer:**

*(and return the submission to the unassigned queue)*

1. Open the submission.

2. Click **Unassign Owner** on the left.  
This activity will only appear after an item is submitted but will not appear when a submission is in the Clarifications Requested state.
3. Click **OK**.

Even if an item is returned to the Unassigned state, the history of any completed review/negotiations are retained on the submission history.

**Note: The owner cannot be changed when a submission is withdrawn.** If a submission is assigned and then withdrawn, the owner cannot be changed via the Assign or Unassign Owner activities until the Submit activity is completed on the submission again.

## Reviewing a Submission

**To view the details of a submission:**

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

## Requesting Clarifications on a Submission

During your review, you can request that the DUA team make changes to the submission or provide additional information. Requesting clarifications sends the submission back to the DUA team so they can edit it.

Requesting clarifications should occur after an owner is assigned and is a useful tool for when the DUA team must initiate an external process or provide required information, including when:

- There are **missing required details** in the SmartForm or on the record (for example, if no IRB review information is attached to the SmartForm or the DUA team has not associated an IRB record via Manage Related Projects, or if there are other required internal/external approvals or training which the DUA team must obtain);
- There is **inconsistent information** between elements of the completed SmartForm which need to be clarified (for example, if the attached draft DUA indicates a different contracting party than the one indicated on the SmartForm);
- To **add a new item that was discovered during review** as missing or incomplete (for example, there were not additional collaborators listed but it was found that additional individuals should be listed); or
- To **obtain faculty sponsor or PI/Agreement Manager confirmation** of approval or approval of revised language.

The agreements system is the system of record for DUAs, so it is important to use these opportunities to ensure the submission is correct during review.

**To request clarifications:**

1. From **My Inbox**, click the name of the submission to open it.
2. Click **Request Clarifications** on the left.

### Next Steps



[← Request Clarification](#)

3. In the Request Clarification activity form, provide detailed questions or requests for changes.
4. **Note:** You can also attach documents that further explain and/or show suggestions for resolving the problems (e.g. a track changes Word document).
5. Click **OK** to send the request to the DUA team and to open the SmartForm for edits. You will receive an e-mail notification when the response is submitted to the clarification request.

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](#)

**Important!** Please consider that adding comments on the agreement will **NOT** send any notifications. To send notifications, make sure to include the comment when completing the Request Clarifications activity described above.

## Viewing Changes to a Submission

When a submission changes based on reviewer requests and a response is submitted, you can click **View Agreement** or **View Amendment** in the workspace to re-review the revised submission, or to look only at what has changed, you can:

1. View the response submitted for a particular request
2. View the differences between two versions of a submission

## SmartForm Compare

**To view the response submitted for a clarification request:**

1. From **My Inbox**, click the name of the submission to open it.
2. Click the **History** tab.

History	Contacts	Snapshots	Related Projects	Agreement Documents	...
Filter by <span>Activity</span> <input type="text" value="Enter text to search"/> <span>+</span> Add Filter <span>×</span> Clear All					
Activity	Author	Activity Date			
<a href="#">Changes Submitted</a>	Lemon, Rose	10/31/2021 4:50 PM	Thank you for advising on how I should edit the SmartForm. Changes are made and the attachment is updated. Thank you! Rose		

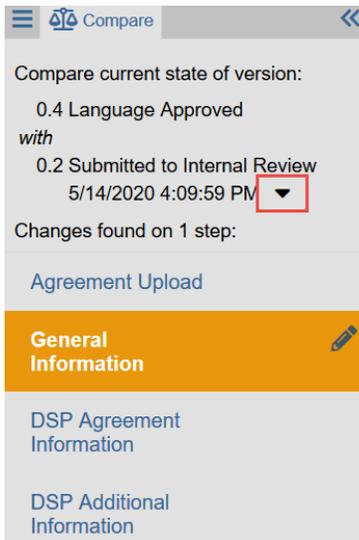
3. Click the **Changes Submitted** activity link to see any notes or documents added to the submission.

**To view the differences between two versions of a submission:**

1. From **My Inbox**, click the name of the submission to open it.
2. Click **Edit Agreement** on the left.
3. In the SmartForm, click the **Compare** tab on the left navigation.



4. Click the dropdown arrow to select a version to compare the current SmartForm to.



5. Look for the pencil icon next to the page(s) where changes have been made.
6. Click the pencil to jump to the page with changes. The changes since the version you selected will appear with the old values highlighted in a gray box.

## General Information

### 1. \* Select the contracting party:

MAC Services, Inc.

**RS** **Rebecca Simms (PI)** • modified 16 minutes ago • version 0.3 (Changes Submitted)

**Old Value:**  
A.C. Ratshesky Foundation

If you cannot find the organization in the list above, enter its information here:

**Contracting Party Name:**

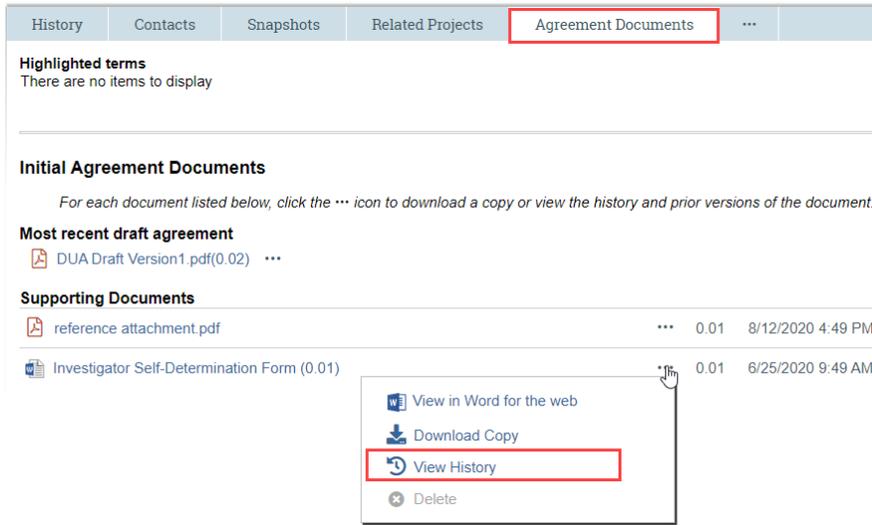
**Tip:** If the team updated the documents, they may contain tracked changes. You can use the review features in Word to toggle between showing the original and final versions of the document.

### Document Compare

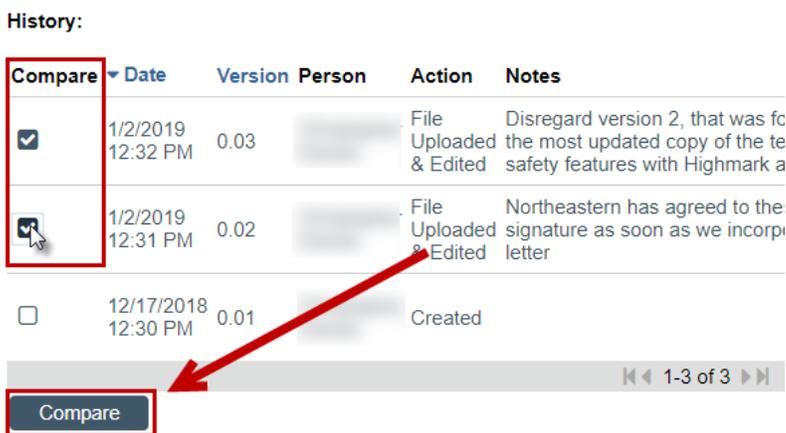
If a revised document is uploaded as a revision, each version of the document is stored on the document history. For Microsoft Office documents which support tracked-changes (such as Word), Two versions may be selected to generate a tracked version for review.

**To access document history and create a tracked-changes version:**

1. From **My Inbox**, click the name of the study to open it.
2. Click on the **Agreement Documents** tab
3. Click the **ellipsis** next to a document and select the **View History** option



4. In the pop up, choose two versions to compare (NOTE: If the same file was uploaded more than once, it will be assigned a new version number each time it is uploaded, but only the most recent version of the duplicated document will display in the document history.)
5. Click the **Compare** button



6. A pop up will appear to save the tracked version to your computer
7. Save the document and view the changes

**Snapshots**

A snapshot is a record of a submission at a particular point in history. The snapshot includes all SmartForm fields, along with attachments. Snapshots can be used to see what was previously reviewed or approved.

Snapshots (noted with camera icon here) are **taken at specific points during the review** of each submission:



Snapshots are taken at minor (ex. 0.1, 0.2, 0.3...) and major increments (ex. 1.0, 2.0, 3.0...). When viewing **snapshots on the tab in a workspace**:

History	Contacts	Snapshots	Related Projects	Agreement Documents	Communication
<b>Version</b>		Snapshot created when in this state and just before the submission moved to the next state because of an activity.		<b>State During Snapshot</b>	<b>Snapshot Taken</b>
Snapshot: 0.4(0.01)				... Clarification Requested	10/31/2021 4:50 PM
Snapshot: 0.3(0.01)				... Clarification Requested	5/25/2021 5:01 PM
Snapshot: 0.2(0.01)				... Pre-Submission	4/1/2021 10:53 AM

**Note:** Snapshots for amendments are only on the associated amendment workspace.

## Basic Administration Tasks

Agreement Owners/Reviewers members play a key role in moving a submission through the stages of review and communicating the results to the DUA team. Here are a few key activities in the process:

1. **Assign Owner.** Assigning each submission to an Owner/Reviewer is a crucial step to allowing further actions to be taken on the submission. Any reviewing/submitting office can assign an Owner/Reviewer, as described in [Assigning Ownership of a Submission](#).
2. **Track Agreement Elements.** Indicate highlighted terms and regulatory elements. This activity can be completed throughout the review but must be completed before the agreement can be activated. The best practice is to complete this activity with each review or update; however, tracking elements and terms may also be added on the **Activate** activity. In addition to a comment that will appear on the submission history and the data security level, the following items are available to select/indicate on this activity:

### Highlighted Terms

- Specific restrictions on naming data provider in publication
- Approved users must be named/approved by Data Provider
- There must be a designated Data Custodian
- Approved users are required to execute separate Confidentiality Agreement/ Joinder
- Restrictions on access by non-US persons
- Data provider requires special training for those who access the data
- Harvard requires special training for those who access the data
- Security/Background Screening Requirements
- Restrictions on combining data sets

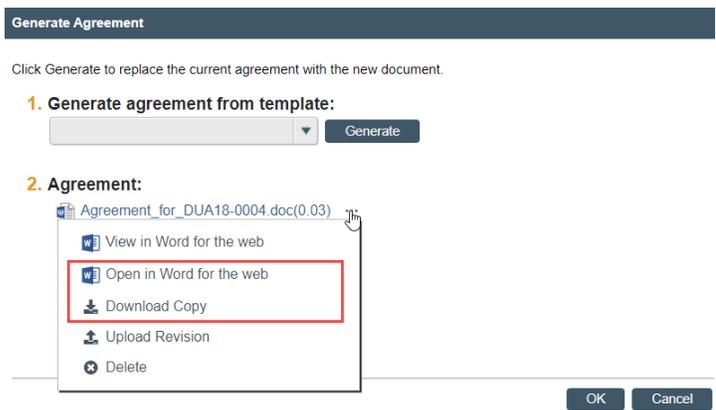
- Certificate of Destruction required
- Notification of breach to data provider less than 48 hours
- Unilateral actions required of Harvard beyond provider notification in event of breach
- Data Security Plan Addendum
- Archival copy authorized
- Destruction required
- Anonymization required
- None

**Tracking Elements**

- Export-controlled data (ITAR/EAR)
- FERPA-protected data
- HIPAA-protected data: Limited Data Set
- HIPAA-protected data: PHI (i.e. more than a Limited Data Set)
- Master Agreement
- Personally Identifiable Data (other than HIPAA/FERPA-covered)
- Subject to DOD requirements (e.g. Covered Defense Information)
- Subject to NIST/FISMA requirements
- Subject to GDPR
- Subject to banking/financial regulation
- Subject to China PIPL requirements
- State specific regulation applies per the terms of the DUA.
- Non-custodial agreement (i.e. the data will not be stored at Harvard)
- None

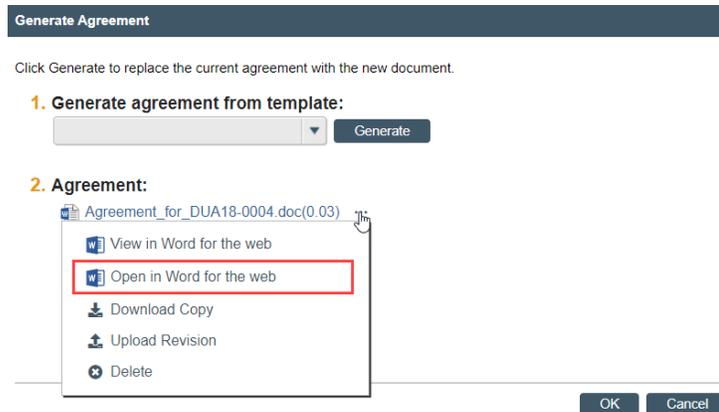
**Data provider agreement reference number or ID (if applicable):**

- Text-entry field for the reviewer to indicate the contracting party’s reference number for easier tracking and searching in Agreements. Information also displays on the Agreement Documents tab of the workspace.
3. **Generate Agreement.** When a draft version of the agreement is not included in the SmartForm, generate the agreement via this activity. Agreements generated will pull key information from the SmartForm into a Harvard template. To further edit the Agreement, you can click on the ellipsis next to the document you generated and select the **Open in Word for the web** option to edit the document in the browser or the **Download Copy** option to save the file to your computer for editing.



**Note:** If you edit the Agreement online, it will open in a tab in your main browser window. When you have finished editing the document, go back to the Generate Agreement activity pop-up and click OK to complete the activity.

4. **Revise Agreement.** When a draft agreement is generated, revised, or updated; upload iterations of the revised agreement via this activity, as the document is changed. The Revise Agreement activity allows you to upload a document from your computer or to edit the Agreement document directly in the browser. To edit the Agreement in the browser, click on the ellipsis next to the Agreement document and select the **Open in Word for the web** option.



**Note:** The **Open 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. If you edit the Agreement online, it will open in a tab in your main browser window. When you have finished editing the document, go back to the Generate Agreement activity pop-up and click OK to complete the activity.

5. **Move to External Review.** Indicates to all individuals accessing the submission that an external review (such as review by the contracting party) is in progress. The contracting party name and contact information can be updated as part of this activity.
6. **Email Agreement.** Documents attached and notes on this activity are included with the system notification. This is also a useful way to communicate with external and contracting parties where Log Correspondence cannot be used because an individual/email cannot be included.

When a contact is not visible in the selection menus in the activity:

a) Put your name in the To space, receive the email, and forward it to the external recipient. If a contact is not available and must be selected within the activity, please contact [duahelp@harvard.edu](mailto:duahelp@harvard.edu) for assistance;

OR

b) Use the *Use Email Client* link at the bottom left of the activity to use this feature. When your email client opens:

Do not delete/change the address that appears in the CC line (this is the system address: [dua\\_notification@harvard.edu](mailto:dua_notification@harvard.edu))

Do not delete/change the submission number tag in the subject (this will be the submission number and a colon (for example: "DUA12-5656: email subject"). You can add text to the right side of the colon; the submission number tag.



**Important!** An email recipient may reply to the message and one of two actions may occur:

**1) Inbound email/email catcher functionality is triggered:** If the system email is a recipient and the submission tag is in the subject of the email, the reply will be captured directly on the submission communication tab for further management (similar to logged correspondence). **You will only receive a notice that an email was captured if you are also included as a recipient of the email.**

If this happens, ensure any information/attachments are appropriately updated in the required spaces. For example, if you receive a fully signed agreement in this way, make sure that the current version is logged in the expected place in the system by viewing the draft agreement which may have been updated to confirm, or by downloading the emailed version and completing the revise agreement activity.

**Note:** With the inbound email/email catcher functionality; you can forward any email into the submission record's communications tab for further management as long as:

- The system email is a recipient ([dua\\_notification@harvard.edu](mailto:dua_notification@harvard.edu))  
AND
- The submission number is the start of the email subject (for example "DUA12-9989: title")

**OR**

**2) You receive the notice to your personal address only:** The reply contains revisions to the subject tag or the email catcher function did not work as expected (for another unexpected reason) and is delivered only to your email address. If this happens, ensure any information/attachments are appropriately updated in the required spaces, as needed.

7. **Administrative Change.** After initial activation, if the final executed agreement or if the main agreement supporting documents require minor update, complete an Administrative Change to upload revisions or add supporting documents. These changes only impact the active record and do not impact any amendments.

#### Administrative Change

8. **Terminate (or Close).** In many cases, an agreement will simply expire at the end of the term. However, it is possible to end the term of the agreement prior to the expiration date. There are two options for closing an agreement prior to expiration.

**1) The Owner/Reviewer can complete the terminate activity.** The agreement will immediately transition to the Terminated state. Terminate reasons allows for a space to confirm the different types of agreement term end reasons. The selected reasons appear under the terminated status on the workspace.

2) The Owner/Reviewer may request that **the DUA team submit an amendment to revise the period of the agreement.** When the amendment is approved by the Owner/Reviewer with the updated expiration date, the Initial/Main Agreement expiration date will update.

**Note:** Once an agreement is terminated, it cannot be re-initiated. DUA Teams can use the Copy Agreement activity to re-start an agreement review based off of the terminated agreement.

9. **Discard.** The Discard activity removes the submission from further consideration. This activity can be used when a submission was created in error or when Harvard or the contracting party has declined the agreement. This activity can also be used when the agreement negotiations have been on hold for a long time and the negotiator and study team agree that the agreement is unlikely to proceed. If negotiations for a previously discarded agreement resume, the Copy Agreement activity can be completed to copy the details of the agreement to a new submission where the review process may resume.

### Standard Review Activities

1. **Completing review of an initial DUA or DUA amendment that requires signature**

A submission has been received for review by the negotiating/submitting office.

Activity	Note
1. <b>Assign Owner</b> ☒	(required activity)
2. Request Clarifications ☒	Other review/negotiation activities may proceed while a submission is awaiting response from the DUA team. Changes must be submitted to move the submission states forward but cycle of “clarifications requested” can occur as many times as needed.
3. Generate Agreement	Only if an agreement draft is not included in the SmartForm or if the template is preferred.
4. Revise Agreement	Upload any edits to the agreement via this activity, including partially signed versions later in the process.
5. Manage Ancillary Review ☒	Notice sends only for reviews marked as required = yes. Any required review will not allow for completion of the “Approve Language” activity.
6. Move to External Review	Only after changes are completed and submitted by the DUA team. This activity does not send a notice.

Activity	Note
7. Email Agreement ☒	Via the internal properties OR your Outlook client (using the link in the upper left on the activity).
8. Log Correspondence ☒	Notice only sends if notify = true or a reminder date is indicated.
9. <b>Approve Language</b>	(required activity) Drafting/negotiations are done, signing process can begin. Blocked if any required ancillary reviews are not completed or are marked as not approved.
10. Track Agreement Elements	Record of Harvard-required elements of an agreement. Agreement elements may be added via this activity or via the Activate activity.
11. <b>Send out for Signature</b>	(required activity) Also complete Route for Signature if only Harvard signatures are pending. Activity does not send a notice, and only changes the state in the system.
12. Email Agreement ☒	To all necessary signing parties, including Harvard signatories. Activity may be completed multiple times.
13. <b>Revise Agreement</b>	(required activity) Upload the fully signed version.
14. <b>Convert to PDF</b>	(required activity) Adds a pdf copy to the signed documents list each time it is completed
15. <b>Activate / Approve</b> ☒	(required activity) Review complete

2. **Completing review of an initial DUA that is actually an amendment to a pre-system DUA**

A submission has been received for review by the negotiating/submitted office.

Activity	Note
1. <b>Assign Owner</b> ☒	(required activity) The previously signed DUA must be included in the supporting documents of the SmartForm.
2. Request Clarifications ☒	Other review/negotiation activities may proceed while a submission is awaiting response from the DUA team. Changes must be submitted to move the submission states forward but cycle of “clarifications requested” can occur as many times as needed.
3. Generate Agreement	Only if an agreement draft is not included in the SmartForm or if the template is preferred. Represents the amendment to be signed, if there is one.
4. Revise Agreement	Upload any edits to the agreement via this activity, including partially signed versions later in the process. Represents the amendment to be signed, if there is

Activity	Note
	one. Represents the amendment to be signed, if there is one.
5. Move to External Review	Only after changes are completed and submitted by the DUA team. This activity does not send a notice.
6. Email Agreement ☒	Via the internal properties OR your Outlook client (using the link in the upper left on the activity).
7. Log Correspondence ☒	Notice only sends if notify = true or a reminder date is indicated.
8. <b>Approve Language</b>	(required activity) Drafting/negotiations are done, signing process can begin. Blocked if any required ancillary reviews are not completed or are marked as not approved.
9. Track Agreement Elements	Record of Harvard-required elements of an agreement. Agreement elements may be added via this activity or via the Activate activity.
10. <b>Send out for Signature</b>	(required activity) Also complete Route for Signature if only Harvard signatures are pending. Activity does not send a notice, and only changes the state in the system.
11. Email Agreement ☒	To all necessary signing parties, including Harvard signatories. Activity may be completed multiple times.
12. <b>Revise Agreement</b>	(required activity) Upload the fully signed version.
13. <b>Convert to PDF</b>	(required activity) Adds a pdf copy to the signed documents list each time it is completed
14. <b>Activate / Approve</b> ☒	(required activity) Review complete

3. **Abbreviated review of an initial DUA that does not require new/additional signatures**

Ordinarily, this is a DUA activated before system availability. In this case, the DUA team would like the record included in the system, but no amendment requiring signature is pending. A submission has been received for review by the negotiating/submitting office.

Activity	Note
1. <b>Assign Owner</b> ☒	(required activity) The previously signed DUA must be included in the supporting documents of the SmartForm, along with any previously completed approvals (so that Ancillary review does not need to be recorded via system activity).
2. Revise Agreement	Upload the already signed version of the DUA.
3. Move to External Review	Only after changes are completed and submitted by the DUA team. This activity does not send a notice.

Activity	Note
<b>4. Approve Language</b>	(required activity)
5. Track Agreement Elements	Record of Harvard-required elements of an agreement. Agreement elements may be added via this activity or via the Activate activity.
<b>6. Send out for Signature</b>	(required activity) Activity does not send a notice, and only changes the state in the system.
<b>7. Convert to PDF</b>	(required activity) Adds a pdf copy to the signed documents list each time it is completed
<b>8. Activate</b> ☒	(required activity) Review complete

#### 4. Completing review of a DUA amendment that does not require signature

A submission has been received for review by the negotiating/submitting office.

Activity	Note
<b>1. Assign Owner</b> ☒	(required activity)
2. Request Clarifications ☒	Other review/negotiation activities may proceed while a submission is awaiting response from the DUA team. Changes must be submitted to move the submission states forward but cycle of “clarifications requested” can occur as many times as needed.
<b>3. Expedite Approval</b> ☒	(required activity) Only after changes are completed and submitted by the DUA team. <i>This activity only appears for amendments that do not include an amendment document or request for draft for the first question on the first page of the amendment request.</i> Review complete.

### External Agreement System Review Activities

The following section includes summary information about activities occurring outside of the Agreements-DUA system, to help advise on the timing and content of Harvard review.

Action or Activity	Note
1. A record is created or exists in an external system	It is expected that the Reviewer (or a member of the reviewing office) also has access to the external system but is not the party primarily responsible for initiating review in that external system. If the Reviewer does not also have access to the external system, it must be the responsibility of the PI/DUA

Action or Activity	Note
	team to submit a DUA under the ordinary submission process.
2. The Reviewer is notified from that external system that a record is in review by the Contracting Party	Notification can be from the external system or the PI/DUA Team.
3. Create Agreement (or Create Amendment, as appropriate) <sup>1</sup>	<p>This activity is ordinarily completed by the PI/DUA Team. The Reviewer/reviewing office has the option to:</p> <ul style="list-style-type: none"> <li>a. request the PI/DUA Team to initiate the record; or</li> <li>b. create it on behalf of the PI/DUA Team.</li> </ul> <p>The person creating the record should fill in the SmartForm with the information provided in the notice/on the external system record. Be mindful of who is indicated as the “creator” on page one of the SmartForm. See the <a href="#">Agreements-DUA Submission Guide</a> for what to include in the SmartForm.</p>
4. <b>Submit</b>	<p>(required activity) <i>This activity is ordinarily completed by the PI/Proxy.</i> The Reviewer/reviewing office has the option to:</p> <ul style="list-style-type: none"> <li>a. request the PI/Proxy complete the submit activity; or</li> <li>b. complete it on behalf of the PI.</li> </ul>
5. <b>Assign Owner</b> ☒	(required activity) This puts the submission in the Reviewer’s queue. The assigned owner/reviewer can make edits to the SmartForm on behalf of the DUA team during internal review.
6. Request Clarifications ☒	Complete this activity only if additional information is needed and the PI/Proxy must provide it via the Agreements-DUA system. If this activity is completed, the Submit Changes activity must be completed to move the submission forward in review. Other review/negotiation activities may proceed while a submission is awaiting response from the DUA team.

<sup>1</sup>At any time after the Harvard record is created, if the Contracting Party declines the entire request and will not complete review, please add the determination to the Harvard record and discard the submission. If only a portion of the request is declined, but an agreement will be executed; please ensure the SmartForm is updated to include only the correct/anticipated approved information (including datasets) prior to approving the agreement in the system.

Action or Activity	Note
7. Manage Ancillary Review ☒	Notice sends only for reviews marked as required = yes. Any required review that remains incomplete will not allow for completion of the “Approve Language” activity.
8. Move to External Review	Complete this activity to indicate that Harvard-side record updating work is complete (terms have been reviewed and approved) and the only remaining work is in the external system or limited to agreement revision with the Contracting Party (i.e., the DUA is in internal or Committee review at the Contracting Party) This activity allows us to manage metrics of “time with Harvard” versus “time with Contracting Party”.
9. Provide/monitor feedback elements in the external system	<p><u>Items required for the Harvard record</u> (such as confirmations/negotiations with the Contracting Party): Forward notice emails or draft items</p> <ol style="list-style-type: none"> <li>a. to <a href="mailto:dua_notification@harvard.edu">dua_notification@harvard.edu</a></li> <li>b. include the Agreements-DUA submission number at the beginning of the email subject.</li> </ol> <p>Information is delivered to the “communications” tab on the submission workspace for further management, as needed.</p> <p><u>Items not required in the Harvard record</u> (such as request for clarifications by the Contracting Party in their external system): leave in the external system.</p>
10. Confirm the agreement in the external system	Once negotiations are complete, confirm/sign the agreement in the external system as you normally would.
11. <b>Revise Agreement</b>	(required activity) When the final agreement (with all appendices) is available upload any document considered to be the final agreement via this activity. For example, with a dbGaP approval, a screen shot of the list of data sets merged with the DUC packet may be uploaded to this activity. Note that you can complete this activity as many times as needed during the drafting phases but be sure to add the final version, once it is available.
12. <b>Approve Language</b>	(required activity) Drafting/negotiations are done, the agreement process is complete, and the Harvard record requires update. This activity: <ol style="list-style-type: none"> <li>1. Allows you to add supporting documents (which are also reflected on the SmartForm). You</li> </ol>

Action or Activity	Note
	<p>can add any relevant DUA appendices to this activity.</p> <p>2. Is blocked if any required ancillary reviews are not completed or are marked as not approved.</p>
13. Track Agreement Elements	Record of Harvard-required elements of an agreement. Agreement elements may be added via this activity or via the Activate activity.
14. <b>Send out for signature</b>	(required activity) Complete this activity to indicate that Contracting Party signatures/approval have been received or are pending. This is a system-required step that for submissions managed in an external system, it is expected this activity will often occur after signatures/approvals are already obtained. Note that this does not send any communication to any external party.
15. <b>Convert to PDF</b>	(required activity) The submission is ready for approval. If the correct version of the final agreement is not linked on the activity pop up, first complete the Revise Agreement activity to upload the confirmed version and then re-complete this activity.
16. <b>Activate / Approve</b> ☒	(required activity) Review complete. As part of this activity, include the same expiration as the Contracting Party system. If the Contracting Party holds multiple expiry dates for one agreement; include the earliest expiry date here, to ensure continued compliance with any required renewals.

### Master and Related Agreement Review Activities

The following section includes summary information about activities occurring outside of the Agreements-DUA system, to help advise on the timing and content of Harvard review. See the following guidance for further information:

- SmartForm contents not otherwise described here: [Agreements-DUA Submission Guide](#), Section “What to Include in a New DUA SmartForm”
- Definitions of terms related to this type of agreement that are not otherwise described here, including the definition of a master agreement: [Agreements-DUA Glossary](#)

Action or Activity	Note
1. Create Agreement (or Create Amendment, as appropriate)	<i>This activity is ordinarily completed by the PI/DUA Team. The person creating the record should fill in the SmartForm with the following additional clarifications:</i>

Action or Activity	Note
	<ul style="list-style-type: none"><li>• A Maser Agreement Principal Investigator/ Agreement Manager (PI) is defined in the system as the individual who is primarily working with the contracting party. PI assignment depends on the level of the master agreement, on the additional DUAs needed, and the terms of the master. In the past, reviewers have observed success in assigning:<ul style="list-style-type: none"><li>○ Department-level agreement: to a faculty member who owns the relationship with the contracting party or the department chair.</li><li>○ School-wide agreement: to an individual who can manage the ongoing updates to the agreement. In the past, this has been a member of the negotiating/ submitting office.</li><li>○ University/Institution-wide agreement: to a member of the Office of the Vice Provost for Research (OVPR). In some cases, a member of the library has also been the PI on a master agreement.</li></ul></li><li>• The Responsible Department named in the system should be associated with the person named as PI on the master agreement. This would only be a department selection, rather than a school-level assignment (even if the master agreement covers many departments)</li><li>• Team members do not need to include contacts on related (non-master/other) agreements. The PI on the master agreement should be able to quickly identify, report on, and address management of associated agreements (including expiry dates). Based on the expected contents of any related DUA, a PI on an associated DUA does not need to be able to additionally access the master agreement.</li><li>• The current space on the form for “related agreements” such as MTAs or NDAs should include a prompt to indicate if this is a master agreement or any master agreement associated with the submission. The PI/Creator should indicate the</li></ul>

Action or Activity	Note
	presence/association of a master agreement in this space of the SmartForm.
2. <b>Submit</b>	(required activity) <i>This activity is ordinarily completed by the PI/Proxy.</i> The Reviewer/reviewing office has the option to: <ul style="list-style-type: none"> <li>a. request the PI/Proxy complete the submit activity; or</li> <li>b. complete it on behalf of the PI.</li> </ul>
3. Assign Owner <input checked="" type="checkbox"/>	(required activity) This puts the submission in the Reviewer's queue. The assigned owner/reviewer can make edits to the SmartForm on behalf of the DUA team during internal review.
4. Manage Related Projects	Add related Agreements, Data Safety, and/or ESTR submissions, where appropriate. The manage related projects activity is bi-directional and will update the relationships on the submission where the activity was initiated and the submissions selected on the activity form. Related agreements should include a copy of the master agreement on the record. The submission owner (negotiating/submitting office staff member) will ensure that the appropriate master agreement document is included in the record.
5. Request Clarifications <input checked="" type="checkbox"/>	Complete this activity only if additional information is needed and the PI/Proxy must provide it via the Agreements-DUA system. If this activity is completed, the Submit Changes activity must be completed to move the submission forward in review. Other review/negotiation activities may proceed while a submission is awaiting response from the DUA team.
6. Manage Ancillary Review <input checked="" type="checkbox"/>	Notice sends only for reviews marked as required = yes. Any required review that remains incomplete will not allow for completion of the "Approve Language" activity.
7. Move to External Review	Only after changes are completed and submitted by the DUA team. This activity does not send a notice.
8. <b>Revise Agreement</b>	(required activity) Note that you can complete this activity as many times as needed during the drafting phases but be sure to add the final version, once it is available.

Action or Activity	Note
9. <b>Approve Language</b>	(required activity) Drafting/negotiations are done, the agreement process is complete, and the Harvard record requires update. This activity: <ol style="list-style-type: none"> <li>Allows you to add supporting documents (which are also reflected on the SmartForm). You can add any relevant DUA appendices to this activity.</li> <li>Is blocked if any required ancillary reviews are not completed or are marked as not approved.</li> </ol>
10. Track Agreement Elements	Record of Harvard-required elements of an agreement. Agreement elements may be added via this activity or via the Activate activity.
11. <b>Send out for signature</b>	(required activity) Complete this activity to indicate that Contracting Party signatures/approval have been received or are pending. Note that this does not send any communication to any external party.
12. <b>Convert to PDF</b>	(required activity) The submission is ready for approval. If the correct version of the final agreement is not linked on the activity pop up, first complete the Revise Agreement activity to upload the confirmed version and then re-complete this activity.
13. <b>Activate / Approve</b> 	(required activity) Review complete. As part of this activity, include the expiration date. If the Contracting Party holds multiple expiry dates for one agreement; include the earliest expiry date here, to ensure continued compliance with any required renewals.

## Logging and Managing Correspondence

Logging Correspondence in the Agreements system allows the reviewer to:

- Communicate directly with anyone with a Harvard University Identity (HUID), including members of the DUA team via notification;
- Indicate/log any points of communication with other parties (including phone call, external email, or meeting)
- View and manage review to-do items;
- Set up reminders via notification to conduct activities; and
- Mark completed activities.

**Tips:**

- If you need to follow up on a submission on a particular date or after a certain amount of time has passed, log a correspondence item for yourself with a reminder set for the date you would like to be reminded to follow up. The system will automatically send you an email for the follow-up correspondence item on the date you selected. You can also assign follow-up to another user and send a reminder to them on the date selected. For more information on setting a follow-up reminder, see the section To Log Correspondence Manually below.
- Logging correspondence via the email catcher is an easy way to document communications related to an agreement and to keep the submission information up to date. If there are communications related to an agreement that you sent from or received in your personal email, you can forward them to system to ensure that important information about the agreement and its status are documented in the system and available for any negotiator to see. For more information on using the email catcher, see the section To Log Correspondence via Email Catcher below.

**To Log Correspondence Manually:**

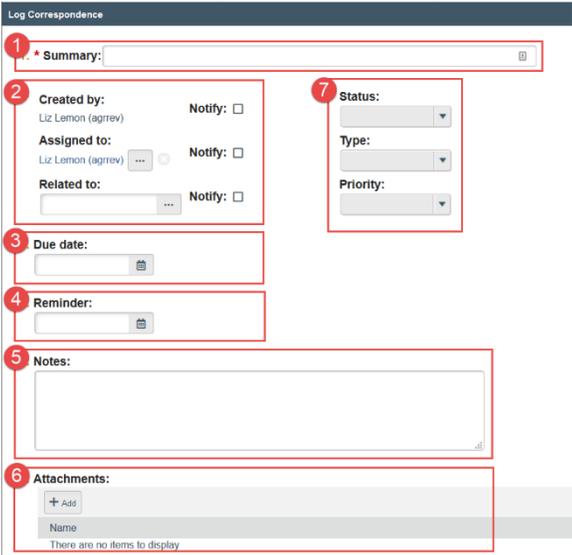
1. From the My Work list on the submissions page, click the name of the submission to open it.
2. Click **Log Correspondence** on the left.

**Next Steps**



 Log Correspondence

3. Fill in elements of the Correspondence pop-up:



The screenshot shows a 'Log Correspondence' pop-up form with the following fields and callouts:

- 1** Summary: A text input field with a calendar icon.
- 2** Metadata section: Includes 'Created by' (Liz Lemon (agrev)), 'Assigned to' (Liz Lemon (agrev)), and 'Related to' (input field). Each has a 'Notify' checkbox.
- 7** Status: A dropdown menu.
- 3** Due date: A date input field with a calendar icon.
- 4** Reminder: A date input field with a calendar icon.
- 5** Notes: A large text area.
- 6** Attachments: A section with an '+ Add' button and a table with 'Name' headers. Below the table, it says 'There are no items to display'.

1. **Summary:** The name of the correspondence used to identify this item in the submission workspace and the message subject, if a notice is sent.

2. Individuals only see correspondence on which they are named. Only members of the reviewing office can see all correspondence.

**Created by:** Defaults to the person completing the activity. Select notify beside this name to send an email notification to this person.

**Assigned to:** Defaults to the person completing the activity and can be changed if needed. Select notify beside this name to send an email notification to this person.

**Related to:** Can be any person with an HUID. Allows for the inclusion of one additional person to relate to the communication or recipient on this notice. Select notify beside this name to send an email notification to this person.

3. **Due Date:** Option to include a due date, if applicable.
4. **Reminder:** Option to include a reminder date, if applicable. The system will send a notice to all marked individuals in section 2 on the day of the reminder date.
5. **Notes:** Details related to this correspondence and the notice content, if a notice is sent.
6. **Attachments:** Relevant attachments, such as copies of external emails relevant to the record, or draft document information and notice attachment, if a notice is sent. If attaching a copy of an email, it must be first converted to pdf before upload to the activity.
7. Selections in this space are optional.

**Status:** Space to indicate the status of this item, such as if it is in progress or completed. If completed is chosen, this correspondence item will display in the workspace as completed all other statuses

**Type:** Space to indicate the method of communication. Can assist with guiding any needed method of follow up, as applicable.

**Priority:** Space to indicate priority of this item.

4. Click **OK**

If a check was placed in the notify space for any person on this activity, once completing this activity, a notice is sent.

#### To Log Correspondence Via Email Catcher:

When sending an email, include the system email as a recipient ([dua\\_notification@harvard.edu](mailto:dua_notification@harvard.edu)) AND the submission number at the start of the email subject (for example "DUA12-9989: title").

OR

Forward the email you received to the system at [dua\\_notification@harvard.edu](mailto:dua_notification@harvard.edu) AND add the submission number at the start of the email subject (for example “DUA12-9989: title”).

Inbound email/email catcher functionality will create a Correspondence To Do from the email. The full text of the email is available by clicking on the Edit link next to the item. These Correspondence items can be further managed using the options described below.

History	Communication	Agreement Documents	Contacts	Snapshots					
<b>Correspondence To Do</b>									
Filter by <span>?</span> Due Date <span>▼</span> <input type="text" value="Enter text to search for"/> <span>Q</span> <span>+ Add Filter</span> <span>✕ Clear All</span>									
Due Date	Owner	Type	Status	For Person	Summary	Date Modified	Edit	Complete	Delete
5/20/2019 4:38 PM		Email In	Not Started		RE: DUA19-0607: Draft Agreement for CEPR review	5/20/2019	Edit	Complete	Delete
5/20/2019 3:08 PM		Email In	Not Started		RE: DUA19-0607: Draft Agreement for CEPR review	5/20/2019	Edit	Complete	Delete
5/20/2019 2:07 PM		Email In	Not Started		DUA19-0607: Draft Agreement for CEPR review	5/20/2019	Edit	Complete	Delete

**To View Correspondence:**

1. From the My Work list on the submissions page, click the name of the submission to open it.
2. On the workspace:
  - *View correspondence in a single page-view format.*  
You can also read through or print all correspondence by clicking **View All Correspondence** on the left.

[View All Correspondence](#)

OR

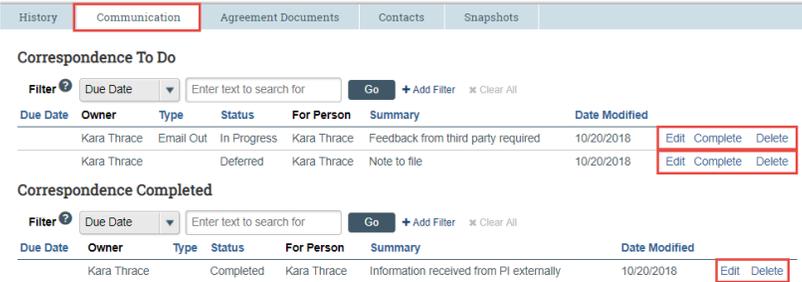
- *View correspondence in list format.*  
You can click items to view additional details on the **Communication** tab of the workspace. To read the correspondence details from this view, click Edit and choose cancel on the pop up to make no changes to the item after reading the details.

History	Communication	Agreement Documents	Contacts	Snapshots		
<b>Correspondence To Do</b>						
Filter <span>?</span> Due Date <span>▼</span> <input type="text" value="Enter text to search for"/> <span>Go</span> <span>+ Add Filter</span> <span>✕ Clear All</span>						
Due Date	Owner	Type	Status	For Person	Summary	Date Mod
	Kara Thrace	Email Out	In Progress	Kara Thrace	Feedback from third party required	10/20/201

**To Manage Correspondence:**

1. From the My Work list on the submissions page, click the name of the submission to open it.
2. Click the **Communication** tab on the workspace.

3. Manage each correspondence item by using the links to the right of each correspondence item.



- **Edit** allows for review and/or revision to the existing item.
- **Complete** moves the status to completed and the correspondence item will move to the completed list.
- **Delete** will remove the correspondence item from the list.

### Managing Ancillary Review

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.

Ancillary review can be used to provide access to the ancillary reviewer/reviewing office, and to track the following consultations or approvals during review of the agreement:

Review Type	Ordinarily required, if applicable	Note about this review
Information Security Consultation	Yes	Can also use Log Correspondence for unofficial recommendations.
Local SSO Review	Yes	Can also use: <ul style="list-style-type: none"> <li>• Clarifications requested for when the PI is responsible for initiating the review and relating projects.</li> <li>• Log Correspondence for unofficial recommendations.</li> </ul>
Local IT Review (such as for resources/provisioning)	No	Can also use: <ul style="list-style-type: none"> <li>• Clarifications requested for when it is not clear if there are resources to meet the requirements of the DUA.</li> <li>• Log Correspondence for unofficial recommendations.</li> </ul>

Review Type	Ordinarily required, if applicable	Note about this review
IRB Consultation	No	This is not intended to replace any required documentation of IRB approval. Can also use Log Correspondence for unofficial recommendations.
Export Control Consultation	Yes	Can also use Log Correspondence for unofficial recommendations.
COMS Consultation	No (could be Yes, if DURC)	Can also use Log Correspondence for unofficial recommendations.
Provost Consultation	Yes	Can also use Log Correspondence for unofficial recommendations
OGC Consultation	Yes (in some cases – it is sought but not required)	Can also use Log Correspondence for unofficial recommendations
OTD Consultation	Yes (in some cases – it is sought but not required)	Can also use Log Correspondence for feedback/recommendations
Department / School Consultation	No (unless there are local requirements, unusual risks, or a substantial charge)	Can also use Log Correspondence for unofficial recommendations
Faculty	No (unless a non-faculty PI is listed, and a faculty sponsor must provide feedback on the record)	
Radiation Safety Consultation	No	Can also use Log Correspondence for unofficial recommendations.
GDPR-Based Evaluation	No	
Safety	No	
Scientific	No	
Other (and others)	No (use category only as applicable)	

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.

**To assign an ancillary review for the reviewer to complete approval:**

1. From the **My Work** list on the submissions page, click the name of the submission to open it.
2. Click the **Manage Ancillary Reviews** activity on the left.

**Next Steps**



3. In the pop up, click **Add** to add a new ancillary review. Another pop up will appear.

**Manage Ancillary Reviews**

1. Identify each organization or person who should provide additional review

**+ Add**

Review Type	Org Person	Reqd	Accepted	Comments	Docs
	Provost	Caprice Pitt	yes		

**Update** **x**

4. In this secondary pop up:

1. **Select either an organization or a person as a reviewer:** Add individuals or organizations/departments as reviewers. Organizations are only available if they have a pre-defined reviewer/set of reviewers. If an expected organization is missing, indicate an individual named reviewer in the “Person” space. Contact [duahelp@harvard.edu](mailto:duahelp@harvard.edu) to initiate the process for adding reviewers to an organization.
  2. **Review type:** Indicate the applicable review type from those available. If the specific review type is not available, use Other and contact [duahelp@harvard.edu](mailto:duahelp@harvard.edu) to initiate the process for adding ancillary review types.
  3. **Is a response required?**
    - Mark Yes: Only when a response is required and the DUA / DUA Amendment review cannot be completed until this review is completed. Activation/approval will be blocked until this review is completed. Marking yes will also send a notice to the assigned reviewer(s) once the manage ancillary reviews activity is completed. This submission will appear in the ancillary reviewer InBox until their ancillary review is completed.
    - Mark No: Only when a response is not required. No notice will be sent to the assigned reviewer(s) by completing this activity. This submission will appear in the ancillary reviewer InBox until their ancillary review is completed.
  4. **Send notification now?**
    - Mark Yes: To ensure a notice is sent to the assigned reviewer(s) once the manage ancillary reviews activity is completed.
    - Mark No: If no notice should be sent. May be appropriate if review is optional or if reviewer is completing ancillary approval on behalf of the reviewer.
  5. **Comments:** Write in comments to the reviewer for inclusion in the email notice to reviewer only.
  6. **Supporting Documents:** Add any information necessary for only ancillary review. Do not attach any materials required for the agreement reviewer as part of the agreement review.
  7. Click **OK** (on the Add Ancillary Review pop up)  
This action will list the assignment, but assignments will not save/notifications will not be sent by adding the review.
5. (optional) Add any additional ancillary reviews as needed; repeating steps 3 and 4 above.
  6. (optional) Remove any previously assigned reviews by clicking the circled x to the right of the item.



7. Click **OK** (on the Manage Ancillary Review pop up)  
This action will save the assignment and notifications will be sent to any reviewers assigned where response is required and notifications were chosen to be sent on assignment.

**Note:** To notify ancillary reviewers where notification was not chosen or a notice needs to be re-sent, remove the previously assigned review and re-add it, choosing the “notify now” option.

#### To complete ancillary review on behalf of the reviewer:

1. From the My Work list on the submissions page, click the name of the submission to open it.
2. Click the **Manage Ancillary Reviews** activity on the left.

#### Next Steps



Manage Ancillary Reviews

3. In the pop up, click **Update** beside the review type. Another pop up will appear.



4. On the pop up:
  1. Fill in the spaces:
    - Question 4** Mark “Yes”.
    - Question 5** Fill in a comment, if one is available.
    - Question 6** Attach an electronic version of the separately received approval/confirmation documentation.
  2. Click OK, the additional (Edit Ancillary Review) pop up will close.
5. See the update to the item displayed on the table in the pop up.
6. Click **OK**.

**Note:** If an assigned reviewer chooses not to complete the ancillary review and to refer it to another person or group instead, they should contact the Owner of the Agreement so that the Owner can manage the ancillary approval on their behalf.

## Completing the Signing Ceremony

The signing ceremony includes a series of steps in- and outside the Agreement system. Steps do not need to be completed in one session and can be completed over the necessary time needed to obtain and record signatures.

#### To start the process to record signatures:

1. From the **My Work** list on the submissions page, click the name of the submission to open it.
2. Click the **Approve Language** activity on the left.

### Next Steps



3. In the pop up:
  1. **Signature type:** Choose the signature type applicable for this agreement.
  2. **Should the agreement be routed for internal signature first?**  
Mark yes if moving to the internal signature process.  
Mark no if moving to the external signature process. (ordinarily this is marked no)
  3. **Does the agreement contain evergreen clauses?**  
Mark yes if the agreement contains evergreen clauses.  
Mark no if there is no evergreen clause. (ordinarily this is marked no)
  4. **Effective date:** Choose the effective date indicated on the agreement. Note that a month, year and day must be selected (in that order).
  5. **Expiration date:** Choose the expiration date indicated on the agreement. Note that a month, year and day must be selected (in that order). The system will send notifications of approaching expiry and expiry, as applicable, based on the date entered here. If the agreement does not contain evergreen clauses and the system requires entry of an expiry date, indicate an expiry of "01/01/3000".
  6. **Notes:** Indicate any notes. These will appear on the submission history.
  7. **Supporting documents:** Shows documents as they are included on the SmartForm.  
**Important!** Changes to this space will change what is included on the first page of the SmartForm. Note that the agreement to be signed should not be attached here.
4. Click **OK**
5. (optional) If Harvard completes some signature activities first, use the **Revise Agreement** activity to upload the partially signed version of the agreement.

#### To send for signature by the PI or other person at Harvard:

1. From the **My Work** list on the submissions page, click the name of the submission to open it.
2. Click the **Route for Signatures** activity on the left. This indicates that internal signatures are being obtained.
 
3. Click **OK** on the pop up.  
This activity only changes the state and does not send a notice.
4. Click the **Email Agreement** activity.
5. In the pop up:
  1. **To:** Choose any individuals with an HUID to receive a notice from the system. CC and bcc may be filled in in the same way.
  2. **Subject:** Write in the subject, including the submission ID. This will be the subject of the email that is sent from the system.
  3. **Body:** Write in the message body. Please consider salutations and formatting; this will be included in the body of the email.

4. **Attachments:** Attach any additional documents that should be sent to the recipient. The most recent version of the Agreement will be included automatically.

6. Click **OK**.

#### To send for signature by the contracting party:

1. From the **My Work** list on the submissions page, click the name of the submission to open it.
2. Click the **Send out For Signatures** activity on the left. This indicates that contracting party signatures are being obtained.

#### Next Steps



3. In the pop up:
  1. **Select an organization:** Defaults to the contracting party indicated on the SmartForm. Choose or write in a different organization if the default is incorrect.
  2. **Contact name:** Indicate the contact name of the contracting party. Does not default to what is written in the SmartForm. Must be written in by the Owner/Reviewer.
  3. **Contact e-mail:** Indicate the contact email of the contracting party. Does not default to what is written in the SmartForm. Must be written in by the Owner/Reviewer.
  4. **Contact phone:** Indicate the contact phone of the contracting party. Does not default to what is written in the SmartForm. Must be written in by the Owner/Reviewer.
4. Click **OK**

**Important! This activity does not send a notice.** To send the agreement to the contracting party for signature, Email Agreement or Log Correspondence must be completed.

#### To finalize the fully signed version of the agreement:

1. From the **My Work** list on the submissions page, click the name of the submission to open it.
2. Ensure that the correct version is associated with the submission via the Agreement Documents tab. If the fully signed version is not uploaded. Click **Revise Agreement** to upload the fully signed version.
3. Click the **Convert to PDF** activity on the left. A pop up will appear. Harvard does not watermark final agreements, so no options will appear on the pop up.

#### Next Steps



**Note:** When this activity is completed, a final version is added to the signed documents list. Completing this activity multiple times will add multiple documents.

4. Click **OK**

**Important!** This step is required even if the current version of the agreement is .pdf.

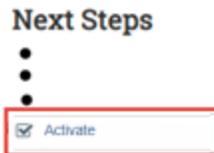
## Activating or Approving an Agreement

There are three ways to complete the review process on an agreement submission: activate, approve, and bypass signatures. Options depend on the type of submission.

### Initial Submission Activation

**To activate an initial agreement:**

1. From the **My Work** list on the submissions page, click the name of the submission to open it.
2. Click the **Activate** activity on the left.



3. In the pop up:
  1. **People who have signed:** Indicate all individuals at Harvard who have signed.
  2. **Internal signing date:** Choose the Harvard date of signature. Note that a month, year and day must be selected (in that order).
  3. **External signing date:** Choose the contracting party date of signature. Note that a month, year and day must be selected (in that order).
  4. **Effective date:** Defaults to what was selected when completing the Approve Language Activity. May be revised. To revise, choose the effective date indicated on the agreement. Note that a month, year and day must be selected (in that order).
  5. **Expiration date:** Defaults to what was selected when completing the Approve Language Activity. May be revised. To revise, choose the expiration date indicated on the agreement. Note that a month, year and day must be selected (in that order). The system will send notifications of approaching expiry and expiry, as applicable, based on the date entered here.

If the agreement does not contain evergreen clauses and the system requires entry of an expiry date, indicate an expiry of "01/01/3000".

**Note: Expiration date** can be updated on active DUAs that are **not in lapsed status** by selecting the "Update Expiration Date" activity from the menu on the left.



6. **Agreement Tracking Elements (mark all that apply):** Indicate regulatory elements. Any items already selected if the Track Agreements Elements activity was completed will display here but can be updated here. Marking tracking elements is required; if there are no appropriate tracking elements in the list, select **None**.

7. **Highlighted Terms (mark all that apply):** Indicate highlighted terms. Any items already selected if the Track Agreements Elements activity was completed will display here but can be updated here. Marking terms is required; if there are no appropriate terms elements in the list, select **None**.

4. Click **OK**

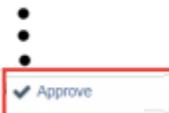
The initial agreement transitions to the Active state and the PI/Agreement Manager, Creator, and Proxy are notified.

### Amendment Submission Approval

There are two ways to approve a proposed amendment. If an amendment:

- a) **Requires new/additional signatures** on an existing agreement or there is a separate amendment document that requires signatures, then the signing ceremony must be completed and then the amendment must be Approved.
  - b) **Does not require signatures** because the proposed revisions do not change the existing signed agreement and do not add a newly signed document, then the Owner/Reviewer may Expedite Approval. These types of amendments can only include updates to supporting documents, changes in collaborators, or minor updates to other elements of the SmartForm/agreement record.
- a) Only when a signing ceremony is completed, to approve the amendment:
1. From the My Work list on the submissions page, click the name of the submission to open it.
  2. Click the **Approve** activity on the left.

#### Next Steps



3. In the pop up:
  1. **People who have signed:** Indicate all individuals at Harvard who have signed.
  2. **Internal signing date:** Choose the Harvard date of signature. Note that a month, year and day must be selected (in that order).
  3. **External signing date:** Choose the contracting party date of signature. Note that a month, year and day must be selected (in that order).
  4. **Effective date:** Defaults to what was selected when completing the Approve Language Activity. May be revised. To revise, choose the effective date indicated on the agreement. Note that a month, year and day must be selected (in that order).
  5. **Expiration date:** Defaults to what was selected when completing the Approve Language Activity. May be revised. To revise, choose the expiration date indicated on the agreement. Note that a month, year and day must be selected (in that order). The system will send notifications of approaching expiry and expiry, as applicable, based on the date entered here.
4. Click **OK**

The amendment transitions to the Approved state and the PI/Agreement Manager, Creator, and Proxy are notified. Additionally, all the approved changes are copied to the Initial/Main Agreement workspace.

b) Only when there is no signing ceremony, to approve the amendment:

1. From the My Work list on the submissions page, click the name of the submission to open it.
2. Click the **Expedite Approval** activity on the left.



3. In the pop up:

1. **Effective date:** Choose the effective date indicated in the Initial/Main Agreement workspace. Note that a month, year and day must be selected (in that order).
2. **Expiration date:** Choose the expiration date indicated in the Initial/Main Agreement workspace. Note that a month, year and day must be selected (in that order). The system will send notifications of approaching expiry and expiry, as applicable, based on the date entered here.

**Important!** Effective and Expiration dates are not expected to change with this approval type. Consider a different review process if dates must be changed.

3. **Comments:** Write in any review or activity notes that should be recorded on the record history.

4. Click **OK**

The amendment transitions to the Approved state and the PI/Agreement Manager, Creator, and Proxy are notified. Additionally, all the approved changes are copied to the Initial/Main Agreement workspace.

## Managing a Person Profile

When reviewing a submission, some elements of a person profile may require update. Only the Site Administrator has permissions to view and edit certain details. For any updates, contact [duahelp@harvard.edu](mailto:duahelp@harvard.edu).

To edit contact information in Agreements, the individual requiring the change must follow instructions provided at: [https://harvard.servicenow.com/ithelp?id=kb\\_article&sys\\_id=840d9ad80f70fe802dfe5bd692050e42](https://harvard.servicenow.com/ithelp?id=kb_article&sys_id=840d9ad80f70fe802dfe5bd692050e42) to update information associated with their central profile. This information comes from the central system, through the IRB system, and then to the Agreements system.

## Managing Guests with View-Only Permissions to the Study

Guests who can view a study and its documents can be added by Reviewers, PIs, and Creators. Guests have view-only permissions and cannot make edits to the study or create follow-on submissions. Adding/removing a guest does not require a Modification to the study itself.

**To add/remove a guest to the study:**

1. Navigate to a study (see [Finding Submissions](#) for more instructions).
2. Click **Manage Admin Contacts** from the Next Steps list oaccessn the left. A new window opens.
3. To **add a guest**, begin typing the name of the new contact in the search box labeled as “Guest list for allowing additional people to view the submission”. A list of matching names appears. Click on the correct name using the mouse.  
To **remove a guest** click Remove on the right, next to their name
4. Click **OK**

**Note:** The Creator/Primary contact can also be changed by executing this activity and changing the name of the person beside the prompt “Select a new Creator/Primary Contact”.

## Using Site Search

Reviewers can see the option to conduct a keyword search of information on submission records and within record attachments.

### To search:

1. Log in to [dua.harvard.edu](http://dua.harvard.edu)
2. Click **Agreements** in the top navigator.
3. In the search bar (at the right, just above the tabbed area), type the keyword(s) then click the **magnifying glass** icon. A pop up will appear and results may take a moment to display.

Search

4. In the pop up of results, identify the items of interest and click to those items, as needed.
  - Results may be records, records and attachments to the SmartForm, or records and attachments on activities. Attachments are listed as Related Items and do not represent all the attachments on that record.
  - If a result displays without an author or record, it means the document was removed from a record but still exists in the system database.

Search

Search For:  ▼

---

EX18-5617: Harvard Study

Owner: Kara Thrace

Status: Closed

Related Items: Protocol-Modification3.docx  
 Study3-Survey.docx

---

MedExternalCollaborators (1).pdf

Author:

Location:

## 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.
5. 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](mailto:duahelp@harvard.edu) for special access.

## Reviewing Agreements Initiated Prior to System Availability

DUA reviews initiated or DUAs activated prior to system availability may not have a record in the Agreements system. The following are steps to review or update of these pre-Agreements system DUAs.

- **DUAs activated under the pre-system process which may need to be revised or extended.** To review revision or extend the term of a DUA that does not currently have a record in the Agreements system:

The PI/DUA Team is advised to enter the revision as an initial agreement.

1. Review the amendment as an initial agreement, with the document for signature attached to Question 3 on the first page of the SmartForm, AND
2. As part of the submission to create the record:
  - a. Include any previous tracking number/reference in the name of the submission (if there is one);
  - b. In the DUA Description, indicate: *“DUA initially activated prior to Agreements system use”*;
  - c. Add the previously executed agreement (and any other signed addenda or amendments) to the Supporting Documents (on the first page of the SmartForm); and
  - d. Include all current details on the SmartForm, to support the review. The reviewer may allow for abbreviated entries of required items.

- **DUAs activated under the pre-system process where there is interest in having a record in the system (and no planned revision or extension).** The PI/DUA Team is advised to contact the reviewing office when there is interest in adding active DUAs to the system where no signatures are required. The record may be populated using the above steps (for DUAs activated under the pre-system process). If needed, signature workaround steps can be obtained by contacting [duahelp@harvard.edu](mailto:duahelp@harvard.edu).
- **(Legacy Instruction) DUAs or DUA amendments that are under review and not yet activated at the time the system became available.** The office conducting review of the submission will consider the status of the review and will either: a) proceed with the review under the existing process or b) will initiate input of the DUA record in the Agreements system so that the review process can be completed in the system. The DUA reviewer should contact the PI/DUA Team during the remaining review to share the anticipated path for the existing review. If the DUA reviewer plans to initiate a record in the system, the Reviewer or the PI/DUA Team may:
  1. Follow the steps in the DUA Submission Guide to create the record, see [Creating a New Data Use Agreement Request](#), AND
  2. As part of the submission to create the record:
    - a. Include any previous tracking number/reference in the name of the submission (if there is one);
    - b. In the DUA Description, indicate: *“DUA review initiated prior to Agreements system use”*;
    - c. Add the previously executed agreement (and any other signed addenda or amendments) to the Supporting Documents (on the first page of the SmartForm), if there are any; and
    - d. Include all current details on the SmartForm, to support the review. The reviewer may allow for abbreviated entries of required items.

## 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 <b>Help Center</b> sub-menu link at the top of the screen. <div data-bbox="812 564 1364 665" data-label="Image"> <p>The image shows a horizontal navigation menu with four items: a double right arrow (»), 'Dashboard', 'Agreements', and 'Reports'. Below these items is a second row of items: 'Agreements', 'Help Center', and 'Reports'. The 'Help Center' item in the second row is highlighted with a red rectangular border.</p> </div>
DUA Agreement Submission Guide	Instructions for submitting an agreement for review.	Click the <b>Help Center</b> 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	<a href="https://ras.fss.harvard.edu/agreements">https://ras.fss.harvard.edu/agreements</a>
DUA Help Desk	Contact for help with DUA access and use	<a href="mailto:duahelp@harvard.edu">duahelp@harvard.edu</a>
Reviewing Office Websites	Information about the DUA review process and requirements	<ul style="list-style-type: none"> <li>▪ Harvard T.H. Chan School of Public Health: <a href="#">Sponsored Programs Administration (SPA)</a></li> <li>▪ Harvard Medical and Dental Schools: <a href="#">Office of Research Administration (ORA) – Research Data Management</a></li> <li>▪ University Area, all other Harvard schools: <a href="#">Office for Sponsored Programs (OSP)</a></li> </ul>

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