DUA Submission Guide

Agreements System

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Logging In

The Agreements system is secure, which means only authorized individuals have access to it. When you log in to the system, you get a personalized view of the information and possible actions pertinent to you.

To log in:

1. Locate your [HarvardKey and password](.).
2. Navigate to [dua.harvard.edu.](.)
3. Ensure the correct log in type tab is selected.
4. Enter your credentials (HarvardKey and password) in the appropriate spaces.
5. Click the "Login" button.
6. Once authenticated, you will be taken into the Agreements system, to your personal workspace.

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

Creating a New Data Use Agreement Request

You can create a new request for Data Use Agreement (DUA) review by entering information into a series of online forms. The number of forms included may change based on the answers you provide. The forms tell you where to attach files to provide supporting information. The forms may contain required information identified by a red asterisk (*), you cannot proceed without providing that information.

The simplest approach is to follow the forms in order, answering the questions and clicking Continue to save your information and move to the next form. When you reach the end of the series of forms, click the Save & Exit button.

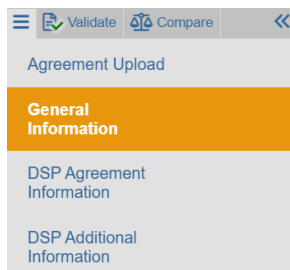**To create a new DUA for review:**

1. From the Agreements page (linked in the top menu), click **Create Agreement**.
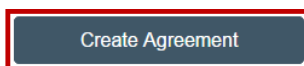
2. Fill in the applicable boxes, answer the questions, and attach appropriate documents.
3. Click **Continue** in the bottom right corner to move to the next page of the form.

4. Use the left navigation to go to a specific section, as appropriate.

5. To save or exit the SmartForm at any time, click on "Save" and "Exit" button in the top toolbar. Exit will take you to that submission's workspace.
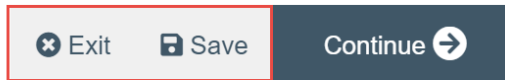
6. When you reach the final page, click **Save & Exit** to exit the SmartForm.

You can continue to edit the submission until you submit it for review. See Editing a Submission.

Important! The DUA has not been submitted for review yet. For instructions, see Submitting the DUA for Review. You will see the following message appear under the project information until the submit button has been clicked:


⚠ **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.

Tips:

- A project team member can create a new DUA submission which is similar to a previous one, by completing the Copy Agreement activity. This will create a partially completed form to update and further edit prior to submission for review.
- Where documents can be included for reference, email files (for example, .msg) cannot be attached. Please convert any non-standard attachment types (like .msg files) to .pdf before uploading to the system.
- Documents can be added to SmartForm spaces by dragging and dropping them from a location on your computer. Mouse over to identify if documents can be added from the main page. This option is not available in every attachment space.
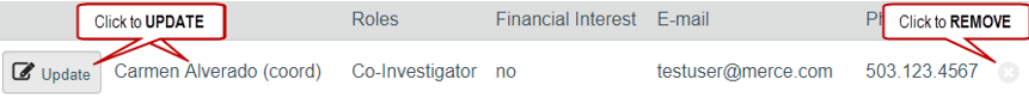
Ex. Supporting documents space in the SmartForm

8. Supporting documents (see below for suggested attachments):

+ Add   Drag and drop files to upload

Name

There are no items to display
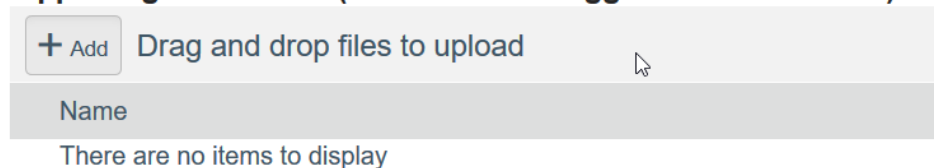
Reminder: Always name document files wisely (such as with the submission number and the document type in the name). Suggested best practice for file names: *DUAnumber_DocumentType*.

- Listed items that have been added but need to be removed may be either updated or removed in the following ways.

Update	Remove
Update items by either clicking on the button on the left side of the item or on the item itself (if no button appears to the left).	Remove items by clicking on the X to the right of the listed entry.

Click to UPDATE	Roles	Financial Interest	E-mail	Pl	Click to REMOVE
✎ Update Carmen Alverado (coord)	Co-Investigator	no	testuser@merce.com	503.123.4567	⊗

- An amendment submission can be handled similarly to an initial agreement submission. For differences, see Making Changes after DUA Activation.

Reference the **Help Center** (linked under the Agreements heading, at the top of any workspace screen) for some of the templates/forms that are requested within the SmartForm, along with guidance materials.

A red asterisk (*****) precedes each question that requires an answer. If you cannot answer a required question at this time, or if you need to stop and continue at a later time, you can save and return to the submission later. You must provide all required information before you can submit the agreement for review.

What to Include in a DUA SmartForm

The SmartForm is the series of web-pages (or forms) where you can input specific information about an agreement. The following section describes what information should go into each space of the SmartForm.

Important! Completing elements of the SmartForm or Clicking "Save & Exit" does not send the DUA for review. The PI, Creator, or PI Proxy must click **Submit** (in the submission workspace) for the submission to proceed on for the next state of review.

SmartForm Section: Agreement Upload

> ***Principal Investigator/Agreement Manager.** Enter the name of the **Harvard Principal Investigator** (PI) or lead on the agreement. This is intended to be a Harvard faculty member. If a Harvard faculty member is not indicated in this space, indicate the faculty sponsor as an agreement collaborator on the General Information page of this form. Instruction will also appear at the bottom of the page.
>
> The name listed here may be changed by selecting clear and typing the name in the space provided (a list will appear with names from which to select), or you can click the ellipses […] option to search the list of names. Use the "%" symbol to replace portions of a name which are unclear or possibly not spelled correctly. This is called a "wildcard" character.

1. ***Agreement Creator/Primary Contact**. This space defaults to the name of the person who initiated the DUA request. The person listed here will automatically be named as a PI Proxy, will receive copies of all notifications sent to the PI. If you are removing your own name from this space, be sure that your name is listed in the PI or contacts spaces on the SmartForm, otherwise when removed, you will lose permission to view this submission.

The name listed here may be changed by selecting clear and typing the name in the space provided (a list will appear with names from which to select), or you can click the ellipses […] option to search the list of names. Use the "%" symbol to replace portions of a name which are unclear or possibly not spelled correctly. This is called a "wildcard" character.

2. ***Upload agreement draft: (or check be box below) || If no agreement to upload, mark here for Harvard to generate first draft.** Either upload a draft of the document that requires signature for review by the appropriate office OR put a check in the box provided to request that Harvard generate the first draft. The form will not let you do both.
   Important! If there is a document that requires signatures, it should be uploaded here. If you are proposing an amendment that includes a document which requires signatures, upload that document to the first page of the amendment request.

3. ***Harvard project title.** The title identifies the study throughout the system, such as in your inbox and in a reviewer's list of submissions to review. This should be 80 characters or less and should not contain quotation marks.

   For amendments, it is suggested that the name of the type of amendment be included with the title in this space (for example if the agreement title is *Happiness Study Data*, amendments could be titled: *Contact Changes #1 for Happiness Study Data, Term Amendment #1 for Happiness Study Data, or Period Extension #1 for Happiness Study Data.*

4. ***Agreement type.** Select Data Use Agreement from the dropdown. Currently, Harvard is only using this system to manage DUA type agreements. When future agreement types are managed in the system, other options will appear for selection.

5. **Description.** Enter a brief description of the project, including information about any collaborations associated with this DUA.

6. **Supporting Documents.** Attach appropriate supporting documents in the space provided, including the following items (if appropriate and available): Investigator Self-Determination Form (when the DUA involves human subjects data and IRB approval will not be obtained), additional documented data information or requirements, associated contracts or agreements

   Note: While this is not a system-required entry, either an IRB determination letter OR a completed Investigator Self-Determination Form is required during review and prior to signature, for a Data Use Agreement involving human data.

   Important! Make sure you attach the Investigator Self-Determination Form in the Supporting Documents section OR link your Harvard IRB application to your Agreements submission using the Manage Related Projects activity available on the submission page, if your agreement covers human data.

7. ***Responsible department.** Indicate the name of the Principal Investigator/Agreement manager's department for this study/agreement.

   Type the department name in the space provided (a list will appear with options from which to select), or you can click the ellipses […] to search the list of available departments. Use the "%"

symbol to replace portions of a word of which may be unclear or possibly not spelled correctly. This is called a "wildcard" character.

If the department name does not appear on the list provided, contact duahelp@harvard.edu for guidance on which department to select.

To fully change the department and reviewing office after a DUA is submitted:

1. Complete the Withdraw activity on the agreement in review
2. Click "Edit Agreement" to change the name of the department on the SmartForm
3. Click "Save" then "Exit" on the SmartForm menu
4. The PI, Creator or PI Proxy must complete the Submit activity on the submission to send it back for review.

SmartForm Section: General Information

1. ***Select the contracting party** Indicate the name of the organization or institution associated with this DUA. If there is more than one contracting party, indicate one here and also indicate all parties in the Description of the project (on the Agreement Upload page of the SmartForm).

   Type the organization name in the space provided (a list will appear with options from which to select), or you can click the ellipses […] to search the list of available organizations. Use the "%" symbol to replace portions of a word of which may be unclear or possibly not spelled correctly. This is called a "wildcard" character.

   - If there is more than one Contracting Party, choose one here and list all other parties in the Description of the project.

   - If the name does not appear on the list provided, type the name of the contracting party in the space provided, labeled: "*If you cannot find the organization in the list above, enter its information here: Contracting Party Name:*"

2. **Contracting party contact name.** Type in the name of the contracting party contact. This should be included even if a contracting party name is available from the selection list at question 1 on this page.

3. **Contracting party contact phone.** Type in the phone number of the contracting party contact. This should be included even if a contracting party name is available from the selection list at question 1 on this page.

4. **Contracting party contact name.** Type in the name of the contracting party contact. This should be included even if a contracting party name is available from the selection list at question 1 on this page.

5. **Agreement collaborators (Harvard staff needing read/edit permissions for this submission).** Individuals can be selected from a list of names. Begin typing a piece of the person's name in the space provided on the pop up, or you can click the "add" option to search the list of available names. Use the "%" symbol to replace portions of a name of which may be unclear or possibly not spelled correctly. This is called a "wildcard" character. Use the email address column for search or as a guide to selecting the correct person. If the correct person cannot be found via name or email, click the ellipses […]. Choose a Filter by: option to search on a single criterion.

Select HUID to search by HUID.
In this space:

- If you would like a person to access this record in the Agreements system, but they are not otherwise associated with the work on this project, they may be listed in this space.
- If you would like a person to access this record in the Agreements system or the data covered under the DUA, and his/her name does not appear in the search results; this individual must obtain an HUID. Please visit the [Agreements support site](#) for detailed instructions on how to obtain an HUID for use with the Agreements system.

SmartForm Section: DSP Agreement Information

1. ***Describe the data to be shared.** In the space provided, describe the data to be shared. Include here any reuse of data, use of confidential/ proprietary information, or combining with any other data sets (and those sources). Include the total anticipated duration of data access and/or use, and if the data are being shared to deposit in a repository. Additional guidance regarding sharing for repository use is available on the [Office for the Vice Provost for Research website](#).

2. ***Is this expected to include international data?** Mark yes or no in the space provided.
If yes is marked: select country/countries if Known by searching from the text-box. Note: Multiple countries can be selected.

3. ***How long would you like access to the data (in years)?** Indicate how long access to data are needed in number of years. For example: Write in the number "5" if access to data is needed during a five-year project and if you anticipate completing closeout procedures (such as anonymization or data destruction) at the end of the period of access. Note that this duration can be revised via Amendment after the initial agreement is activated.

4. ***Are there any anticipated fees for the data?** Mark yes or no in the space provided.

5. ***Are there any sponsored funding sources for this project?** Mark yes or no in the space provided. If yes is marked:
**Indicate the source and describe the relationship* (including if funds are used to pay for the data): In the space provided, indicate the funding source; including the GMAS fund or Project number if there is one, and cost if funds are used to pay for the data.

6. **If there are any other known agreements applicable to the project/DUA, describe.** In the space provided, describe any other associated actual or pending agreements, including Non-Disclosure Agreements (NDAs), Material Transfer Agreements (MTAs), or Licence Agreements. Any additional agreements should be attached to the supporting documents section on the first page of the SmartForm.

SmartForm Section: DSP Additional Information

1. **Which institution is providing the data?** Select the most appropriate option from those provided: Contracting Party, Harvard, Both Harvard & Contracting Party, Other.
If Other is chosen:
If other, please explain: In the space provided, provide information about the provider(s).

2. ***Will the data be stored or managed at Harvard or otherwise using Harvard resources (e.g. physically on the premises or in Harvard Cloud Storage)?** Mark yes or no in the space provided.

3. ***Will any incoming data be made available to non-Harvard personnel?** Mark yes or no in the space provided. If yes is marked:
   * *Describe plans to manage approval for access:* In the space provided, indicate the plan for data access management. For dbGaP (or similar) requests, this should include all individuals listed as external collaborators on the dbGaP application.

4. **Describe any confidentiality concerns that should be considered as part of this agreement**: In the space provided, include any concerns about confidentiality (such as any plan to link the data with other datasets), along with information about use for publication, if the data are identifiable/de-identified, or if data covered under policies/regulations (such as HIPAA, FERPA, GDPR, Patent, or other privacy reserving the right to remain anonymous).

Important! For all Data Use Agreements, there must be an approved Data Safety protocol. Go to https://researchsafety.harvard.edu/ and create a Safety submission. Then link the Safety protocol to your Agreements submission using the Manage Related Projects activity available on the submission page. You will see the following reminder until a Data Safety protocol (DATxx-xxxx) has been linked to the data use agreement:

> ⚠ **Important!** For all Data Use Agreements, there must be an approved Data Safety protocol. Click on the Safety tab above and create a Safety Submission. Then link the Safety protocol to your Agreements submission using the Manage Related Projects activity on the left side of this workspace.

Editing a Submission

You can make changes to a DUA while it is in *pre-submission* and *unassigned* project state. You can also make changes if clarifications are requested. **Note:** steps indicated here can also be completed for an Amendment.

To edit a submission before it has been submitted:

1. From **My Inbox**, click the name of the submission to open it.
2. **Note:** If the submission does not appear in your inbox, see Accessing a Submission.
3. Click **Edit Agreement** on the left. For an Amendment, click Edit Amendment.
4. Make changes as appropriate.
5. Exit the submission. Choose one of these ways to exit:
   - Click the **Exit** link. If prompted to save the submission, click **Save Changes & Exit**.
   - Click **Continue** on each form, and then click the **Save & Exit** buttons on the last page of the form.

If you are unable to make edits, or edits are requested from an Ancillary Reviewer, you can still make edits to the submission without having to make a special request to the reviewer to open the record.

To edit a submission after it has been submitted:

1. Go to the **Agreements** page (click "Agreements" on the menu at the top of the page).

2. From the **All Agreements** or **In Progress** tab, click the name of the submission to open it. See Accessing a Submission for more instructions.
3. Click **Withdraw** on the left. Completing the Withdraw activity only affects the submission. If an amendment to an active DUA is being withdrawn, this action will only withdraw the amendment submission and will not affect the status of the DUA.

    (Optional) On the withdraw activity pop up, use the comment box space, or document upload, to provide additional information. Do not upload any required documents here; required documents should be uploaded to the SmartForm.

4. Click **OK**.
5. Make changes as appropriate.
6. Exit the submission. Choose one of these ways to exit:
    *   Click the **Exit** link. If prompted to save the submission, click **Save Changes & Exit**.
    *   Click **Continue** on each form, and then click the **Save & Exit** buttons on the last page of the form.
7. After edits are completed, the PI, Creator or Proxy must complete the **Submit** activity again, to send the submission back for continued review.

Tip: Click **Discard** to completely remove a submission from further consideration. Completing the Discard activity only affects the submission. If an amendment on an active DUA is being discarded, it will only discard that submission and will not affect the current status of the agreement.

Checking a Submission for Errors

Checking the agreement for errors and omissions helps you include all the relevant information, which is critical for receiving a timely review.

Using these types of error checking helps you supply all the needed information:

*   **Automatic system error checking** identifies any omitted answers to required questions on the form when you click Continue. A red asterisk (*****) precedes each blank or question that requires an answer. Keep in mind that the system cannot catch every omission while you edit the submission if you skip questions that cause more forms to be added to your submission.
*   **Visually inspecting the forms** to see what you may have missed. To perform a visual inspection, open the submission and look through the forms in order. To open the submission, see Editing a Submission. Note especially the following items:
    *   Questions that are relevant to your request but are not required for all agreements, and
    *   Documents that should be attached.
*   **Using the Validate option** to find and correct all errors before submitting the DUA. The system automatically checks for errors as part of the submit activity. However, it is best to check the submission for errors before completing the submit activity, using the steps below.

To use Validate option to find and correct errors:

1. Open the submission, as explained in Editing a Submission.
2. From the left navigation area, click **Validate.**
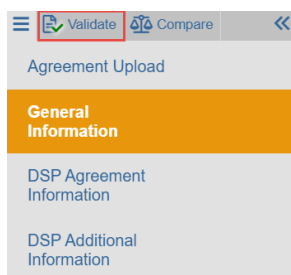
3. The Error/Warning Messages will appear in the left navigation, listing all the current errors and where to find them.
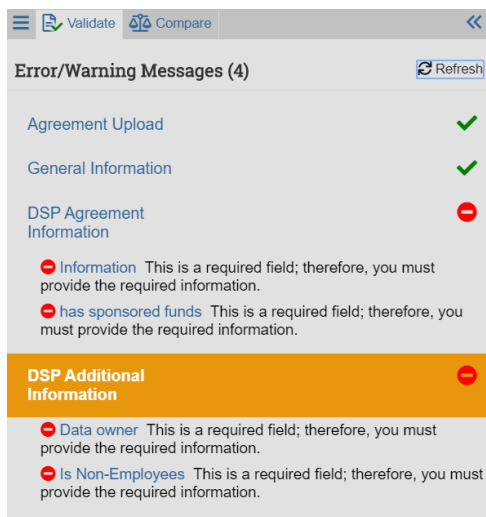
4. For one of the errors listed, click the link in the field go directly to the field containing the error.
5. Fill in the missing information.
6. Click **Refresh** in the Error/Warning Messages pane to update the list of errors.
7. Continue correcting errors until no errors are listed.

Managing Related Projects

When a submission has other associated records in Data Safety, ESTR, and/or Agreements, completing the Manage Related Projects activity will connect the records across the systems so the reviewer may consider the status of associated records and any additional context of these associated records in the review.

This activity can be completed by the PI, PI Proxy, Primary Contact and members of the project team at any time in the review process.

To Manage Related Projects:

1. On the main protocol/study/agreement workspace (marked in the center as "Submission Type: Initial Protocol"), click the **Manage Related Projects** activity.

2. In the pop up, search for the related project by typing or pasting the its complete ID number into the search box (1). When it appears below, highlighted in yellow, click on the ID to choose

the submission (2). You can also click the ellipses […] to search the list of available submissions. One or more selected project(s) will appear on the list in the pop up.

Note: You may only search for submissions to relate by their IDs.

3. Click **OK** to create the relationship between projects and return to the workspace.

Click on the "Related Projects" tab of your protocol workspace to view related projects. Additional details about related projects will appear, including ID, name, state, date modified, PI, Study Team, and Expiry date. Click on the gear symbol to the left of "Add Filter" to sort, filter, and export to .csv.

A link to the workspace of the related project. Confirm that you have selected the correct projects on this tab.

Important! Notes about using Manage Related Projects:

- Relationships between projects are bi-directional. Once you have created a relationship between projects, it will appear (within a few moments) on the "Related Projects" tab for both submissions. You do not need to manage the relationship in both places.
- You may only create relationships between two initial/main studies. Follow-on submissions (such as amendments/modifications and continuing reviews) are not available for selection.
- Project states may not update automatically. The correct state will always be displayed on the workspace of that project.
- The Manage Related Projects activity replaces the Manage Relationships activity. Agreements submissions related through the Manage Relationships activity will appear on the "Related Projects" tab under the heading "Legacy Related Projects."

To remove a relationship between projects using the "Manage Related Projects" activity:

1. On the main protocol workspace (marked in the center as "Submission Type: Initial Protocol"), click the **Manage Related Projects** activity.

2. Remove projects by clicking on the "X" at the far right of the entry (1).

3. Click **OK** (2) to confirm the removal and return to the protocol workspace.

Submitting a DUA for Review

After entering all required information into the SmartForm and attaching files, the PI/AM, Creator, or Proxy must submit the DUA for review.

Tips:

- Make sure you include all applicable information for the submission, as identified in What to Include in a DUA SmartForm.
- Check for missing information before attempting to submit the submission, as described in Checking a Submission for Errors. Any errors or omissions not corrected are shown when attempting to submit the agreement and must be corrected before you can submit it for review.

To submit the agreement for review:

Important! Only the Principal Investigator/Agreement Manager, Creator, or Proxy can complete the following steps. For additional information about proxies, see Managing Principal Investigator (PI) Proxy.

1. From **My Inbox**, click the name of the submission to open it. It should be in the Pre-Submission state.

If the submission does not appear on this list, perhaps it was already submitted, or it does not include you as a Principal Investigator/Agreement Manager, Creator, or team member. To find the submission, try clicking **Agreements** in the top navigation area. If you do not see it in that

list, see Accessing a Submission for more other options, or contact the help desk at
duahelp@harvard.edu.

2. Click the **Submit** button from the Next Steps list on the left.

The system will conduct an 'error check' to identify if any required questions were missed. If any
errors or warnings are shown, click the link in the left navigation to go to the form page
containing the problem. For more information, see Checking a Submission for Errors. When all
errors are corrected, try submitting the agreement by clicking Submit again.

3. Click **OK** to agree to confirm the statement presented on the pop-up screen.

The submission will transition to the **Unassigned** state, for next steps by the appropriate reviewing
office.

Submitting information initiates a series of activities that may include:

- Review within your department
- Assignment to a Sponsored Programs/Research Administration staff member. For agreements,
  assignment is within the following offices:
  - Harvard T.H. Chan School of Public Health: Sponsored Programs Administration (SPA)
  - Harvard Medical and Dental Schools: Office of Research Administration (ORA) – Research
    Data Management
  - University Area, all other Harvard schools: Office for Sponsored Programs (OSP)
- Review by an OSP/SPA/ORA staff member
- Communication of the negotiations to the investigator

Any of these may lead to a request for the agreement team to take further action, such as providing
clarifications or modifying the submission. **Whenever the agreement team needs to take action, the
PI/PI Proxy and Creator receive an e-mail notification, and the submission appears in My Inbox for all
team members when they log in to the agreements system.**

Important! Make sure the appropriate person is listed as the creator to receive e-mail and see the
submission in My Inbox (along with the PI and any PI proxies, who also receive these). By default, the
person who created the initial agreement submission is the creator. See Changing the Agreement
Creator.

Checking the Status of a Submission

You can see a diagram showing the review status (state) of your submission by opening the submission
and viewing the submission workspace (webpage). The bubble shaded orange indicates the present
status in the workflow. For example, the following image indicates that this submission has been
submitted for review, the submission is not yet assigned to an OSP/SPA/ORA staff member, and review
is not yet completed:

To find out more about what each status (state) means, please view the DUA Glossary.

You can easily open your submission from one of the following lists (depending on its status):

- Dashboard > My Inbox
- Agreements > In-Review
- Agreements > Active

For instructions about opening your submission from these lists, see Accessing a Submission.

Communicating with the Reviewer

At any time after an item is submitted and owner/reviewer is assigned, members of the DUA team (the PI/Agreement Manager, Creator, or Collaborators) can complete the Contact Owner activity.

To contact the Owner/Reviewer:

1. Click the **Contact Owner** activity on the left side of the Agreement workspace.
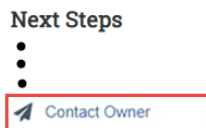
2. In the pop-up, type a message to the assigned Owner/Reviewer and attach a document (if needed).
3. Click **OK**.

Completing this activity will send a notification to your assigned Owner/Reviewer.

Additionally, you have the option to complete the **Add Comment** activity to post a note on the agreement history that all individuals with access to the agreement may view.

Important! Adding comments on the agreement will **NOT** send any notifications. This activity only adds a note on the submission page history.
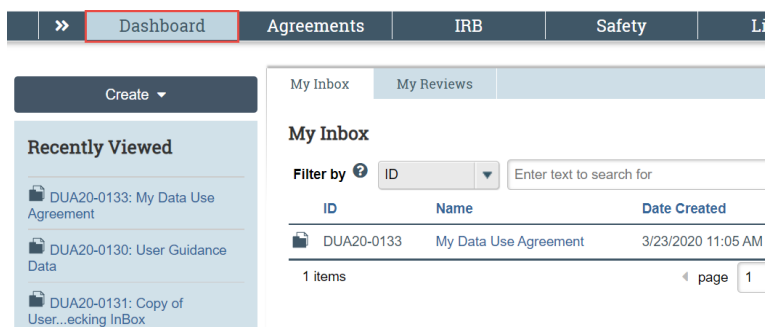
Accessing a Submission

You may want to go to a specific submission workspace (webpage) to view or update its contents, submit it for review, review it, or take other actions. Note that your access to a submission is personalized based on your role in the system and the role you play in relation to the particular submission. In addition, the actions you can take on a submission are personalized.

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

To find a list that includes the submission name:

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

OR

- **Agreements** (all items to which you have access in the Agreement System)**:** Click **Agreements** in the top navigation header and select the **All Submissions** tab. The lists display workspaces for all agreements and amendments entered into the agreements system that you have permissions to view.
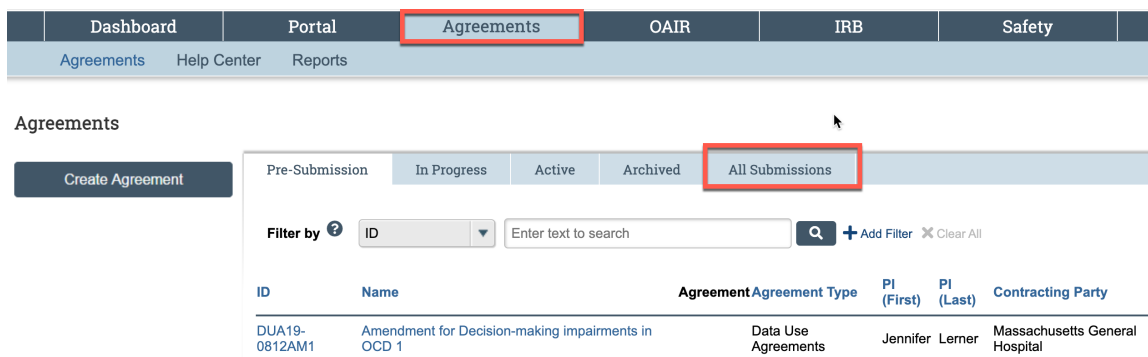
Tips:

- Try filtering this list by the submission name or Principal Investigator (PI) last name. Next to Filter by, select **Name** or **PI (Last)**. Then type the beginning of the name and click **Go**.
- View the **Status** column to see where the submission is in the review process.

The **All Submissions** listing can be exported to Excel. Click the **Export** button at the top of the list.

Note: 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.

Managing Submission Permissions

Permissions on a submission are different, depending on your role on the agreement submission. The Principal Investigator/Agreement Manager (PI/AM), Agreements Creator/Primary Contact (AC/PC), and agreement team permissions are different than OSP/SPA/ORA office staff or ancillary reviewers.

Principal Investigators/Agreement Managers, Creators, Proxies, and team members have the following permissions:

Agreements Role*	PI/AM	AC/PC	Proxy	Team Member
Can access to the submission in the Agreements system?	☑	☑	☑	☑
Receives **system notifications**?	☑	☑	☑	
Can create submissions on behalf of the PI/AM? *All Types of Submission*	☑	☑	☑	☑
Can <u>submit</u> submissions on behalf of the PI?	☑	☑	☑	
Can <u>submit changes</u> for submissions where clarifications were requested?	☑	☑	☑	
Amendment required to add or update this role?	☑	☑	Proxy must be a Team Member, but Proxy assignment does not require an amendment.	☑

*For view access to many records in a department or school, contact duahelp@harvard.edu for expanded guest access.

Submission Workspace Overview

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

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

Workspace Regions

Image displays the Initial/Main Agreement workspace for reference.

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

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

Responding to a Request for Clarifications

At any stage during the review process, the Owner/Reviewer may request clarifications to the agreement. When this occurs, the PI/Agreement Manager, the Agreement Creator/Primary Contact, and any PI proxy will receive a system notification requesting either clarifications or modifications. The agreement also appears in My Inbox for each member of the agreement team.

Important! Any team member can make changes to the agreement submission. However, only the PI/Agreement Manager, the Agreement Creator/Primary Contact, or any PI proxy can submit a response. Failure to respond promptly slows the review and approval process. A reminder is sent every

seven days for submissions in the clarifications requested state, where the submit response activity is not yet completed.

To view the details of the request and respond with the changes:

1. From **My Inbox**, click the name of the submission to open it.
2. Locate the details of the request, in the Activity column under Clarification Requested, read the request details. If applicable, click the **read more** link to display any extended text.

3. Edit the SmartForm to incorporate changes as needed. For instructions, see Editing a Submission.
4. Click **Submit Changes** to return the submission to the Owner/Reviewer. The Submit Changes form gives you space to type a point-by-point response to the requests and to attach a file. However, any permanent agreement information should be incorporated into the SmartForm itself.


5. Click **OK**. The submission returns to the review process.

Providing Signature on the Agreement

The Owner/Reviewer may request that the Principal Investigator/Agreement Manager (and others) provide wet signature on an Agreement document.

To provide signature:

1. From **My Inbox**, click the name of the submission to open the workspace
2. Click the Agreement **Documents** tab
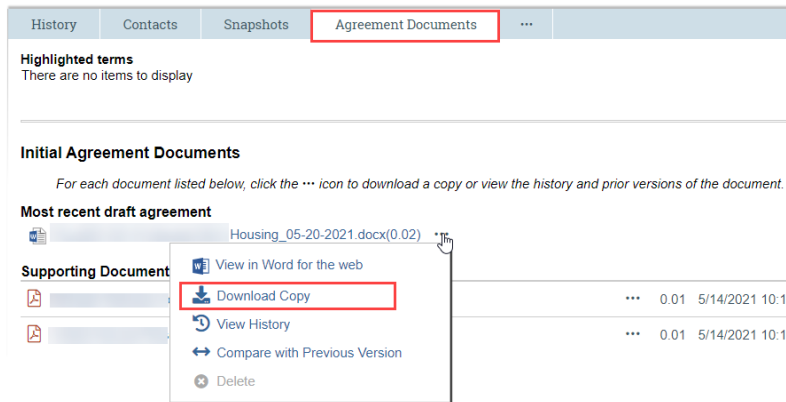
3. Click the **ellipsis** next to the draft agreement, select the **Download Copy** option, and save it to your computer
4. Open the saved document and sign
5. When finished recording signature, save the signed document on your computer
6. Go to the submission workspace:

    A. If signature was requested by "Clarifications Requested":

    1. Click **Edit Agreement** on the left. For Amendments, click **Edit Amendment**. The SmartForm will open.
    2. At question 3 on the first page of the SmartForm, replace the current document with the revised signed version by clicking the **ellipsis** next to the document on the SmartForm and selecting the **Upload Revision** option.
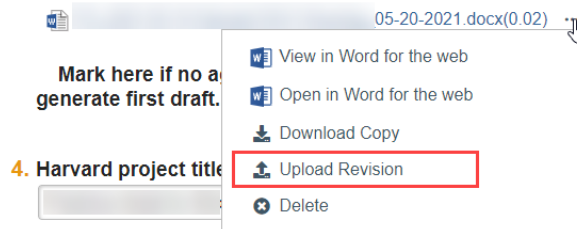
    3. Complete any further updates and submit the changes for further review. See the section [Editing a Submission](#) for further details.

    OR

    B. If signature was requested via another method and you are unable to Edit Agreement.
    1. Click **Contact Owner** on the left.
    2. Attach the signed document in the **Attachments** space on the pop up.
    3. Click **OK** to send the version to the Owner/Reviewer assigned to the submission.

Changing Documents on a Submission

You may need to modify agreement documents when:

- The Owner/Reviewer requests changes prior to activation/approval.
- Submitting an amendment to an active agreement.

To change documents prior to initial activation:

There are two ways to change documents (when the submission is in an editable state).

A. Edit Document Directly in Office Online
Note: This option is only available for Microsoft XML documents (file extensions .docx, .xlsx, .pptx, and .vsdx).

1. From **My Inbox**, click the name of the submission to open the workspace.
2. Click **Edit Agreement** on the left. For Amendments, click **Edit Amendment**. The SmartForm will open.
3. Click the **ellipsis** next to the document and select the **Open in Word for the web** option.
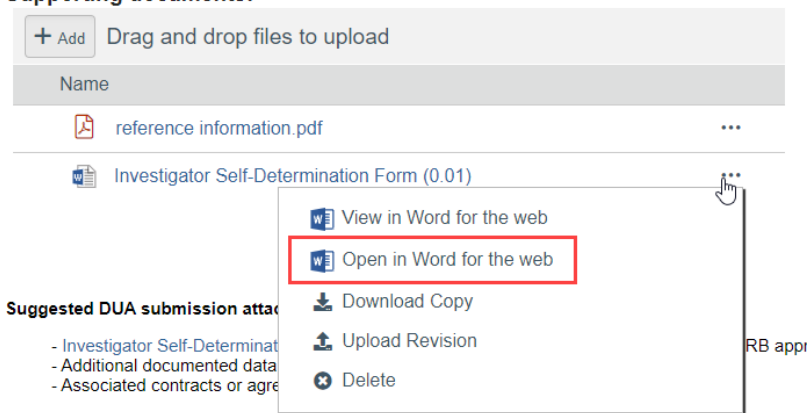
4. The document will open in Word for the web in a new tab. Make edits, enabling the Tracked Changes feature as needed, and close the tab once you have finished editing. Changes to the document will be saved automatically.
5. Complete any further updates and submit the changes for further review. See the section [Editing a Submission](#) for further details.
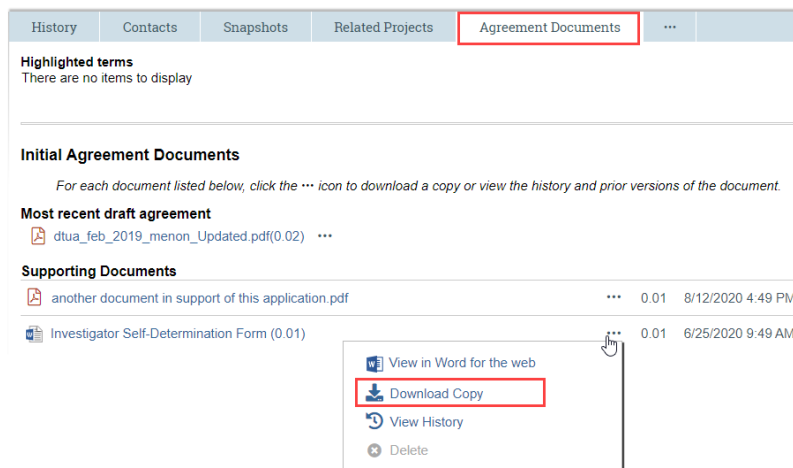
Note: You will not see the document version change on the SmartForm, but it will update when you close the Form.

OR

B. Download a Copy and Upload New Version
1. From **My Inbox**, click the name of the submission to open the workspace

2. Click the Agreement **Documents** tab

3. Click the **ellipsis** next to the document, select the **Download Copy** option, and save it to your computer
4. Open the saved document and make edits (enable the Tracked Changes feature as needed).
5. When finished with the changes, save the revised document on your computer
6. Go to the submission workspace and click **Edit Agreement** on the left. For Amendments, click Edit Amendment.
7. Navigate to the location of the current document within the SmartForm
8. Replace the original document with the revised version by clicking the **ellipsis** next to the document and selecting the **Upload Revision** option. You can use the following other controls to make document changes.
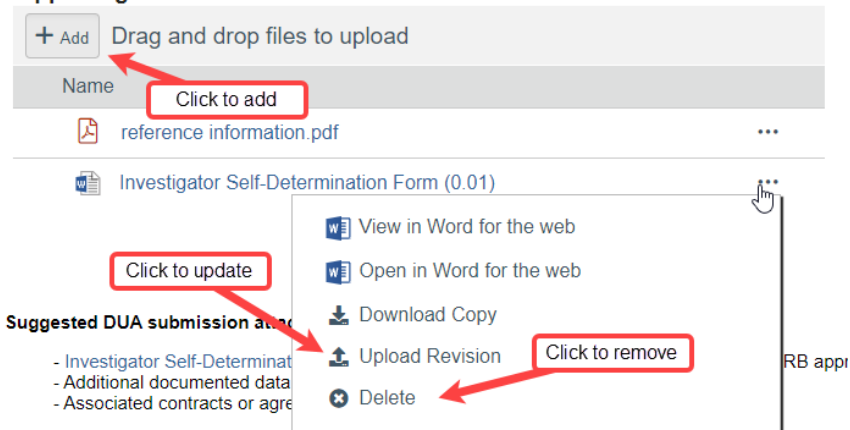
9. Complete any further updates and submit the changes for further review. See the section Editing a Submission for further details.

To change documents on an active agreement:

1. Click **Agreements** in the top left navigation area and select the **Active** tab.

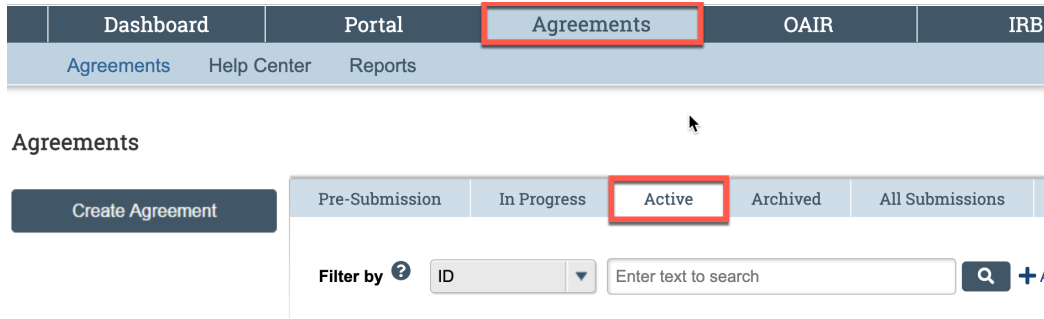2. Click the name of the Active agreement.
3. Click the Agreement **Documents** tab.

4. Click the **ellipsis** next to the document to Download a Copy or View the History to access a previous version and save it to your computer. In some cases, this document may contain previously approved tracked changes and comments. To update contents, match the current final-approved version, use the review features in Word to accept all the changes and remove any comments. Use this clean document as a starting point for your revisions.
5. Open the saved document and make edits.
6. When finished with the changes, save the revised document to your computer
7. Go to the active agreement workspace and create an amendment to update the SmartForm and submit the proposed changes for review. See the section Creating an Amendment after DUA Activation for further details.

Finding Signed Agreements

To find signed documents:

1. Click **Agreements** in the top left navigation area and select the **Active** tab.
   Most recent signed documents are visible on this list.
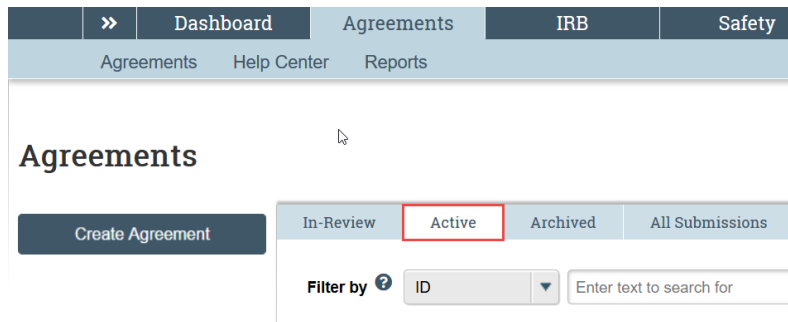
2. To see more details than just the most recent document, click the name of the Active agreement.
3. Click the **Agreement Documents** tab to view Signed Amendment and Agreement Documents and current Supporting Documents.
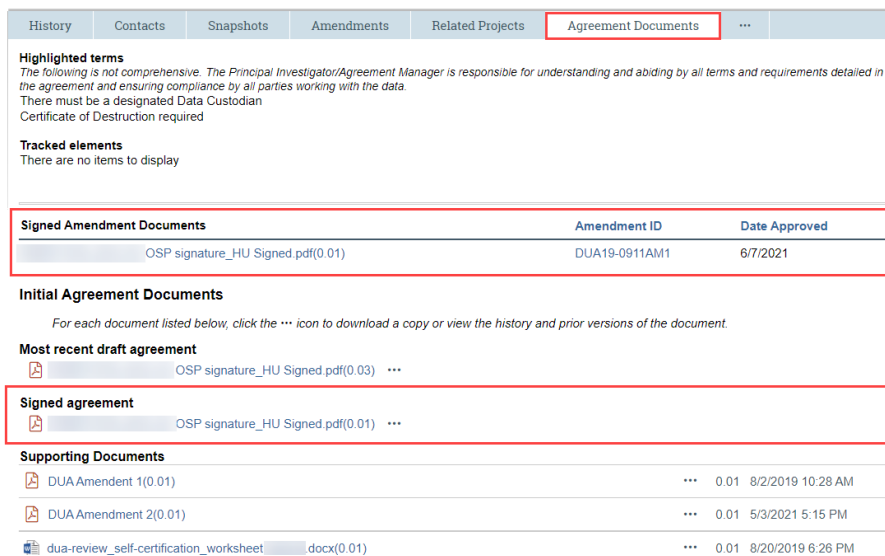
View a limited list of highlighted items and other tracked elements: The reviewer may identify one or more attributes of an agreement of which there should be increased awareness. This is to help support appropriate management of the data under this agreement.

Important! The attributes that may be highlighted/indicated are a limited list and do not address all requirements detailed in any agreement. Always reference the signed DUA (and any signed amendments) to view and address all terms and conditions associated with the agreement.

In addition to the data security level, one or more of the following items may be indicated on the Agreement Documents tab:

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

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

Managing Principal Investigator (PI) Proxy

The Principal Investigator may assign proxy permissions so that system activities only available to PIs can be completed by another member of the agreement team. The PI Proxy must be a member of the collaborator team that is listed on the SmartForm.

The purpose of assigning a system-based proxy is to assist with the management of submissions. PI Proxy permissions do not imply that the named proxy has PI responsibilities; only the Principal Investigator holds Principal Investigator responsibilities.

Important! The agreement creator is assigned PI Proxy permissions in the system, by default.

Once a PI Proxy has been assigned, the Proxy:

- Can complete the submit or submit changes activities on behalf of the PI.
- Will receive all system notifications pertaining to the agreement submission.
- Cannot assign additional proxies; the PI is the only person who is able to designate a PI Proxy.

Tip: Faculty Sponsors listed as a contact will not receive system notifications by default. Faculty Sponsors may be added as a PI Proxy so that they will receive system notifications about the agreement submission.

**To assign or remove a PI Proxy:**

1. Navigate to an Initial/Main Agreement workspace (see Accessing a Submission for more instructions).
2. On the main agreement workspace (marked in the center as "Submission type: Initial Agreement"), under Next Steps, click **Assign PI Proxies**.

&+ Assign PI Proxies

3. A pop up will appear. A list of names will show only team members that are listed on the General Information page of the SmartForm. If an individual you wish to assign as PI Proxy is not listed, they first must be added to the submission by clicking Edit Agreement or by amendment. From the list, you can:

    ▪ **Assign Proxies:** Put a check beside the name of individual(s) you would like to designate as PI Proxy.
    ▪ **Remove Proxies:** Remove the check beside the name of individual(s) where you would like to remove PI Proxy permissions. This action only removes proxy permissions and does not remove a contact from the agreement team.

4. Click **OK**.

All updates to PI Proxy will be recorded on the main agreement workspace, capturing the name, date, and time that the PI completed the activity.
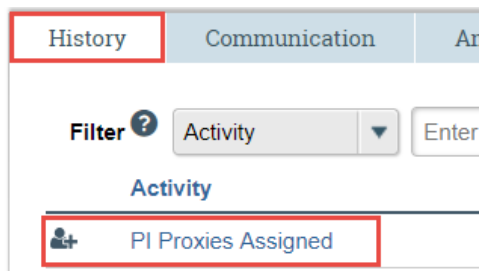
Important! Any PI Proxy that is removed from the agreements team via amendment will be automatically removed as PI Proxy.

Changing the Agreement Creator/Primary Contact

By default, in addition to the PI and PI Proxy, the Agreement Creator/Primary Contact is a recipient of all system emails (including notification of activation, or when clarifications are requested). Changing the Creator requires revision to the SmartForm. If the agreement is activated and the creator needs to be changed, an amendment is required.

- To change the Creator during initial review while the submission can be edited, see Editing a Submission.
- To change the Creator after initial activation or while the SmartForm cannot be edited, complete the **Manage Admin Contacts** activity.

To change the Agreement Creator/Primary Contact:

1. Navigate to a study (see Accessing a Submission for more instructions).
2. Click **Manage Admin Contacts** from the Next Steps list on the left. A new window opens.
3. In the first space for Agreement Creator/Primary Contact, click the x beside the name and begin typing the name of the new contact in the search box. A list of matching names appears. Click on the correct name using the mouse.
4. Click **OK**

Important! The agreement creator is also assigned PI Proxy permissions, by default.

Managing Guests with View-Only Permissions to the Study

During the course of a project, you may want to add a guest who can view your study and its documents. 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 Accessing a Submission for more instructions).
2. Click **Manage Admin Contacts** from the Next Steps list on 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**

Copying an Agreement Submission

Over the course of submission and review, it may be appropriate to copy the elements of one agreement into a new submission which then can be edited and submitted for review. For example, it is appropriate to copy an agreement if:

- There are basic elements of the agreement (such as the list of Agreement collaborators) that are similar to a new project that will be proposed;
- An agreement was discarded in error;
- A member of the ORA/SPA/OSP office requests that you copy the agreement; or
- The agreement expired but requires extension.

Copying a submission will replicate all information on a submission (including documents) into a new submission. An agreement submission can be copied at any time. However, note that:

- The status of the copy is completely independent of the status and management of the original agreement.
- Only a Main/Initial Submissions can be copied. Amendments cannot be copied.
- The new copy must be further edited and submitted before review may begin.
- If the copy was created in error, it can be discarded.

Important! Do not copy a submission to propose changes to an active DUA. See Making Changes after DUA Activation for instructions to create an amendment.

To copy an agreement:

1. Navigate to an agreement (see Accessing a Submission for more instructions).
2. Click **Copy Agreement** from the Next Steps list on the left. A new window opens.
3. Write in the name of the new submission (this can also be edited after the submission is created).
4. Click **OK.**

The copy activity will appear under the History tab of the Initial/Main Agreement workspace. While the system is creating the copy, a progress note may appear. Refreshing the browser page will update the view to display a link to the copy.

Note: The number of the copy here is not the official submission number. Visit the new submission workspace (by clicking on that number) to view the official new submission ID.

Navigate to the new submission by either:

- Refreshing the page to view and click on a link to the new copy, or
- Clicking Dashboard in the top navigator bar and click on the new submission.

Complete steps to edit the submission and submit it for review. (see Editing a Submission for more instructions).

Amendment-Making Changes after Activation

After DUA activation, it may be appropriate to change the confirmed elements of an agreement. This can be done by creating an amendment for review. For example, it is appropriate to create an amendment if:

- A legal amendment to the original DUA is needed.
- There are basic elements of the agreement (such as the list of team members) that requires revision.
- A member of the ORA/SPA/OSP office requests that you amend the agreement.
- The agreement requires extension.
- The certificate of destruction is completed and must be added to the supporting documents.
- Individuals listed as contacts must be changed.

During the creation and review of an amendment, the changes are only visible on the amendment workspace. After amendment approval, all updated elements of the agreement are also updated on the Initial/Main Agreement workspace.

To create an amendment:

1. Navigate to an agreement (see Accessing a Submission for more instructions).
2. Click **Create Amendment** from the Next Steps list on the left. The SmartForm will open.
3. In the first page of the Amendment SmartForm
   - Upload any legal amendment document draft or request a draft that requires signatures. The document uploaded here is only for the amendment.
   - Add amendment supporting documents. Amendment supporting documents are specific to this amendment only.
   - Provide a description of the planned changes in the Amendment.
4. Click continue to make the necessary revisions to the original agreement and agreement record, including (but not limited to):
   - Changes to the PI/Agreement Manager (Agreement Upload page of the SmartForm); or

- Revisions to the agreement team (Question 5 on the General Information page of the SmartForm).

Leave any unchanged elements of the submission as-is. Make additional changes as appropriate.

Note: It is helpful to revise the submission title, where "Amendment # for …" represents a legal amendment and "Record Update # for …" represents a proposed revision not requiring signature. Revisions to the submission title will not change the title of the main agreement.

5. Exit the submission. Choose one of these ways to exit:

   - Click the **Exit** link. If prompted to save the submission, click **Save Changes & Exit**.
   - Click **Continue** on each form, and then click the **Save & Exit** button on the last page of the form.
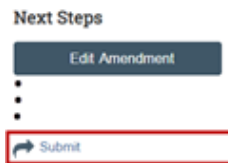
6. Click the **Submit** button from the Next Steps list on the left.

The system will conduct an 'error check' to identify if any required questions were missed. If any errors or warnings are shown, click the link in the Jump To column to go to the form containing the problem. For more information, see Checking a Submission for Errors. When all errors are corrected, try submitting the agreement by clicking Submit again.

7. Click **OK** to agree to confirm the statement presented on the pop-up screen.

The submission will transition to the Unassigned state, for next steps by the appropriate reviewing office.

On approval, all updates (except the submission title) will be reflected on the Initial/Main Agreement workspace.

Important! Neither completing the Create Amendment Activity nor updating the SmartForm will send the submission for review**. The PI, Creator, or PI Proxy must click Submit (in the submission workspace)** for the submission to proceed on for the next state of review.

Amendment-Extending the Agreement Term

After initial activation, the DUA may need to be extended beyond the expiration date. To extend the term of the DUA, create an amendment and indicate the requested extension/new expiration date in the Create Amendment activity pop-up. It is important to also submit the amendment for review. For additional amendment details, see Making Changes after DUA Activation.
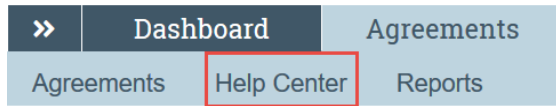
Important! The agreement creator is also assigned PI Proxy permissions, by default.

Managing 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 manage, 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 propose revision or extend the term of a DUA that does not currently have a record in the Agreements system:

    1. Enter the revision as an initial agreement (to create the record, see [Creating a New Data Use Agreement Request](#)).

    AND

    2. As part of the submission to create the record:
        - Include any previous tracking number/reference in the name of the submission (if there is one);
        - In the DUA Description, indicate: *"DUA initially activated prior to Agreements system use"*;
        - Add the previously executed agreement (and any other signed addenda or amendments) to the Supporting Documents (on the first page of the SmartForm); and
        - 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).** There is no change to the terms, conditions and requirements associated with managing and complying with any existing active DUAs. If your team would like to populate the system with an existing active DUA and there is no proposed revision or extension; contact the office conducting review to determine an appropriate method and time to add a record that would not otherwise require review.

- **(Legacy Instruction) DUAs or DUA amendments that are under review and not yet activated at the time the system becomes 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. Your DUA reviewer will contact you during the remaining review to share the anticipated path for the existing review.

Finding More Information

Resource	Description	How to Access It
Help for a field or page	More information about a question or form.	Click the question mark icon ❓ next to the question or at the top of the form.
Help system	The full online help system, with search and table of contents. The online help contains procedures and information for all users.	Click the **Help Center** sub-menu link at the top of the screen.
DUA Agreement Submission Guide	Instructions for submitting an agreement for review.	Click the **Help Center** sub-menu link at the top of the screen. On the Guides tab, click the name of the guide to open it.
DUA Agreement Reviewer's Guide	Instructions for reviewing an agreement submission.	
Agreement Support	External website with additional information about using the Agreements system	https://ras.fss.harvard.edu/agreements
DUA Help Desk	Contact for help with DUA access and use	duahelp@harvard.edu
Reviewing Office Websites	Information about the DUA review process and requirements	- Harvard T.H. Chan School of Public Health: Sponsored Programs Administration (SPA) - Harvard Medical and Dental Schools: Office of Research Administration (ORA) – Research Data Management - University Area, all other Harvard schools: Office for Sponsored Programs (OSP)

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