HURON

Huron COI

Administrator's Guide

February 2022

Table of Contents

Introduction

Higher education institutions and academic medical centers need a system for tracking researcher, staff, and leadership training and disclosures to ensure that conflicts of interest and conflicts of commitment are disclosed and, when necessary, managed.

This guide shows how to perform administrative activities in Huron COI to identify conflicts and ensure they are properly managed.

Important features covered in this guide include:

- **Certification:** A certification is a record of the determination regarding a disclosure. For more information, see Certifications Overview on page 8.
- **Retrospective Review:** A retrospective review involves information that was brought to the attention of COI Administrators outside the COI system about a possible misrepresentation of the discloser's interests. For more information, see Create a Retrospective Review or Mitigation Plan on page 9.
- **Ancillary Review:** An ancillary review allow individuals, departments, and other organizations to give feedback in parallel with the normal review workflow. For more information, see Ancillary Review Process on page 10.

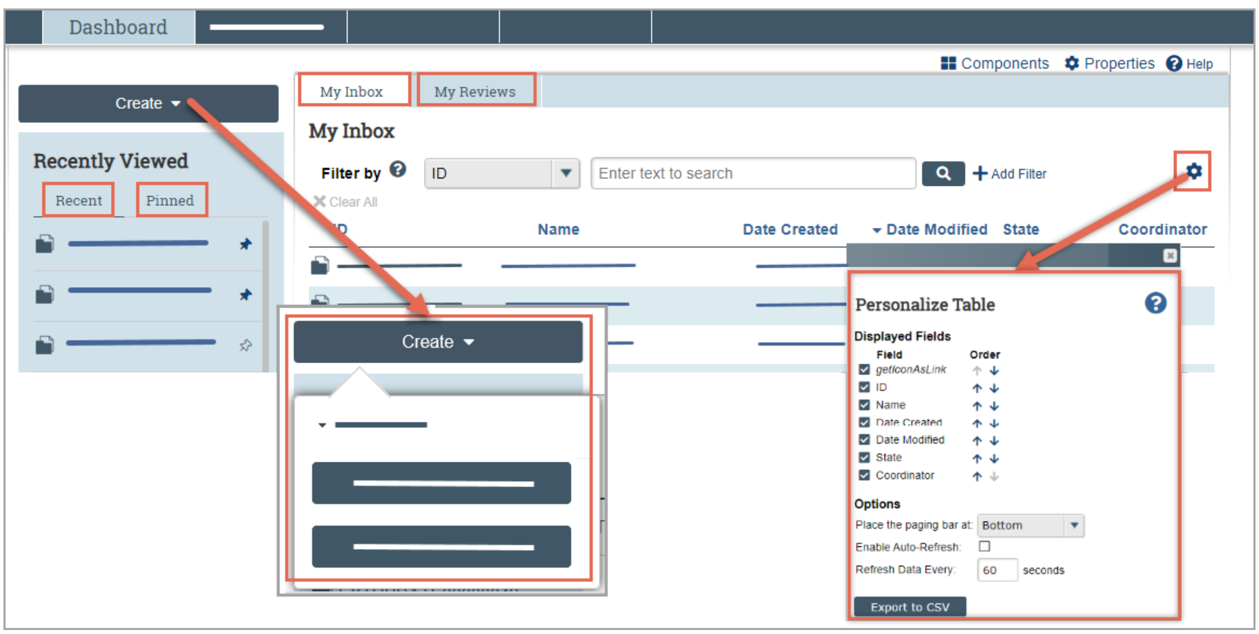
Navigation and Basic Tasks

When you first log in, you will be on your Dashboard, which is the starting point for finding items and performing many basic tasks.

To find key items

From your Dashboard, you will see:

- **My Inbox:** Items that require you to take action.
- **My Reviews:** Items assigned to you to review if you are a reviewer. These are a subset of the items in My Inbox.
- **Recently Viewed:**
  - **Recent**: The last several items you viewed. Scroll through this list to find an item you worked on recently.
  - **Pinned:** You can pin the items in the Recently Viewed section for quick and easy access. This is where those pinned items are listed.
- **Personalize Table:** You can alter the tables displayed on the dashboard by using the Personalize Table gear icon.



To identify what action is needed

- Review the state of the project in My Inbox.
  The state gives a clue as to what to do next. For example, Committee Review means a certification is scheduled or in-review by a COI committee.

To open a certification

- From My Inbox, or from the Certifications page, click the certification name.
  The certification workspace opens.

To open a management plan

- From My Inbox, or from the Plans page (**Management Plans** tab), click the management plan name.
  The management plan workspace opens.

To open a retrospective review

- From My Inbox, click the retrospective review name. Alternatively, from the Plans page, click **Retrospective Reviews** tab and click the retrospective review name.
  The retrospective review workspace opens.

To open a triggering event

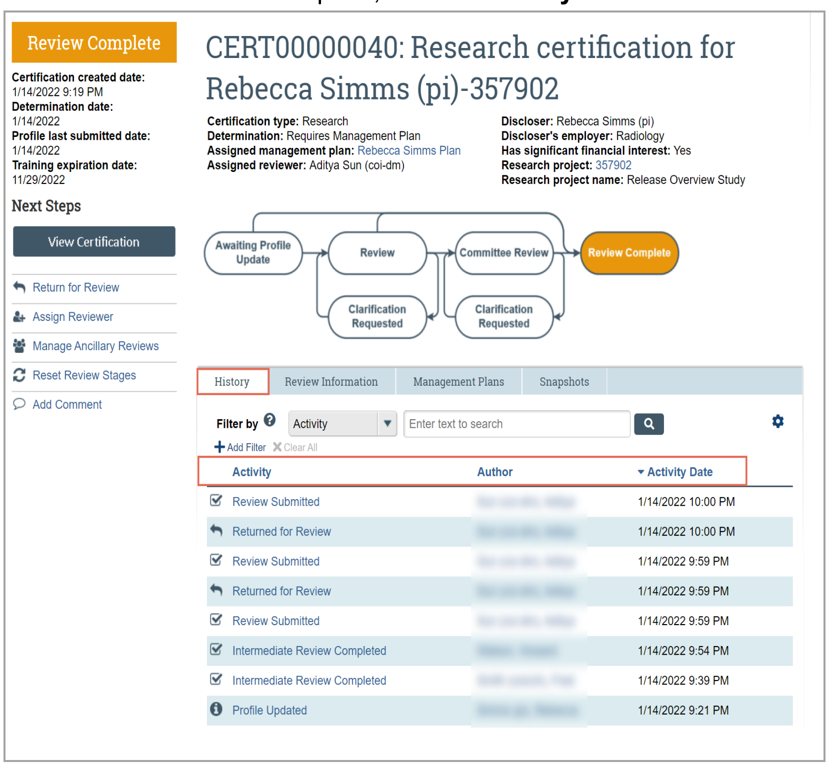
- From My Inbox, or from the Triggering Events page, click the triggering event name.
  The triggering event workspace opens.

To open a pre-approval request

- From My Inbox, or from the Requests page, click the pre-approval request name.
  The pre-approval request workspace opens.

To view history

- From the certification workspace, click the **History** tab.



The **History** tab lists the activities performed on a certification including any comments, attachments, or profile updates.

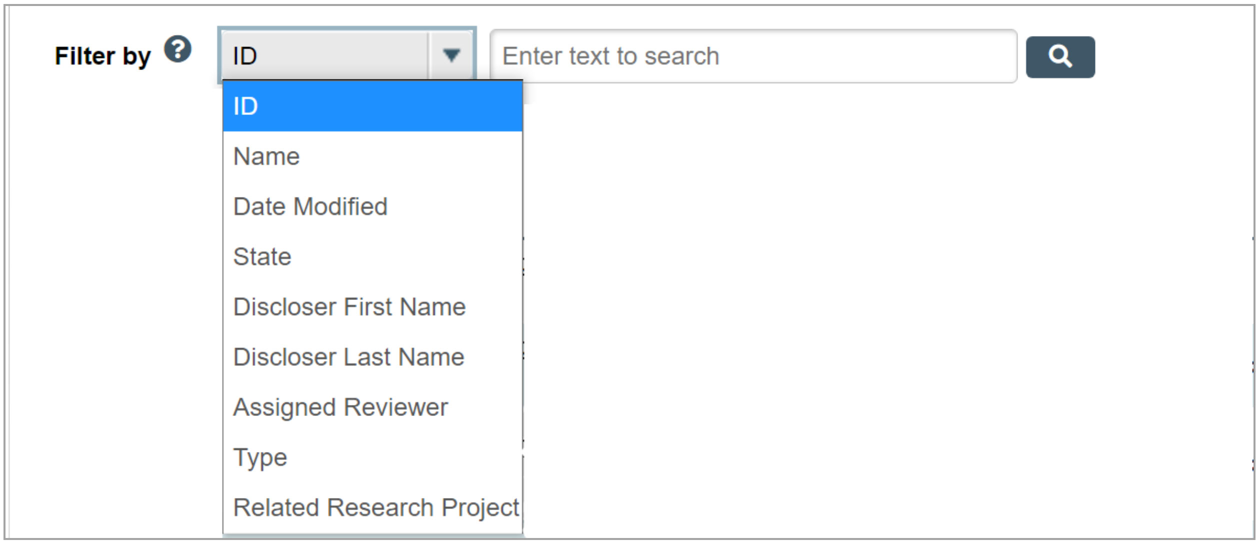
Filter and Sort Data

Many pages contain tables you can filter and sort to help you find the required data.

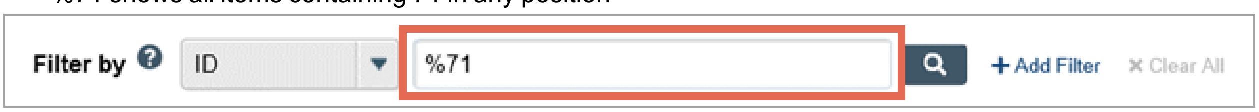
- Filtering reduces the list to only the data that meets the criteria. The advanced filter lets you combine multiple filter criteria together.
- Sorting displays the data in ascending or descending order by a particular column.

To filter data

1. Select the column to filter by from the drop-down menu. The menu lists only the columns you can filter by.
   Note: To combine multiple filter criteria, such as, ID, Name, and Date Created, see To use advanced filters on page 7.



2. In the text box, type the beginning characters for the items you want to find. If you do not know the beginning characters, type a % symbol as a wildcard before the characters. Examples:
   - 71 shows all items beginning with 71
   - %71 shows all items containing 71 in any position



Tip: For examples and a list of operators you can use, click the Help icon.

3. Click the magnifying glass icon to apply the filter.

The table shows only those rows that are an exact match.

Tip: If you do not see the expected items in the list, click **Clear All** in the Filter By area to remove the filter.

To use advanced filters

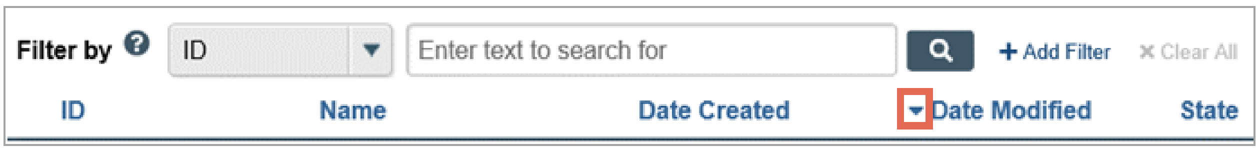
1. In the Filter by area, click **Add Filter**.

2. Enter filter criteria as explained in the previous section. See To filter data on page 6.
3. To add more criteria, click **Add Filter** once more.
4. Click the magnifying glass to apply the filter.
   The table shows only those rows that match all the filter criteria.

To sort data

1. Click the column header you want to sort by.
2. Click it a second time to reverse the sort order.
   The arrow indicates the column by which the data is sorted and the sort order, either ascending (up arrow) or descending (down arrow).

Note: If the column header is not a link, you cannot sort by that column.



Certifications Overview

A certification is a project for tracking the review of a disclosure profile and documenting the determinations and findings. A certification contains disclosure profile details that are referenced and reviewed throughout the COI process. A certification can be created in the following ways:

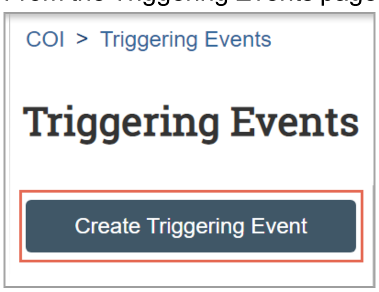
- If Huron COI is integrated with Huron IRB or Grants, research certifications are created automatically.
- If Huron COI is not integrated with Huron IRB or Grants, you can manually create triggering events that cause research certifications to be created. For more information, see Create Triggering Events on page 8.
- Regardless of integration, non-research certifications and research portfolio reviews can be created automatically at certain intervals depending on your institution's COI Settings. Research portfolio review certifications are also created automatically as needed when disclosers complete their disclosure profile updates.

Create Triggering Events

Triggering events are events that require a person’s interests to be reviewed by the COI office, for example, involvement in a research study, grant proposals and awards. Triggering events are created manually. The triggering event contains key details of the project (IRB Submission or Grants project) that needs to be available in Huron COI as a part of the review process such as the project and personnel.

To create triggering event

1. From the Top Navigator, click **COI** and then click **Triggering Events**.
   The Triggering Events page appears.
2. From the Triggering Events page, click **Create Triggering Event**.



3. Enter the Project title.
4. Update other fields if required. and then click **Continue**.
5. Complete the pages. On the last page, click **Finish**.

Create and Update Certifications

The Manage Certifications activity performs both actions - adding or withdrawing certifications based on the personnel identified in the triggering event - each time the activity is run.

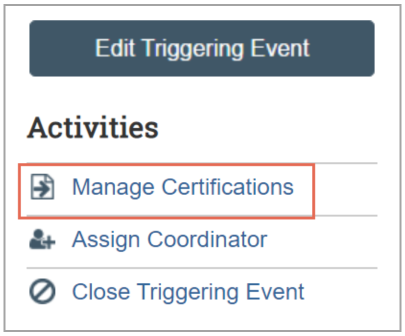
Hence, you can use the Manage Certifications activity to:

- Create a new research certification for personnel who do not have a research certification.
- Withdraw open research certifications for personnel who are no longer part of a research project.

To create and update certifications

1. From the Top Navigator, click **COI** and then click **Triggering Events**.
   The Triggering Events page appears.

2. From the Triggering Events workspace, click **Manage Certifications**.



3. Click **OK** to create and withdraw certifications as appropriate.

New certifications appear in the **Current Certifications** tab in the Triggering Events workspace. Withdrawn certifications can be viewed from the **Historical Certifications** tab in the Triggering Events workspace.

Create a Retrospective Review or Mitigation Plan

A retrospective review is performed when issues arise that might impact the integrity of a research project. You create a retrospective review when these issues have come to your attention so you can document the concerns and the outcome of the review.

Once the retrospective review project is created, its details must be reviewed to determine if there is a bias in the research project. After the retrospective review is submitted, the retrospective review moves to Drafting Plan state if a bias has been determined.

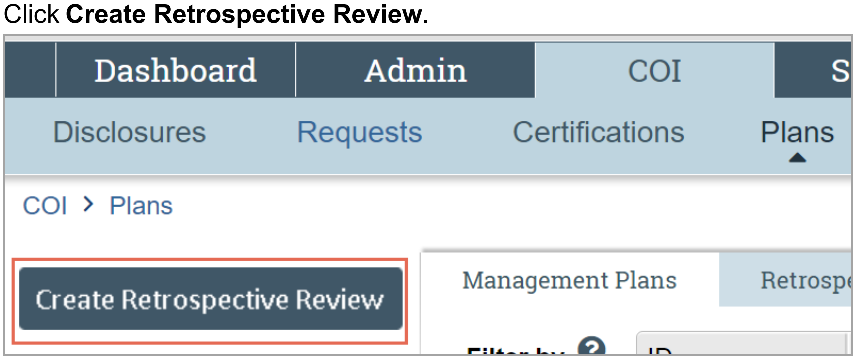
If bias is found in the research project, a mitigation plan is created. The plan includes details on how the institution will eliminate or mitigate the effect of bias and the date on which the mitigation plan was submitted to the funding agency.

Once the mitigation plan is submitted, the retrospective review moves to the Review Complete state.

Data captured in the retrospective review and mitigation plan could be part of COI Reports.

To create a retrospective review

1. From the Top Navigator, click **COI** and then click **Plans**.
   The Plans page appears.
2. Click **Create Retrospective Review**.



3. Enter the retrospective review name.
4. Select the user for whom you are creating this retrospective review.
5. Select the date on which the institution determine non-compliance.

6. If required, enter other details and click **Continue**.
7. Complete the pages and click **Finish**.

Ancillary Review Process

Ancillary reviews allow individuals, departments, and other organizations to give feedback on certifications, management plans, retrospective reviews, and pre-approval requests in parallel with the COI review.

Ancillary reviews can be configured to block the workflow if a required ancillary review is not complete. If necessary, the COI Staff can bypass any workflow stoppage. Refer to your COI policies about how, when, and whether to interrupt the COI review process to wait for ancillary reviews.

Manage Ancillary Reviews

COI Administrators and staff can set up ancillary reviews when a certification, management plan, retrospective review, or pre-approval request is in a valid state. When an ancillary review is assigned to a reviewer, the reviewer receives an e-mail notification. The project appears in the reviewer's inbox if the project is a required ancillary review.

If outstanding reviews are blocking you get a warning message and you cannot execute the activity that moves the project through the workflow (OK button is disabled). If an ancillary review is blocking the workflow, either of the following actions will allow the project to move forward:

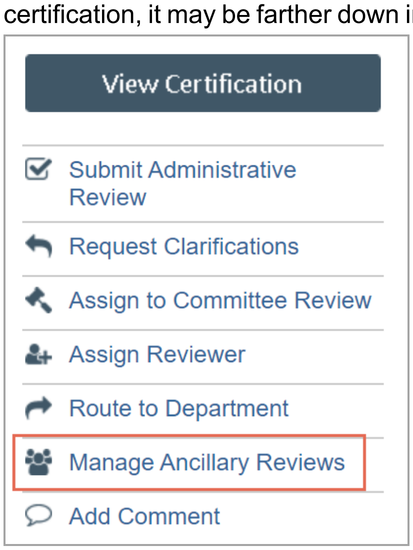
- The reviewer completes the ancillary review.
- A COI staff member overrides the blocking ancillary review. For more information, see Override Blocking Ancillary Reviews.

Manage Ancillary Review activity is used to set up an ancillary review as well as to override blocking ancillary reviews.

Note: For the sake of simplicity, let us take certifications as an example for the procedure.

To set up an ancillary review

1. From My Inbox, click the certification name.
   Alternatively, click the certification name in the **In Review** certifications tab.
2. From the certification workspace, click **Manage Ancillary Reviews**. (Depending on the state of the certification, it may be farther down in the list.)



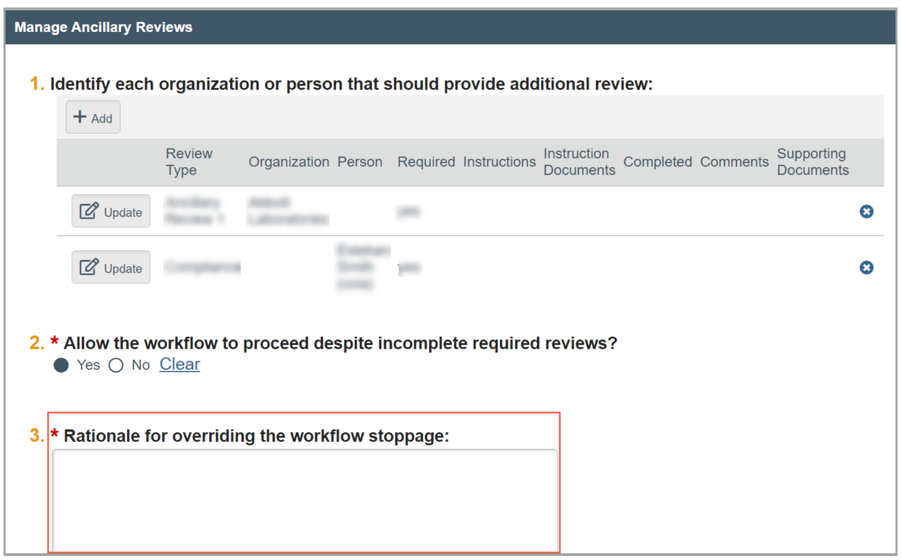
3. Click **Add**.
   The Add Ancillary Review page appears.
4. Select reviewers by organization or by person.
5. (Optional) Select the type of review.
6. Select whether a review is optional or required for the specified reviewers.
7. (Optional) Type instructions and upload instruction documents for the ancillary reviewer.
8. Click **OK** to add the ancillary review or click **OK and Add Another** to add the ancillary review and then add another ancillary review.
9. When you finish adding reviewers, click **OK** in Manage Ancillary Reviews page.

The newly added reviewers receive an e-mail notification. If the reviewer's response is required, the project will appear in reviewer's inbox until they have responded.

To override blocking ancillary reviews

If an ancillary reviewer does not complete a required ancillary review, the certification is blocked from moving forward.

1. From My Inbox or one of the tabs on the appropriate COI page, click the name of the certification for which you want to override the ancillary review.
2. In the certification workspace, click **Manage Ancillary Reviews**.
3. Select **Yes** for the statement "Allow the workflow to proceed despite incomplete required reviews."
4. Provide the rationale for the override, then click **OK**.



You can now continue with the action that was previously blocked.

Reset Review Stages in a Certification or Pre-Approval Request

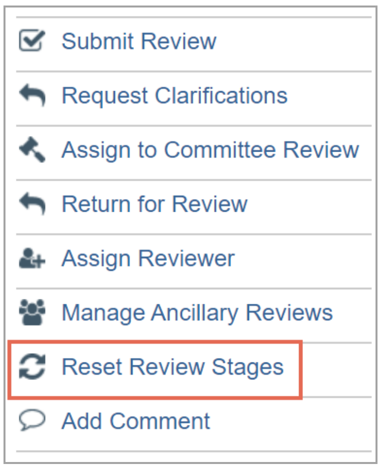
The review stages on a certification or pre-approval request are based on the review workflow template assigned at the time they are submitted. If the review workflow template changes after the certification or pre-approval request is submitted, then the review stages in the certification or pre-approval request do not update automatically.

If appropriate, you can use the Reset Review Stages activity to update the review stages on the certification or pre-approval request to reflect the current review stages on the review workflow template. Regardless of the review stage the certification or pre-approval request is in, using this activity will restart the review process, and the appropriate reviewer for the first stage will be assigned. The assigned reviewer also gets an e-mail notification that the task is assigned for review.

For example, a research certification is submitted at a time when your institution has configured review workflow template A (with a two-stage review process). However, due to an institutional policy change, a change is required and a configuration update is made to apply review workflow template B (with a three-stage review process) that requires an initial review by the discloser's supervisor. You use the Reset Review Stages activity to apply template B to the research certification and restart the review process with the new supervisor review. For more details on review workflow templates, see the *COI Deployment Guide*.

To reset review stages

1. From the certification or requests workspace, click **Reset Review Stages**.



2. Click **OK**. The review stages on the certification or pre-approval request are updated based on the new review workflow template. The review process restarts from the first stage.

Central Actions

Huron Conflict of Interest (COI) automates the general process of initiating updates to disclosure profiles, and discloser training details, as well as creation of certifications. However, there might be specific instances where you need the discloser to:

- Update their disclosure profile
- Update training details
- Manage the usage of write-in entities
- Manage eligible proxies
- Assign proxy
- Remove assigned proxy

You can perform these tasks on an ad-hoc basis from the Central Actions area. You can also create certifications from the central actions area.

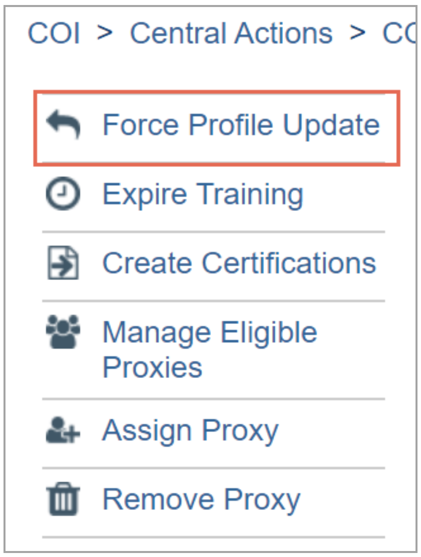
Force Profile Update

The Force Profile Update activity allows you to prompt all disclosers, specific disclosers, or disclosers in a particular category to update their disclosure profiles. The system will notify the disclosers to update their disclosure profiles.

Note: Forcing a profile update does not mean a review has to be performed, because a certification is not created automatically.

To force a disclosure profile update

1. From the Top Navigator, click **COI** and then click **Central Actions**.
   The COI Central Actions page appears.
2. From the COI Central Actions page, click **Force Profile Update**.



3. Complete the page by selecting the individuals who need to update their profiles and then click **OK**.

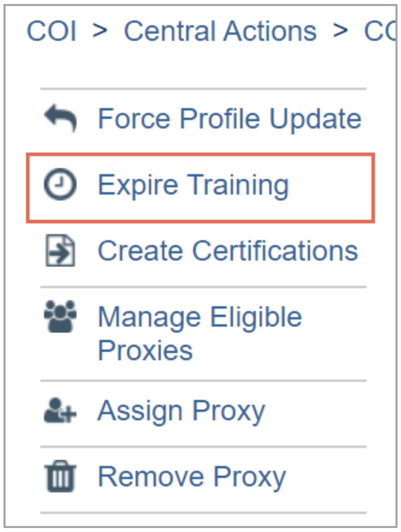
Cause Training to Expire

You can use the Expire Training activity to cause training to expire for all disclosers, specific disclosers, or disclosers in a particular category. Training expiration notifies disclosers that they must complete their training.

To cause training to expire

1. From the Top Navigator, click **COI** and then click **Central Actions**.
   The COI Central Actions page appears.

2. From the COI Central Actions page, click **Expire Training**.



3. Complete the page by selecting the individuals who need to complete their training and then click **OK**.

Create Certifications

The Create Certifications activity allows you to create certifications related to a specific COI category for all disclosers assigned to the categories or specific disclosers in those categories. The certification is used to review details about a project and the interests of the disclosers involved in the project. Creating a certification does not automatically move the disclosure profile to Action Required state.

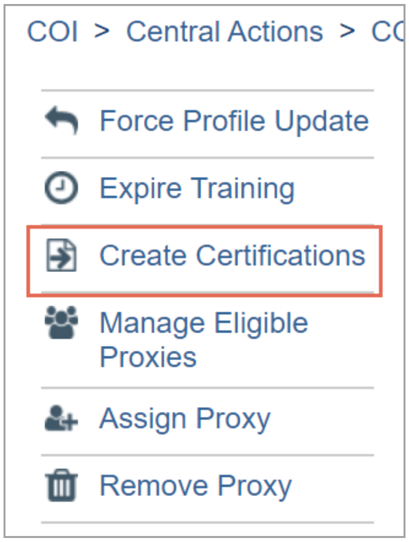
Notes:

- The certification will be created only if a discloser does not already have an open certification of that type created in that specific COI category.
- A research portfolio review will only be created through this activity if the selected disclosers have research certifications in a final state.

To create certifications

1. From the Top Navigator, click **COI** and then click **Central Actions**.
   The COI Central Actions page appears.

2. From the COI Central Actions page, click **Create Certifications**.



3. Select the category of the certifications.
4. If you want to create certifications for all disclosers in the selected categories, select **Yes**. If you want to create certifications only for certain individuals of the selected categories, select **No**. You get an option to select the specific individuals.
   Note: The individuals you select must be part of the category that you choose in the beginning of this activity.
5. Click **OK**.

Manage Write-In Entities

A discloser uses write-in entity when they do not find their intended organization in the list. There are several reasons why the discloser is not getting the intended organization in the list. Some of the reasons are mentioned below:

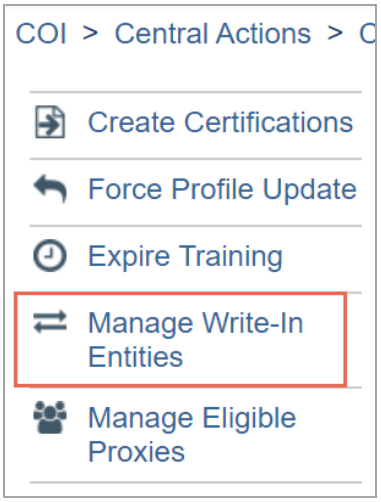
- The discloser might be using wrong spelling of the organization while searching in the list.
- The institution has not added the organization in the list.

COI Administrators can look at the Write-In Entities report on the **Write-In Entities** tab of the workspace and can check if the organizations need entities created for them in the store so they can be included in the selection list. The Manage Write-in Entities activity is used to inform disclosers that their intended organization is available in the list of organizations. The disclosers can then update their disclosure profile with their intended organization instead of the write-in entity.

To manage write-in entities

1. From the Top Navigator, click **COI** and then click **Central Actions**.
   The COI Central Actions page appears.

2. From the COI Central Actions page, click **Manage Write-In Entities**.



3. Select the organization that you want disclosers to update their write-in entities to. You can use one of the following methods:
   a. In the box, start typing the name of the organization, and select the organization from the list of results. Click **OK**.
   b. Click the **ellipsis** (…) button, select the organization from the list and click **OK**. You can also use the filtering tools to search for an organization.
4. Select the write-in entities that you want their discloser to update to the above selected organization.
   Note: You can select more than one write-in entity at a time.
5. If required, enter comments and upload supporting documents.
6. Click **OK**.

An e-mail notification is sent to each discloser regarding the correct organization and their write-in entity that should be updated to use it.

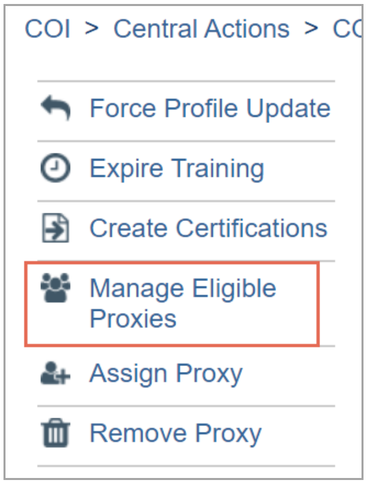
Manage Eligible Proxies

A proxy is a person who is authorized to manage disclosures for a discloser. The Manage Eligible Proxies activity is used to maintain the list of individuals who can be assigned as proxies. Eligible proxies must be assigned to this list before they can be assigned to act as proxies for disclosers.

To manage eligible proxies

1. From the Top Navigator, click **COI** and then click **Central Actions**.
   The COI Central Actions page appears.

2. From the COI Central Actions page, click **Manage Eligible Proxies**.



3. Select the user you want to add to the list of proxies using one of the following methods:
   a. In the Eligible proxies box, start typing the name of the user, and select the user from the list of results. Click **OK**.
   b. Click the **ellipsis** (…) button, select the reviewer from the list and click **OK**. You can also use the filtering tools to search for a person.

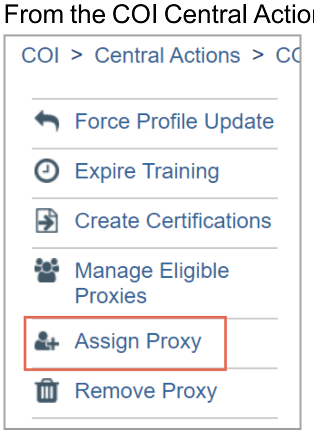
Assign Proxy

A proxy is a person who is authorized to manage disclosures for discloser. You can administratively assign a proxy to one or more disclosers using the Assign Proxy activity. The person must already have been identified as an eligible proxy using the Manage Eligible Proxies activity. Similarly, a discloser can also assign a proxy for themselves depending on their institutions COI Settings.

Note: You can select a proxy and then select one or more disclosers so that the proxy can act on behalf of the specified disclosers.

To assign a proxy

1. From the Top Navigator, click **COI** and then click **Central Actions**.
   The COI Central Actions page appears.
2. From the COI Central Actions page, click **Assign Proxy**.



3. Select the proxy.
4. Select the disclosers who will have the selected proxy assigned to their disclosure profiles and click **OK**.

The proxy receives an e-mail notification about the assignment, and the discloser profile appears in the proxy's inbox. Proxy can now perform tasks on behalf of the discloser.

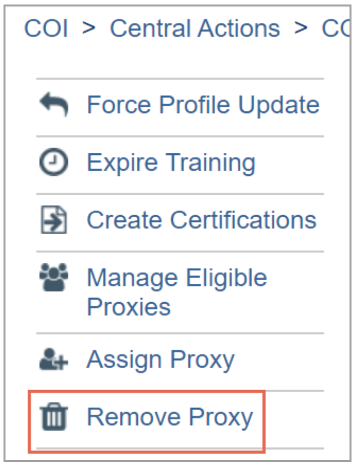
Note: Proxy can only update the disclosure profile's SmartForm, they cannot perform any other activities for the discloser.

Remove Assigned Proxy

You can use the Remove Proxy activity to administratively remove the assigned proxy from the discloser's disclosure profile. You can remove assigned proxies for multiple disclosers by using this activity.

To remove assigned proxy

1. From the Top Navigator, click **COI** and then click **Central Actions**.
   The COI Central Actions page appears.
2. From the COI Central Actions page, click **Remove Proxy**.



3. Select the disclosers for whom you want to remove the assigned proxy and click **OK**.

The proxy receives an e-mail notification about the removal, and the disclosure profile does not appear in the proxy's inbox anymore. Proxy can no longer manage the discloser's disclosure.

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