



Huron COI Discloser's Guide

February 2022

Table of Contents

- Introduction 3
- Navigation and Basic Tasks 3
 - Filter and Sort Data 5
- Update Disclosure Profile 6
 - Update Disclosures 6
 - Review and Certify your Training 7
- Respond to a Clarification Request 7
- Review and Accept Plans 9
- Pre-Approval Request 10
 - Pre-Approval Request Process 10
 - Create and Submit a Pre-Approval Request 10
 - Copy a Pre-Approval Request 12
 - Add Comment to a Pre-Approval Request 13
- Allow a Proxy to Disclose for You 14
 - Assign a Proxy 15
 - Complete the Proxy Update 16
 - Remove the Assigned Proxy 16

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 discloser activities in Huron COI to identify conflicts and ensure that conflicts are properly managed.

Important features covered in this guide are:

- **Disclosure Profile** - The disclosure profile is the focal point of the Huron COI system for the discloser. It provides a summary of discloser's interest and everything that was disclosed previously. For more information, see [Update Disclosure Profile on page 6](#).
- **Proxy** - A proxy is a person who is authorized to act for the discloser. For more information, see [Allow a Proxy to Disclose for You on page 14](#).
- **Pre-Approval Requests** - A pre-approval request allows you to submit a request to participate in certain activities, which is then reviewed before making a determination. For more information, see [Pre-Approval Request on page 10](#).

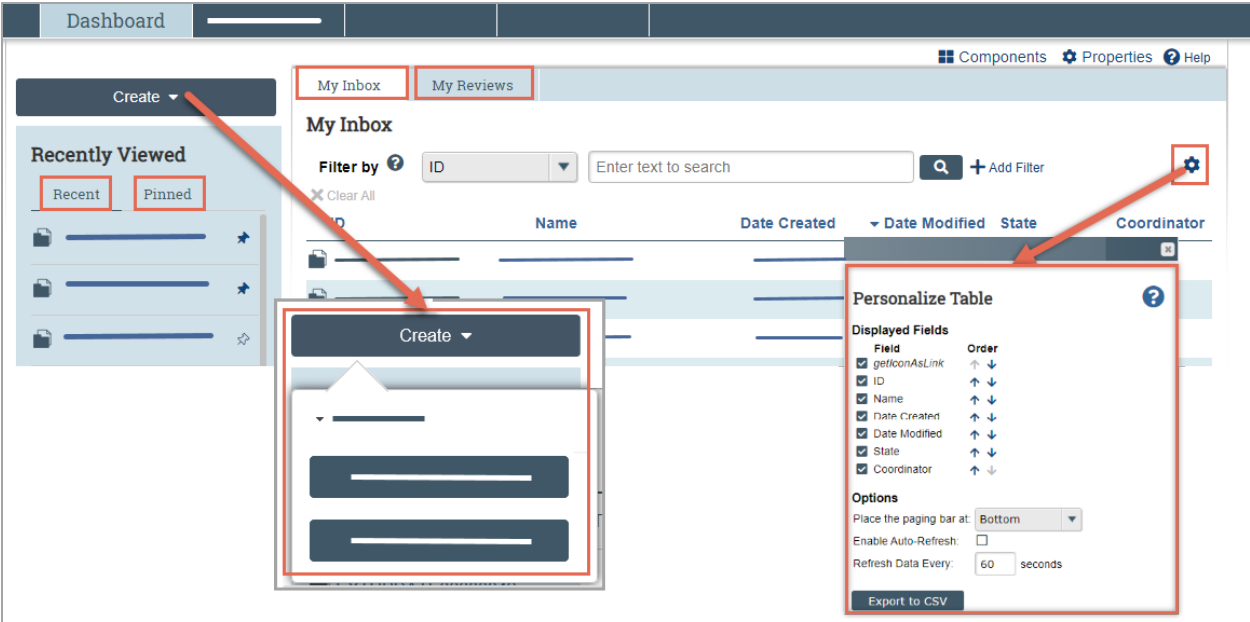
Navigation and Basic Tasks

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

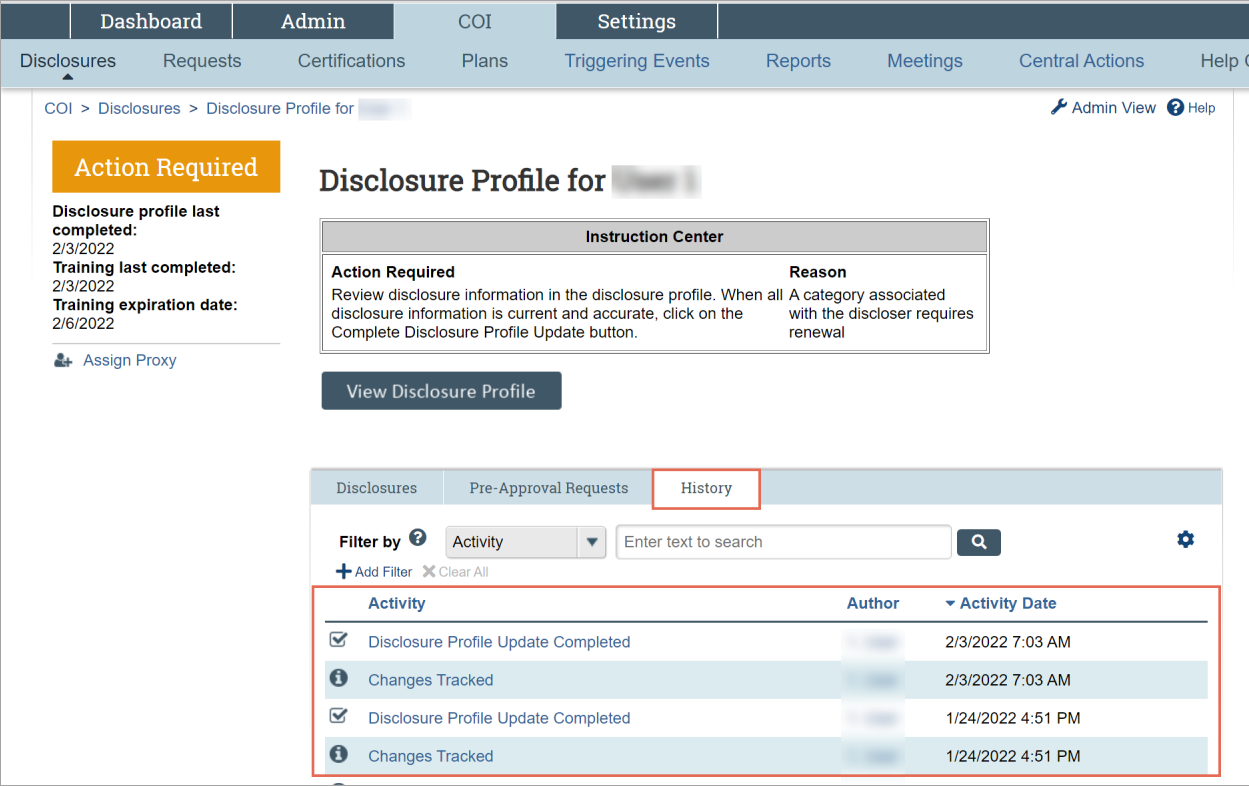
From your Dashboard, you will see:

- **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 view history

- From the disclosure profile workspace, click the **History** tab.



The **History** tab lists the activities performed on a disclosure profile including any comments, attachments added, or disclosure 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 5](#).

The screenshot shows a filter control with a 'Filter by' label and a question mark icon. A dropdown menu is open, showing 'Activity' selected. Below it are 'Author's First Name', 'Author's Last Name', and 'Activity Date'. To the right is a search input field with the placeholder text 'Enter text to search' and a magnifying glass icon. A '+ Add Filter' button is visible on the left, and a gear icon is on the right.

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

The screenshot shows the filter control with 'ID' selected in the dropdown. The search input field now contains '%71'. The magnifying glass icon is highlighted with a red box. '+ Add Filter' and 'x Clear All' buttons are also visible.

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

The screenshot shows the filter control with 'ID' selected in the dropdown. A red box highlights the question mark icon next to the 'Filter by' label.

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**.

The screenshot shows the filter control with 'ID' selected in the dropdown. The search input field contains the placeholder text 'Enter text to search for'. A magnifying glass icon and a '+ Add Filter' button (highlighted with a red box) are visible. 'x Clear All' is also present.

2. Enter filter criteria as explained in the [To filter data on page 5](#).
3. To combine multiple filter criteria, click **Add Filter** once more.

- Click the magnifying glass to apply the filter.
The table shows only those rows that match all the filter criteria.

► To sort data

- Click the column header you want to sort by.
- 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.

Update Disclosure Profile

The Disclosure Profile is the focal point of the Huron COI system for the discloser. It provides a summary of discloser's interest and everything that was disclosed previously.

Disclosers need to disclose their interests related to their institutional responsibilities. They also need to complete training related to the regulations and their institution's conflict of interest policy.

Update Disclosures

As a discloser you need to record your interests in the Huron COI system. You will receive an e-mail notification when you need to disclose your interests in Huron COI. You can either click the link in the e-mail notification or go to your Disclosure Profile in the Huron COI application to disclose your interest. You can refer the Instruction Center in the Disclosure Profile for the action that you need to take and also the reason for that action.

Note: You need to update your profile if your Disclosure Profile is in the Action Required state.

► To update your disclosure profile

If you do not have anything to disclose, do the following:

- On the disclosure workspace, click **Edit Disclosure Profile**.
- After you have completed your COI training (this could be Huron COI or a third-party training partner like CITI), select the check box for the question 'I certify that I have read and understood the education materials presented to me' on the Instructions and Policies page. Click **Continue** to move to the next page.
- Select **No** for the question 'Do you have any financial interests and/or outside activities to report?'.
Note: The Discloser Profile moves to No Action Required state.
- Click **Continue** to go to the Complete Disclosure Profile page.
- Click **Complete Disclosure Profile Update** and click **OK**.

To disclose your interests, do the following:

1. On the disclosure workspace, click **Edit Disclosure Profile**.
2. After you have completed your COI training (this could be Huron COI or a third-party training partner like CITI), select the check box for the question 'I certify that I have read and understood the education materials presented to me' on the Instructions and Policies page. Click **Continue** to move to the next page.
3. Select **Yes** for the question 'Do you have any financial interests and/or outside activities to report?'.
4. Click **Add** in the entity disclosures section.
5. Select the Entity, Relation to discloser and Disclosure types.
Based on the Disclosure type selected, you get further questions.
6. Answer the questions and click **OK** to add the entity disclosure or click **OK and Add Another** to add another entity disclosure.
7. Click **Continue** to go to the Complete Disclosure Profile page.
8. Click **Complete Disclosure Profile Update** and then click **OK**.
Note: The Disclosure Profile moves to No Action Required state.

You can view your disclosures by clicking **View** on the Disclosures tab.

Review and Certify your Training

Institutions require disclosers to complete training prior to engaging in research projects. This also depends on your institution's COI policies. You can review and certify your training in Huron COI if your institution has not integrated the training with a third-party like CITI.

► To review and certify your training

1. On the disclosure workspace, click **Edit Disclosure Profile**.
2. After you have completed your COI training and education materials, select the check box for the question 'I certify that I have read and understood the education materials presented to me' on the Instructions and Policies page. Click **Continue** to move to the next page.
3. Click **Finish** and then click **Complete Disclosure Profile Update**.
4. Click **OK**.

Respond to a Clarification Request

If a reviewer has questions or requires you to provide additional information about disclosure profile or pre-approval request, you will receive an e-mail notification indicating this. Review the request details and then respond to the request. Depending on the request, you may need to update your disclosure profile or pre-approval request. Log on to the system and navigate to your disclosure profile to respond to this request.

► **To review the request details and submit your response**

1. On the disclosure workspace, click **Submit Response**.

Action Required

Disclosure profile last completed:
1/8/2021

Training last completed:
1/4/2021

Training expiration date:
1/4/2022

→ [Submit Response](#)

2. Click **Update** on the request you are responding to.

Note: There may be multiple clarification requests outstanding at the same time.

The screenshot shows the 'Submit Response' interface. On the left, a table lists pending clarification requests. The first request is highlighted with a red box around the 'Update' button. A red arrow points from this button to the right-hand pane, which displays the details of the selected request.

	Request Date	Requestor
	12/10/2021	System Administrator
	12/10/2021	System Administrator

Edit COI Clarification

Clarification requested for Research certification for Juan Pablo (pi3)-TE00000087

- 1. Request date:**
12/10/2021
- 2. Requestor:**
System Administrator
- 3. Request source:**
Research
- 4. Request text:**
- 5. Request documents:**
There are no items to display

* Required OK Cancel

3. In the Request text field, review the request sent by the reviewer.
4. Review any attached documents.
5. In the Response text field, type your response to the reviewer and click **OK**. You can also attach documents that explain your response.

Note: If you responded to the reviewer's request in a document, you can add the document in the Response documents field.
6. Click **OK**.

After you have responded to all outstanding clarification requests, your Instruction Center will be updated accordingly. If your disclosure profile is in a No Action Required state, you can log off the system.

Review and Accept Plans

When a management plan is created due to a conflict, it is important that you understand the plan and agree with the steps that have been documented. You will receive a notification when a management plan has been routed for your review. Log on to the system and navigate to your Disclosure Profile to complete the review.

► To review and accept the management plan

1. On the disclosure workspace, click **Review and Accept Plans**.

Action Required

Disclosure profile last completed:
11/24/2020

Training last completed:
11/23/2020

i Your training has expired

Complete Disclosure Profile Update

Review and Accept Plans

2. Click **Update** next to the management plan that you want to review.

Note: There may be multiple management plans to review.

Review and Accept Plans

1. Management Plans

Name	Manager
Management Plan for Bob Smith	Bob Smith
Update	Update

2. Comments:

Edit Management Plan Document Information

1. Management plan document:
📄 Management Plan for Bob Smith.docx(0.01) ...

2. Date of plan creator's comments:
1/13/2021

3. Comments from plan creator:
Here's your management plan. Review and accept the management plan.

4. Supporting documents from plan creator:

Name
There are no items to display

5. * Do you accept this plan? ?

Yes No [Clear](#)

* Required OK Cancel

3. Click the management plan document to review the details of the management plan.
4. Select **Yes** to accept the management plan. Alternatively, select **No** if you need to clarify the details of the management plan or suggest edits to it.

Note: If you select No, then you have to provide a reason for not accepting the management plan. You can also upload documents to indicate the reason.

5. Click **OK**.

Pre-Approval Request

A pre-approval request allows you to submit a request to participate in certain outside activities (such as board service, outside academic appointment, expert witness etc.), which is then reviewed by the appropriate individual before making a determination.

The pre-approval request is pro-active in nature, wherein you create requests in COI system before you participate in those activities. The pre-approval request is then sent for review by the appropriate reviewers, determined by your institution in COI Settings. Based on the details of the pre-approval request submitted, the reviewer makes an appropriate determination.

Note: The pre-approval request feature depends on your institution's COI Settings.

Pre-Approval Request Process

When you submit a pre-approval request, you will be notified if it is approved or disapproved. The approved pre-approval requests appear on the Approved requests section in your disclosure profile. Once you complete the activity mentioned in this pre-approval request, you can click the Mark Complete button. The pre-approval requests marked as completed will be removed from the Approved requests section in your disclosure profile when your disclosure profile update is completed.

Editing: DP00000004

Entity Disclosure Information

1. * Do you have any financial interests and/or outside activities to report? ?
 Yes No [Clear](#)

2. Approved requests:

Request	Request Type	Entity	Foreign Entity?	Start Date	End Date	Approval Date	Review Group	Applied to Disclosures
Board of Trustee for a nonprofit organization	Board Service	Abbott Laboratories	No	6/1/2021	3/31/2022	6/7/2021	Research	Mark Complete

i Requests marked as completed will be removed from this listing when a profile update is completed.

Note: These requests are still available for reference in the Disclosure Profile workspace, under the Pre-Approval Requests tab.

Create and Submit a Pre-Approval Request

A pre-approval request allows you to submit a request to participate in certain activities, which is then reviewed before making a determination. You can only select one activity in a pre-approval request. If you have more than one activity that you need to request permission for, submit a pre-approval request for each activity.

▶ To create a pre-approval request

1. From the disclosure profile workspace, click **Request Pre-Approval**.



2. Enter a name for this pre-approval request.
3. Select the type of pre-approval request that you want to submit. The type of request that you select here drives the questions that you have to complete for this pre-approval request. Click **Continue** to move to the next page.

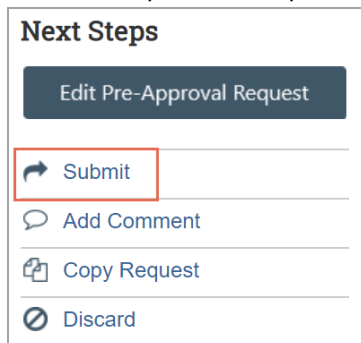
Note: You can only select one type of request at a time. If you need to submit requests for more than one type, complete the details of the first type and then create additional requests.

4. Complete the page and click **Continue**.
5. On the final page, click **Finish**.
The newly created requests workspace appears.

★ **Important!** Clicking **Finish** does not send the pre-approval request for review. It remains in the Pre-Submission state. You can continue to edit the pre-approval request (Edit Pre-Approval Request button) until you submit it for review. When the study is ready for COI review, you must submit it using the steps that follow.

▶ To submit a pre-approval request from the requests workspace

1. From the Top Navigator, click **COI** and then click **Requests**.
The Requests page appears.
2. Click the **All Requests** tab.
3. Select the pre-approval request that you wish to submit.
4. From the requests workspace, click **Submit**.

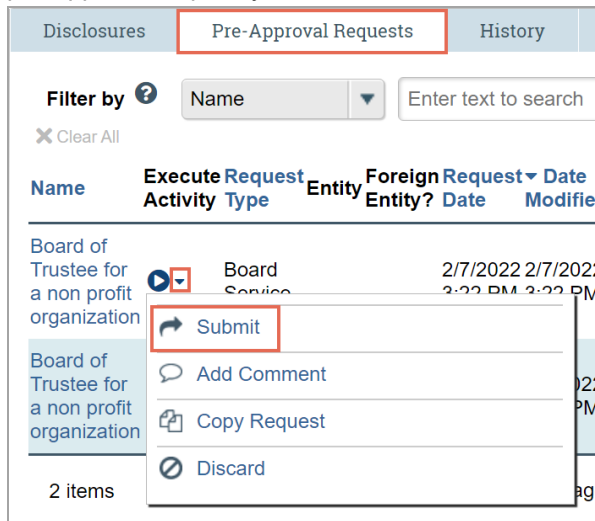


5. Click **OK** to agree to the terms.

▶ To submit a pre-approval request from your disclosure profile

1. From the Top Navigator, click **COI** and then click **Disclosures**.
The Disclosure workspace appears.

- On the **Pre-Approval Requests** tab, select the drop-down menu in the **Execute Activity** column of the pre-approval request you wish to submit.



- Click **Submit** to submit this pre-approval request for review.
- Click **OK** to agree to the terms.
The requests workspace appears. The pre-approval request is submitted and moves to the Review state.

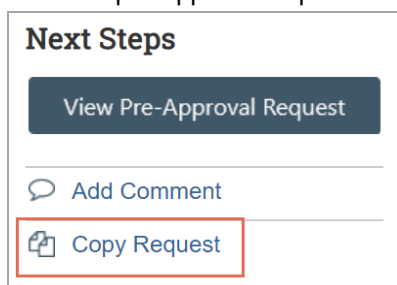
Copy a Pre-Approval Request

The COI system allows you to copy a pre-approval request that you previously submitted. Copying a pre-approval request is helpful if the pre-approval requests are similar but the start and end dates of the activity are different.

When you copy a pre-approval request, all details, including the type of request and activity information are copied along with it. Once the pre-approval request is copied, the new pre-approval request can be edited before the new pre-approval request is submitted for review. You remain the discloser for the new pre-approval request, and it appears in your inbox.

► To copy a pre-approval request from the pre-approval request workspace

- From the Top Navigator, click **COI** and then click **Requests**.
The Requests page appears.
- From the Requests page, open the pre-approval request you wish to copy.
- From the pre-approval request workspace, click **Copy Request**.

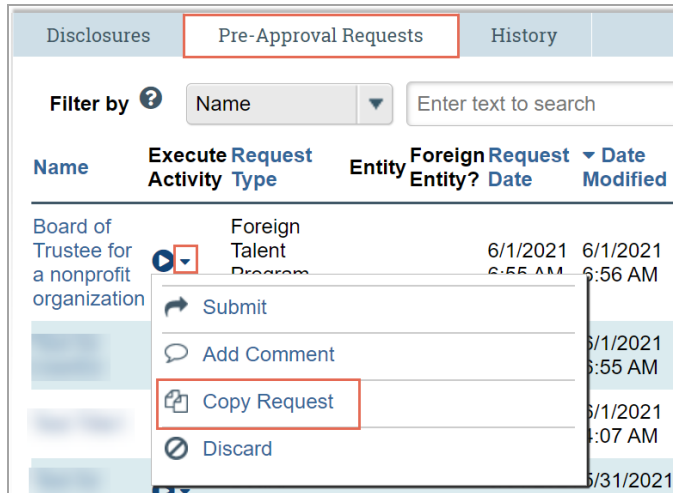


- Type a name for the new pre-approval request in the **New request name** box.
- Click **OK**.
You are taken back to the pre-approval request workspace.

- On the **History** tab, click the new pre-approval request ID link.
The new pre-approval request workspace appears.

► To copy a pre-approval request from your disclosure profile

- From the Top Navigator, click **COI** and then click **Disclosures**.
The Disclosure workspace appears.
- Click the **Pre-Approval Requests** tab, select the drop-down menu in the **Execute Activity** column of the pre-approval request you wish to copy.



- Type a name for the new pre-approval request in the **New request name** box.
- Click **OK**.
You are taken back to the disclosure profile workspace.
- The new pre-approval request workspace appears on the pre-approval requests tab. Click the new pre-approval request to open it.

Note: You can continue to edit the pre-approval request until you submit it for review.

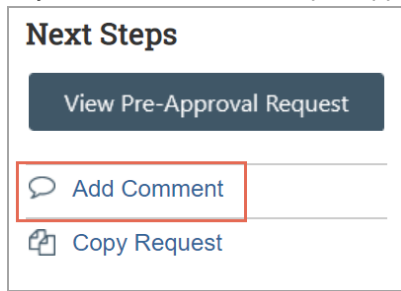
Add Comment to a Pre-Approval Request

You may want to add comments for reviewers to see when they review the pre-approval request. When you add a comment, it appears in the pre-approval request's **History** tab. Comments are viewable by any COI user who can view the pre-approval request.

► To add comment to a pre-approval request

- From the Top Navigator, click **COI** and then click **Requests**.
The Requests page appears.
- From the Requests page, select the pre-approval request to which you wish to add the comment.

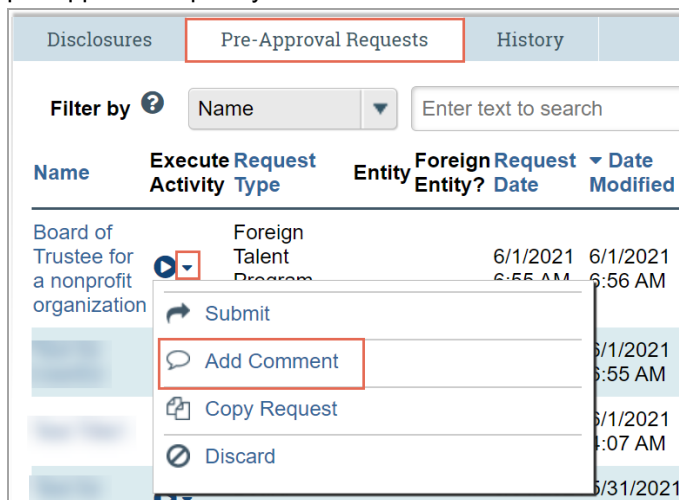
- From the pre-approval request workspace, click **Add Comment** to add a comment that is visible to anyone with access to this pre-approval request.



- Type your comments.
- If required, add supporting documents.
- Select any roles related to this pre-approval request that should receive an e-mail notification.
Note: No one will receive duplicate e-mail notifications about your comment.
- Click **OK**.

► To add a comment to a pre-approval request from your disclosure profile

- From the Top Navigator, click **COI** and then click **Disclosures**.
The Disclosure workspace appears.
- Click the **Pre-Approval Requests** tab, select the drop-down menu in the **Execute Activity** column of the pre-approval request you wish to add comment to.



- Click **Add Comment** to add a comment that is visible to anyone with access to this pre-approval request.
- Type your comments.
- If required, add supporting documents.
- Select any roles related to this pre-approval request that should receive an e-mail notification.
Note: No one will receive duplicate e-mail notifications about your comment.
- Click **OK**.
You are taken back to the disclosure profile workspace.

Allow a Proxy to Disclose for You

A proxy is a person who is authorized to act for a discloser. The proxy functionality is enabled depending on your institution's COI Settings.

The proxy can perform the following tasks for the discloser in Huron COI:

- View the COI Disclosure Profile workspace, including management plans, pre-approval requests, and disclosure summary table.
- View the Instructions and Policies page in the SmartForm.
- Edit the Entity Disclosure Information page in the SmartForm.
- Assign and remove proxy assignments for the discloser. For more information, see [Assign a Proxy on page 15](#) and [Remove the Assigned Proxy on page 16](#).
- Notify the discloser when the proxy has completed the updates. For more information, see [Complete the Proxy Update on page 16](#).

However, the discloser must do the following tasks personally. The proxy cannot:

- [Respond to a Clarification Request on page 7](#)
- [Review and Accept Plans on page 9](#)
- [Review and Certify your Training on page 7](#)
- [Update Disclosures on page 6](#)

Assign a Proxy

The Assign Proxy activity is used to add a new proxy assignment or change it to someone else. The availability of this feature depends on your institution's COI Settings.

► To assign a proxy

1. On the disclosure workspace, click **Assign Proxy**.



2. Select the proxy using one of the following methods:
 - In the Discloser proxy box, start typing the name of the user, and select the user from the list of results. Click **OK**.
 - Click the **ellipsis (...)** button, select the proxy from the list and click **OK**. You can also use the filtering tools to search for a person.

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

After a proxy is assigned to the discloser, the proxy's name is displayed in the workspace.



Complete the Proxy Update

A critical piece of the proxy functionality is that the COI system requires the discloser to complete the disclosure profile update. The Complete Proxy Update activity is used to notify the discloser that proxy has prepared the disclosure profile with the appropriate information and interests.

Note: This activity is performed by the proxy.

▶ To complete the proxy update

1. On the disclosure workspace for whom you want to complete the proxy update, click **Complete Proxy Update**.



2. If required, enter comments and upload supporting documents.
3. Click **OK**.

The discloser receives an e-mail notification that the proxy has completed the updates. The discloser needs to review the updates done by the proxy and then complete the discloser profile update. See [Update Disclosures](#).

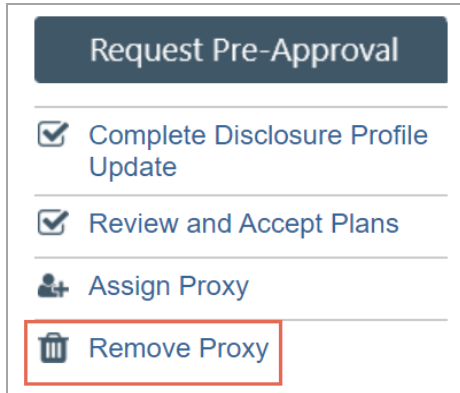
Note: The proxy details appear in the **History** tab of the disclosure profile. Just below the state of the disclosure profile, the discloser can see the date on which proxy completed the latest update.

Remove the Assigned Proxy

The Remove Proxy activity is used to remove the proxy assignment from the discloser's profile. After executing this activity, the proxy will no longer have access to the discloser's profile.

► **To remove the assigned proxy**

1. On the disclosure workspace, click **Remove Proxy**.



2. Click **OK** to remove the assigned proxy.
The proxy receives an email notification about the removal, and the discloser profile disappears from the proxy's inbox. Proxy can no longer perform tasks on behalf of the discloser.

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