



COI Discloser's Guide

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Introduction

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

Faculty, Staff and Researchers at Baylor University must submit disclosures when applicable:

Faculty – All faculty members who are eligible to receive benefits from Baylor University are required to complete an annual disclosure.

Staff – All staff members who are eligible to receive benefits from Baylor University are required to complete an annual disclosure.

Researchers - Individuals who are involved in the design, conduct, or reporting of research must complete and/or update the disclosure when engaging in research studies

This guide shows how to perform discloser activities in CARA 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 CARA COI system for the discloser. It provides a summary of discloser's outside activities and interests and everything that was disclosed previously. For more information, see Update Disclosure Profile on page 7.

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 11.

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:

- o **Recent:** The last several items you viewed. Scroll through this list to find an item you worked on recently.
- o **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.

COI > Disclosures > Disclosure Profile for [redacted] Help

Action Required

Disclosure Profile for [redacted]

Instruction Center

Action Required	Reason
Review disclosure information in the disclosure profile. When all disclosure information is current and accurate, click on the Complete Disclosure Profile Update button.	The disclosure profile is new and has never been completed

View Disclosure Profile

Disclosures

Training

History

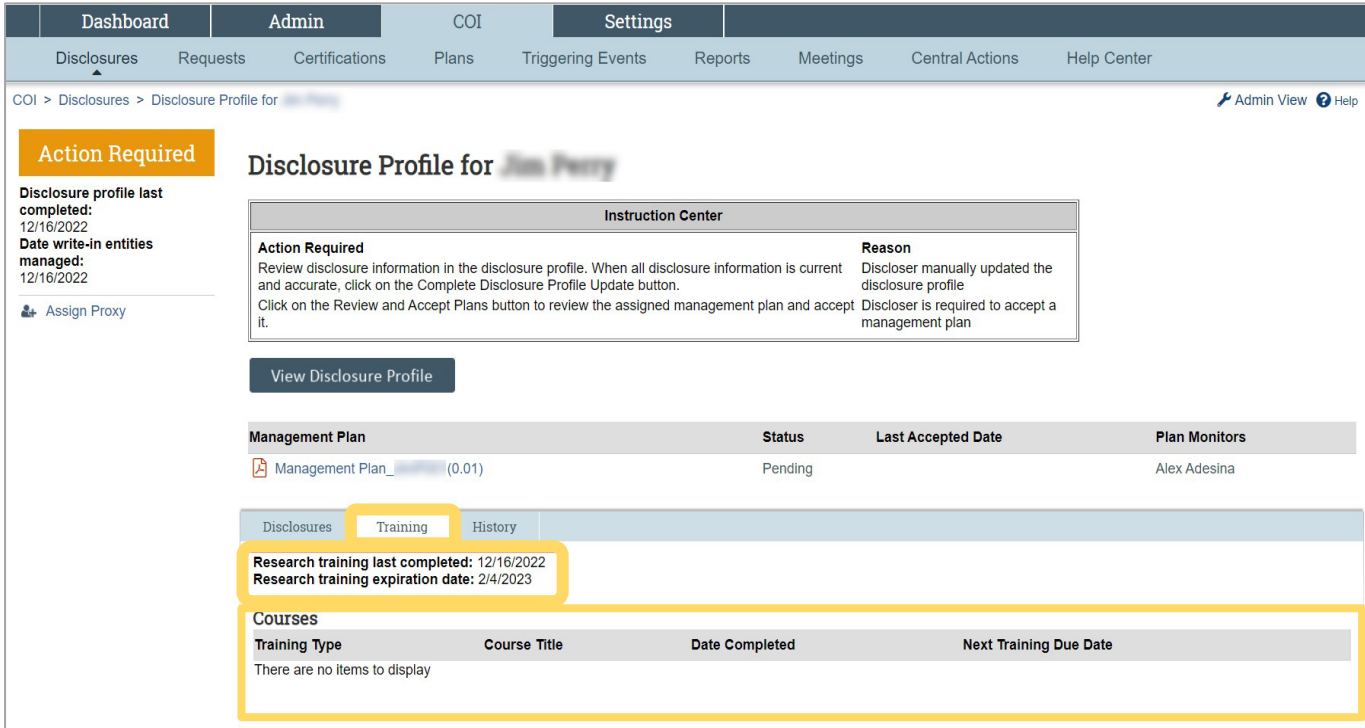
Filter by ? Activity ▼ 🔍 + Add Filter ✕ Clear All ⚙️

Activity	Author	Activity Date
📌 Retrospective Review Completed	Smith (coia), Esteban	4/25/2023 11:47 AM

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

To View Training Completion Details

From the disclosure profile workspace, click the **Training** tab.



COI > Disclosures > Disclosure Profile for **Jim Perry** Admin View Help

Action Required

Disclosure profile last completed: 12/16/2022
Date write-in entities managed: 12/16/2022
[Assign Proxy](#)

Disclosure Profile for Jim Perry

Instruction Center	
Action Required	Reason
Review disclosure information in the disclosure profile. When all disclosure information is current and accurate, click on the Complete Disclosure Profile Update button. Click on the Review and Accept Plans button to review the assigned management plan and accept it.	Discloser manually updated the disclosure profile Discloser is required to accept a management plan

[View Disclosure Profile](#)

Management Plan	Status	Last Accepted Date	Plan Monitors
Management Plan_ (0.01)	Pending		Alex Adesina

Disclosures **Training** History

Research training last completed: 12/16/2022
Research training expiration date: 2/4/2023

Courses

Training Type	Course Title	Date Completed	Next Training Due Date
There are no items to display			

The **Training** tab displays the following information:

Research training last completed and Research training expiration date - These dates refer to the COI specific training that a researcher must complete at required intervals. The COI module keeps track of the expiration date and notifies the discloser when their training has expired.

Courses - This section lists the courses related to COI that were administered outside the COI system and completed by a researcher (e.g. CITI Trainings such as Conflict of Interest and Responsible Conduct of Research).

Filter and Sort Data

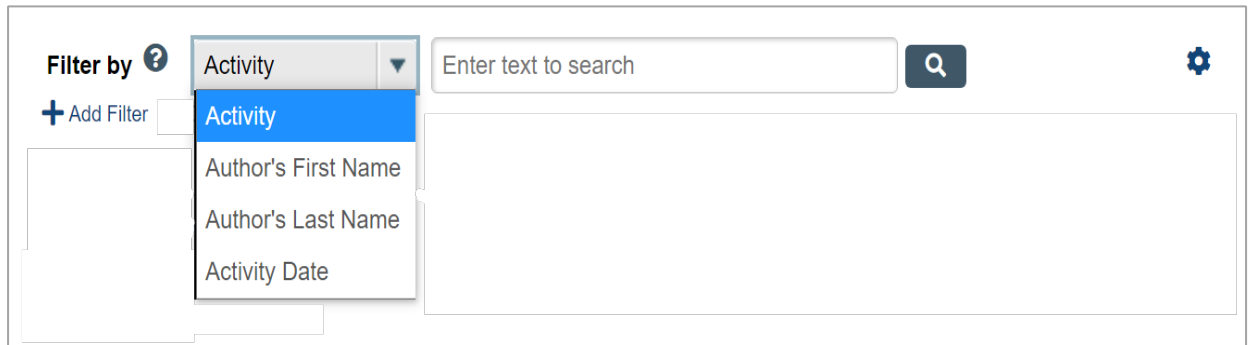
Many pages contain tables you can filter and sort to help you find the required data.

Filtering reduces the list to only the data that meets the criteria. The advanced filter lets you combine multiple filter criteria together.

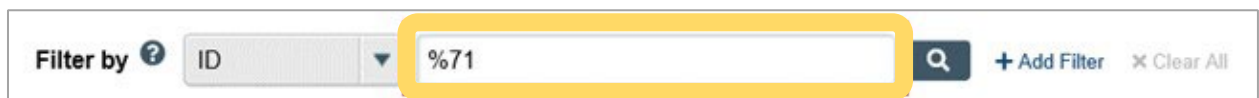
Sorting displays the data in ascending or descending order by a particular column.

Filter Data

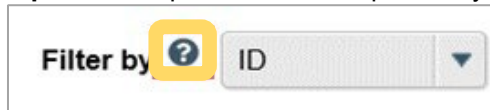
1. Select the column to filter by from the drop-down menu. The menu lists only the columns you can filter by. **Note:** To combine multiple filter criteria, such as, ID, Name, and Date Created, see Use Advanced Filters on page 6.



2. In the text box, type the characters contained in the items you want to find and include a % symbol as a wildcard either before or after the desired characters. Examples: %71 shows all items containing those characters, 71% shows all items beginning with 71.
3. Click the magnifying glass icon to apply the filter. The table only shows those rows that are an exact match.



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



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

Use Advanced Filters

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



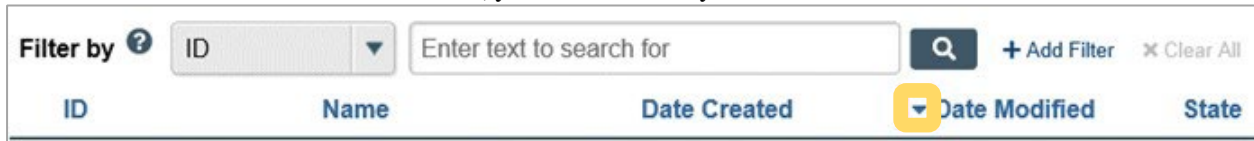
2. Enter filter criteria as explained in the Filter Data section on page 5.
3. To combine multiple filter criteria, click **Add Filter** once more.
4. Click the magnifying glass to apply the filter.
The table shows only those rows that match all the filter criteria.

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.



The screenshot shows a table header with the following elements:

- A 'Filter by' dropdown menu currently set to 'ID'.
- A search input field with the placeholder text 'Enter text to search for' and a search icon.
- Buttons for '+ Add Filter' and 'x Clear All'.
- Table column headers: 'ID', 'Name', 'Date Created', 'Date Modified', and 'State'.
- The 'Date Modified' header has a yellow dropdown arrow icon next to it, indicating it is the current sort column.

Update Disclosure Profile

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

Disclosers need to disclose their outside activities and interests related to their institutional responsibilities as referenced in Baylor's [Outside Activities and Interests Policy](#). Disclosers that are researchers also need to complete training as required by federal regulations and Baylor's [Policy for Conflicts of Interest in Research and Technology Transfer](#).

Update Disclosures

As a discloser, you will record your outside activities and interests in the CARA COI system. You will receive an e-mail notification when you need to complete your disclosure in CARA COI. You can either click the link in the e-mail notification or go to your Disclosure Profile in the CARA COI application to complete your disclosure. You can refer to 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:

1. On the disclosure workspace, click **Edit Disclosure Profile**.
2. Review the Instructions and Policies page, and the status of any External Training (which includes research training through [CITI Program](#)). Click **Continue** to move to the next page.
3. Select **No** for the question 'Do you have any financial interests and/or outside activities to report?'
4. Click **Continue** to go to the Complete Disclosure Profile page.
5. Click **Complete Disclosure Profile Update** and click **OK**.

Note: The Discloser Profile moves to No Action Required state.

To disclose your interests, do the following:

1. On the disclosure workspace, click **Edit Disclosure Profile**.
2. After you have completed your COI training (only applicable to researchers) 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.

Note: If you do not find your organization name in the Entity list, click the ellipsis (...) button under "If you cannot find the entity in the above list, enter the details here". The Write-In Entity form allows you to add your organization name.

6. Select Relation to discloser and Disclosure types.
Based on the Disclosure type selected, you will see additional questions.
7. Answer the questions and click **OK** to add the entity disclosure or click **OK and Add Another** to add another entity disclosure.
8. Click **Continue** to go to the Complete Disclosure Profile page.
9. 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

Research personnel are required to complete training prior to engaging in research projects (for more information on required education and training please visit the [Research Compliance Education and Training site](#)). Non-research personnel are not required to complete compliance training; however information on optional training can be found on the [Outside Activities and Interests site](#).

To Review and Certify your Training

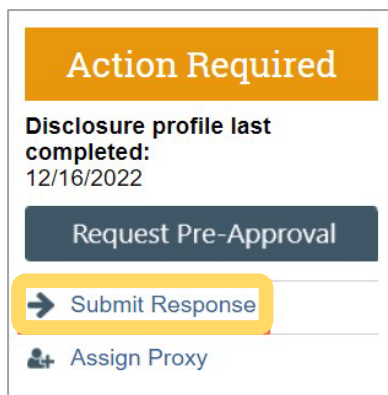
1. On the disclosure workspace, click **Edit Disclosure Profile**.
2. After you have completed your COI training and education materials, select the check box for the question 'I certify that I have read and understood the education materials presented to me' on the Instructions and Policies page. Click **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 your disclosure, 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. Log on to the system and navigate to your disclosure to respond to this request.

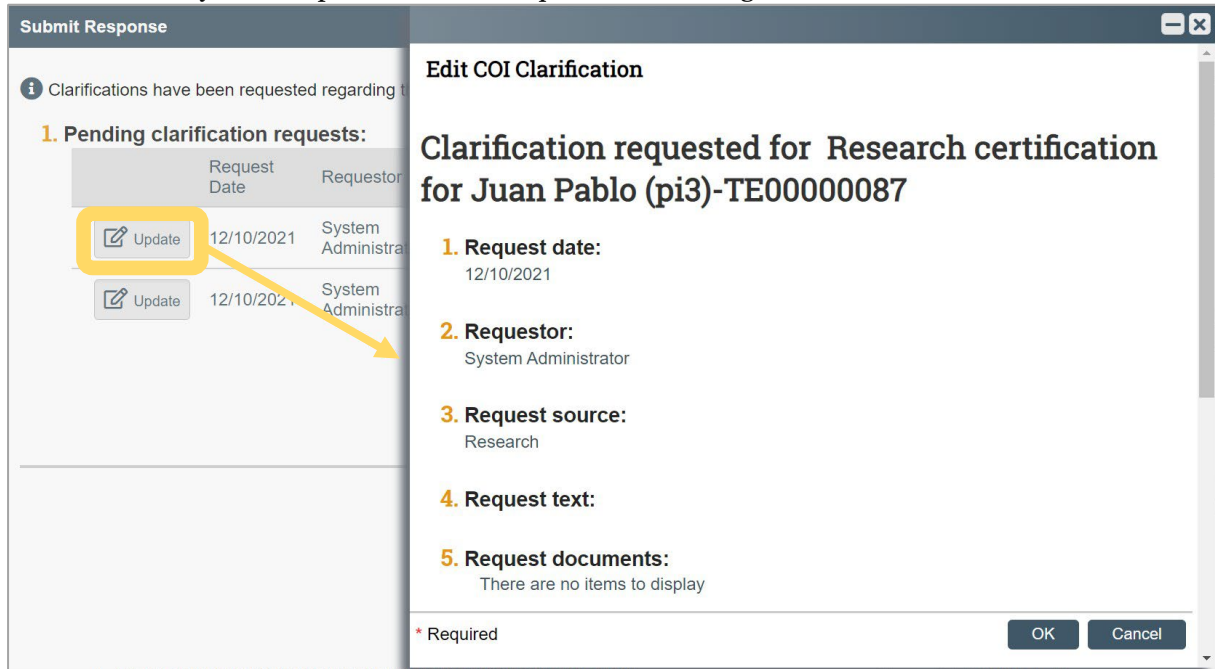
To review the request details and submit your response

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



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

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



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 is in a No Action Required state, you can log off the system.

For clarification request for a Pre-Approval Request, see Respond to a Clarification Request for a Pre-Approval Request on page 16.

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:
12/16/2022

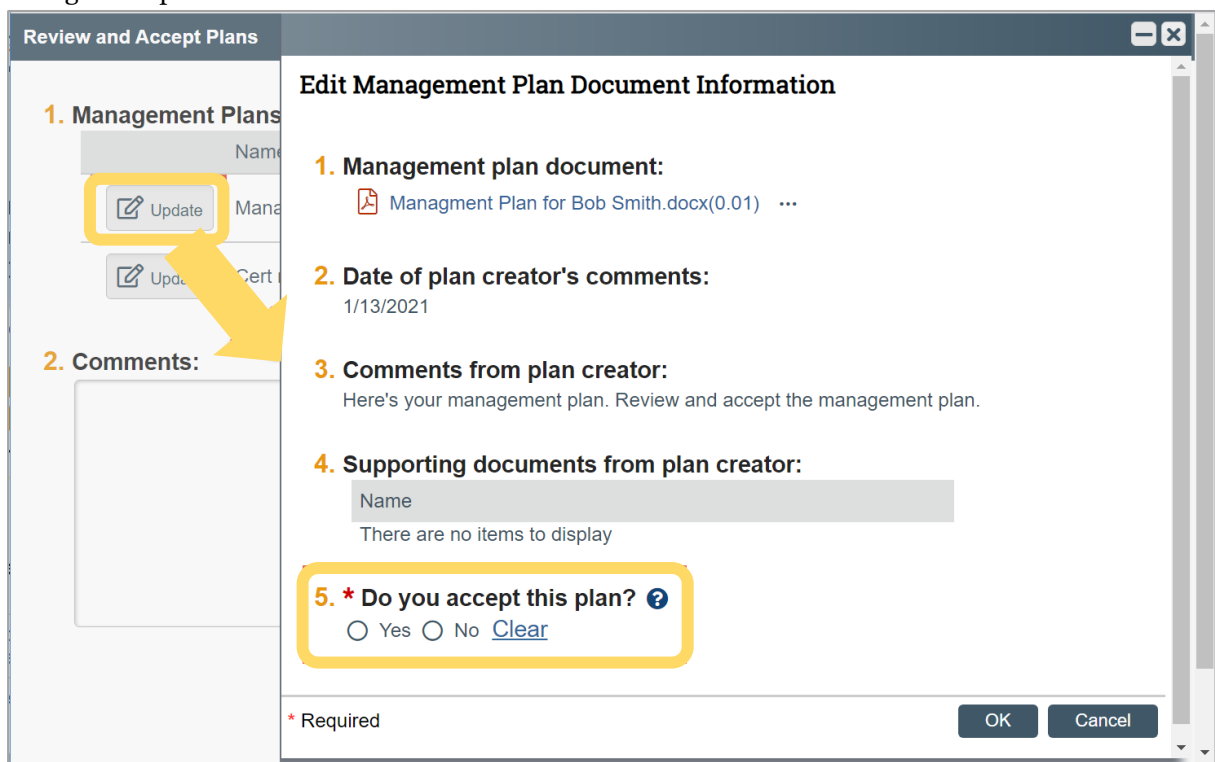
Request Pre-Approval

→ Submit Response

Review and Accept Plans

👤 Assign Proxy

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

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**.

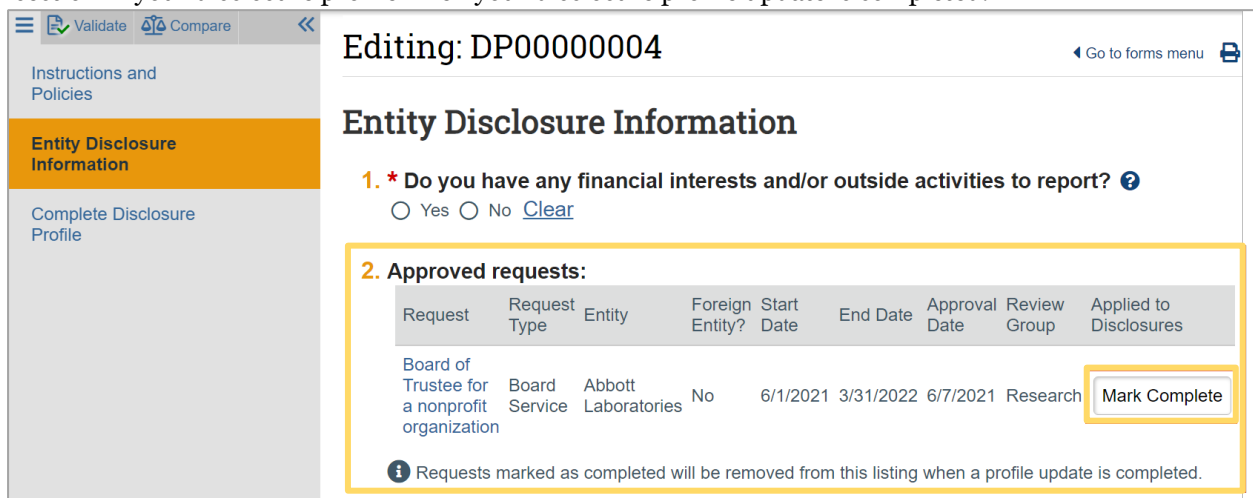
Pre-Approval Request

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 CARA COI before you participate in those activities. The pre-approval request is then sent for review by the appropriate reviewers, and based on the details of the pre-approval request submitted, the reviewer makes an appropriate determination.

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 Trustees for a nonprofit organization	Board Service	Abbott Laboratories	No	6/1/2021	3/31/2022	6/7/2021	Research	Mark Complete

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**.

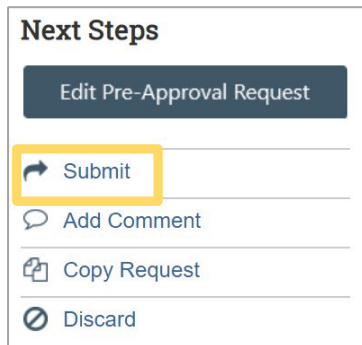


2. Enter a name for this pre-approval request.
3. Select the type of pre-approval request that you want to submit. The type of request that you select here drives the questions that you have to complete for this pre-approval request. Click **Continue** to move to the next page.
Note: You can only select 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**.
Note: You must enter the description of the proposed activity before submitting the request.
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 PreSubmission state. You can continue to edit the pre-approval request (Edit Pre-Approval Request button) until you submit it for review. When the request is ready for COI review, you must submit it using the steps that follow.

To submit a pre-approval request from the request's workspace

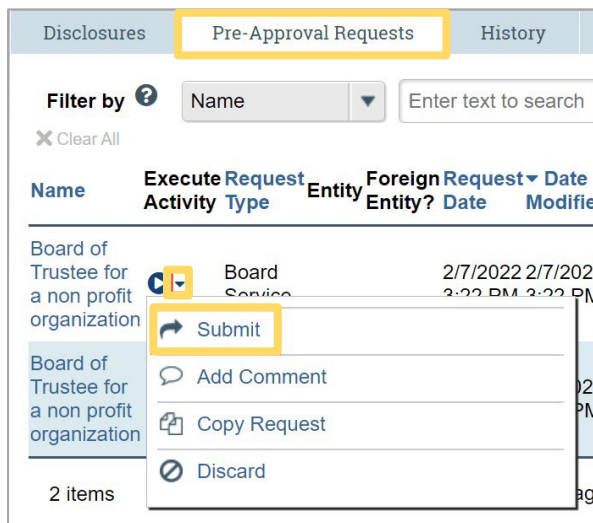
1. From the Top Navigator, click **COI** and then click **Requests**.
 The Requests page appears.
2. Click the **All Requests** tab.
3. Select the pre-approval request that you wish to submit.
4. From the requests workspace, click **Submit**.



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.
2. 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.



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

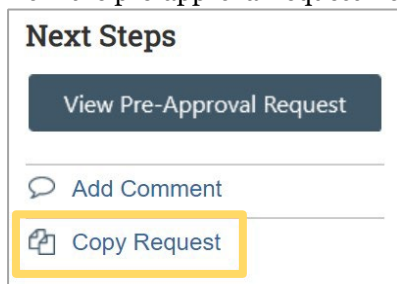
Copy a Pre-Approval Request

The COI system allows you to copy a pre-approval request that you previously submitted. Copying a preapproval 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 preapproval request, and it appears in your inbox.

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

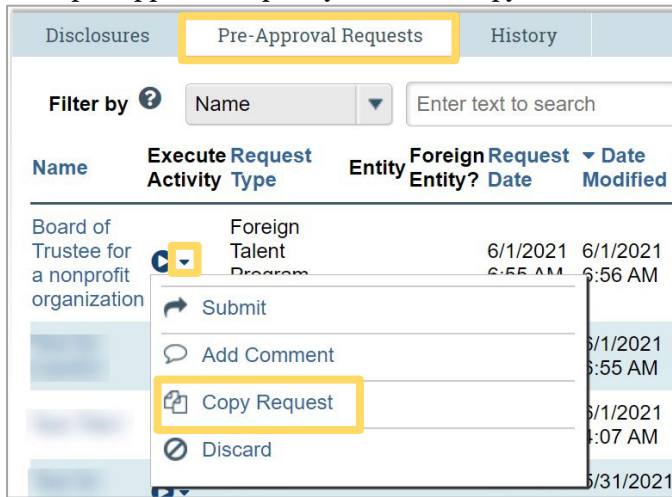
1. From the Top Navigator, click **COI** and then click **Requests**. The Requests page appears.
2. From the Requests page, open the pre-approval request you wish to copy.
3. From the pre-approval request workspace, click **Copy Request**.



4. Type a name for the new pre-approval request in the **New request name** box.
5. Click **OK**.
You are taken back to the pre-approval request workspace.
6. 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

1. From the Top Navigator, click **COI** and then click **Disclosures**. The Disclosure workspace appears.
2. 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.



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

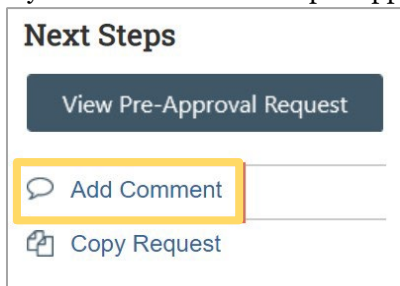
Note: You can continue to edit the pre-approval request until you submit it for review.

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

1. From the Top Navigator, click **COI** and then click **Requests**. The Requests page appears.
2. From the Requests page, select the pre-approval request to which you wish to add the comment.
3. 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.

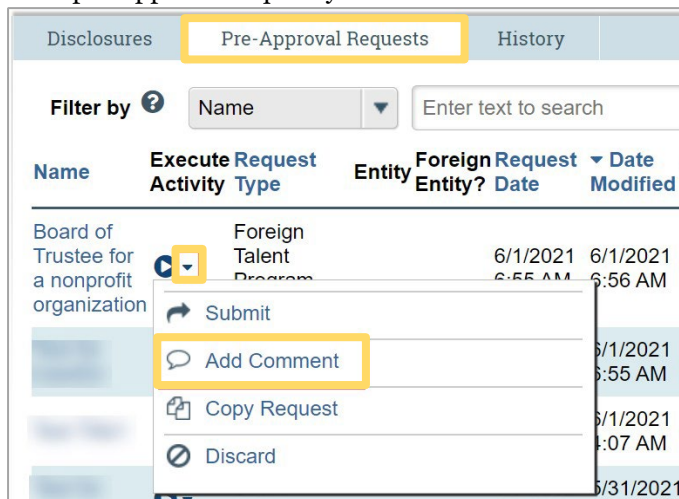


4. Type your comments.

5. If required, add supporting documents.
6. 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.
7. Click **OK**.

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

1. From the Top Navigator, click **COI** and then click **Disclosures**. The Disclosure workspace appears.
2. 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.



3. Click **Add Comment** to add a comment that is visible to anyone with access to this pre-approval request.
4. Type your comments.
5. If required, add supporting documents.
6. 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.
7. Click **OK**.
You are taken back to the disclosure profile workspace.

Respond to a Clarification Request for a Pre-Approval Request

If a reviewer has questions or requires you to provide additional information about a 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 pre-approval request. Log on to CARA to submit your response to this request.

To review the request details and submit your response

1. On the disclosure profile workspace, click the **Pre-Approval Requests** tab.
2. Select the drop-down menu in the **Execute Activity** column of the pre-approval request that requires clarification. Notice that the status of the pre-approval request is Clarifications Requested.
3. Click **Submit Response**.

Disclosures											
Pre-Approval Requests											
Training											
History											
Filter by Name <input type="text" value="Enter text to search"/> + Add Filter × Clear All											
Name	Execute Activity	Request Type	Entity	Foreign Entity?	Request Date	Date Modified	Start Date	End Date	Status	Owner	Review Group
PAR002_Jim		Outside Academic Appointment	Huron Consulting, Inc.	No	12/21/2022 7:18 AM	2/27/2023 10:28 AM			Clarifications Requested	Orlando Max (rev1)	Orlando Max (rev1)
PAR001_Jim			nc.	No	12/19/2022 12:08 PM	12/21/2022 7:24 AM			Pre-Submission		
2 items page 1 of 1											

If you clicked on the e-mail link in the notification e-mail, and are on the Pre-Approval Request workspace, click **Submit Response**.

Clarifications Requested

PAR00000072: PAR002_Jim

Request type: Outside Academic Appointment
Assigned reviewer: Orlando Max (rev1)
Current review stage: Int Stage#1
Review stage: 1 of 2

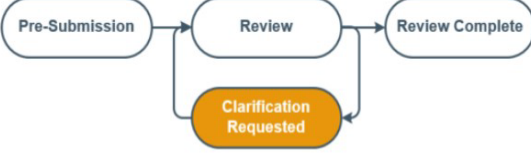
Date created: 12/21/2022 7:18 AM
Date submitted: 12/21/2022
Date write-in entities managed: 12/21/2022

Next Steps

Edit Pre-Approval Request

→ Submit Response

Add Comment



History
Review Information

4. In the Clarification request text field, review the request sent by the reviewer.
5. Review any attached documents.
6. In the Comments 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.
7. Click **OK**.

After you have responded to the clarification request, a notification will be sent to the assigned reviewer. The status of the pre-approval request will be updated to Under Review.