



COI Reviewer'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 outside activities and interests are disclosed and, when necessary, managed.

When an individual discloses outside activities and interests that exceed the review thresholds, a certification is routed for review. The review process determines if the interests are related and if so, if there is conflict. If a conflict exists, a management plan is created. Compliance with the management plan is reviewed by a monitor.

This guide shows how to perform review activities in CARA COI to identify conflicts and ensure that any conflicts are properly managed.

Two important features covered in this guide are:

- **Certification** - A certification is a record of the determination regarding a disclosure.
- **Management Plan** - A plan to manage a discloser's conflict. For more information on creation of a management plan, see [Create and Manage a Management Plan](#) on page 19.

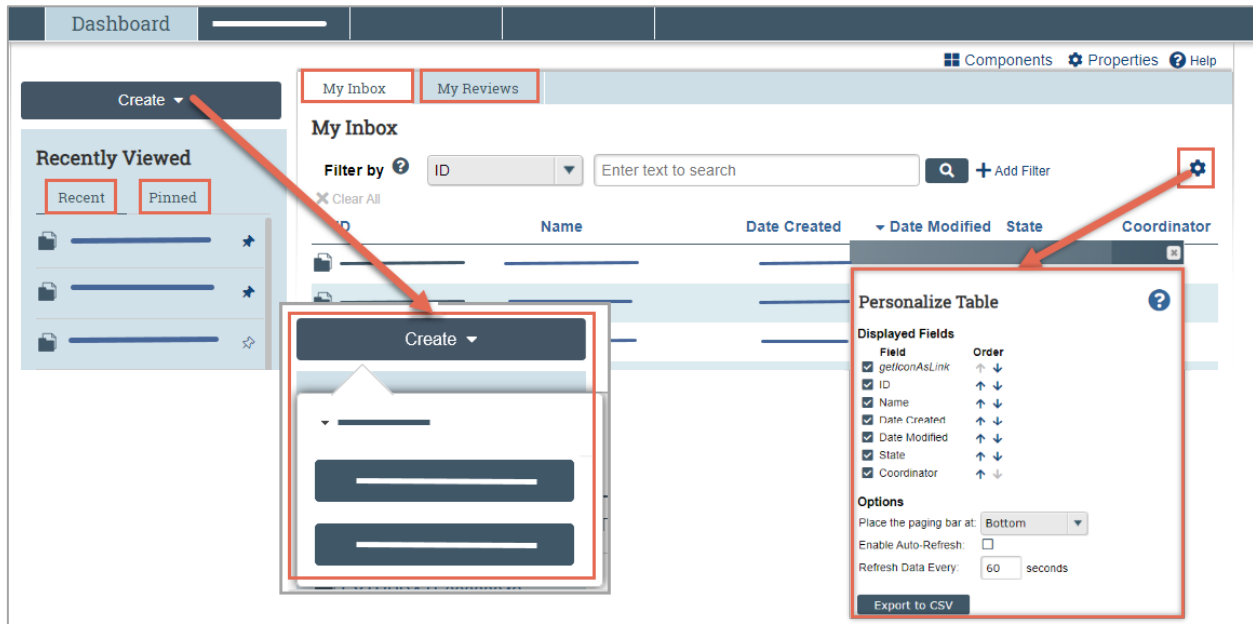
Navigation and Basic Tasks

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 certification or management plan 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 Plan tab), click the management plan name. The management plan workspace opens.

▶ To open a retrospective review

- From My Inbox, or from the Plans page (Mitigation Plan tab), 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.

Review Complete

Certification created date:
1/14/2022 9:19 PM

Determination date:
1/14/2022

Profile last submitted date:
1/14/2022

Training expiration date:
11/29/2022

Next Steps

View Certification

[Return for Review](#)

[Assign Reviewer](#)

[Manage Ancillary Reviews](#)

[Reset Review Stages](#)

[Add Comment](#)

CERT00000040: Research certification for Rebecca Simms (pi)-357902

Certification type: Research **Discloser:** Rebecca Simms (pi)
Determination: Requires Management Plan **Discloser's employer:** Radiology
Assigned management plan: Rebecca Simms Plan **Has significant financial interest:** Yes
Assigned reviewer: Aditya Sun (col-dm) **Research project:** 357902
Research project name: Release Overview Study

History

Review Information

Management Plans

Snapshots

Filter by Activity ⚙️

[+ Add Filter](#) [✕ Clear All](#)

Activity	Author	Activity Date
<input checked="" type="checkbox"/> Review Submitted	[blurred]	1/14/2022 10:00 PM
<input type="checkbox"/> Returned for Review	[blurred]	1/14/2022 10:00 PM
<input checked="" type="checkbox"/> Review Submitted	[blurred]	1/14/2022 9:59 PM
<input type="checkbox"/> Returned for Review	[blurred]	1/14/2022 9:59 PM
<input checked="" type="checkbox"/> Review Submitted	[blurred]	1/14/2022 9:59 PM
<input checked="" type="checkbox"/> Intermediate Review Completed	[blurred]	1/14/2022 9:54 PM
<input checked="" type="checkbox"/> Intermediate Review Completed	[blurred]	1/14/2022 9:39 PM
<input type="checkbox"/> Profile Updated	[blurred]	1/14/2022 9:21 PM

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

► **To see information about reviews**

- From the project (certification or pre-approval request) workspace, click the **Review Information** tab.

Review Complete

Certification created date:
1/14/2022 9:19 PM

Determination date:
1/14/2022

Profile last submitted date:
1/14/2022

Training expiration date:
11/29/2022

Next Steps

[View Certification](#)

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[Add Comment](#)

CERT00000040: Research certification for Rebecca Simms (pi)-357902

Certification type: Research
Determination: Requires Management Plan
Assigned management plan: Rebecca Simms Plan
Assigned reviewer: Aditya Sun (coi-dm)

Discloser: Rebecca Simms (pi)
Discloser's employer: Radiology
Has significant financial interest: Yes
Research project: 357902
Research project name: Release Overview Study

Review Information

Order	Current?	Type	Name	Routing	Default Reviewer
1.00		Department	Department Review	Radiology	
2.00		Admin Office	Foreign Interest Review	Foreign Interests Review Office	
3.00		Admin Office	Central Compliance Office	University Compliance	

Reviews: Latest Intermediate

Stage Order	Stage Name	Routing	Reviewer	Comments	Supporting Documents	Action Needed?	Completed Date
1.00	Department Review	Radiology		It seem to me like there is relatedness and conflict that we need to manage...		Yes	1/14/2022
2.00	Foreign Interest Review	Foreign Interests Review Office		looks fine to me		No	1/14/2022

Reviews: Final

Reviewer:
 Stage name:
 Routing:
 Completed date:
 Relatedness determination:
 Conflict determination:
 Follow-up action:
 Conflicts:

Description	Disclosure Entities

Previous final reviews:
 + 1/14/2022 9:59:51 PM
 + 1/14/2022 9:59:24 PM

The **Review Information** tab summarizes the important information you need to know about the review of this project.

The **Review Information** tab has the following sections:

- **Review Stages** section contains information on the order of review stages and their default reviewer, as well as name and type of the review.
- **Reviews: Latest Intermediate** section contains review information provided by the assigned reviewer in each intermediate review step. This information is provided in the Submit My Review activity.
Note: If an intermediate review step is completed more than once, the previous review information can be accessed through the History tab.
- **Reviews: Final** section appears after the final review is completed. It contains review determination data from the most recent final review that was performed.
- **Previous final reviews** section appears only if a final review was performed multiple times (i.e. a certification had all stages of review completed and then it was re-opened for another review).

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 8.

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**.

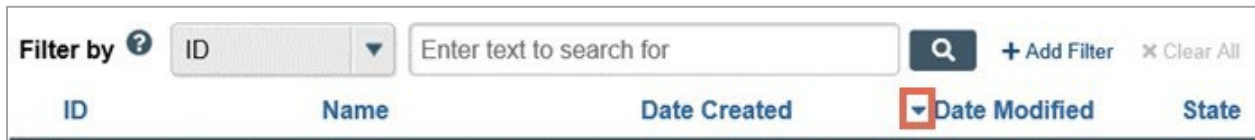


2. Enter filter criteria as explained in the previous section.
3. To add more criteria, click **Add Filter** once more.
4. Click the magnifying glass to apply the filter.
The table shows only those rows that match all the filter criteria.

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.



Review a Certification

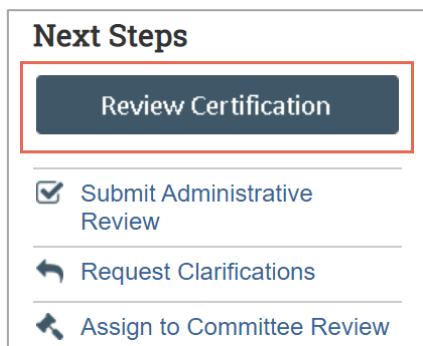
When a certification is assigned to you, it will display in your inbox and you will also receive an e-mail notification.

The certification SmartForm contains the outside activities and interests of the discloser and the research project (for research disclosures) you are comparing them against.

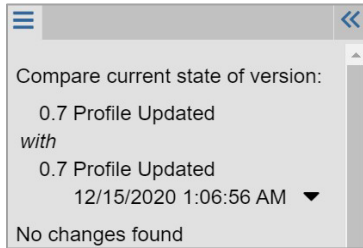
To review a certification

1. From the certification workspace, click **Review Certification**.

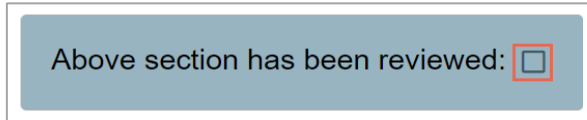
Note: You can scroll through the certification or use Left Navigator to jump to specific sections of the form.



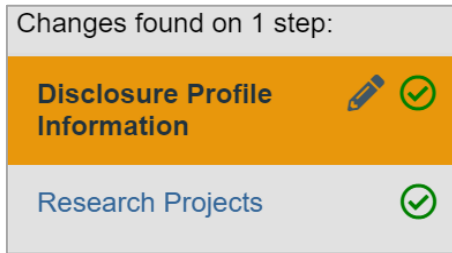
- To see what changed between this and a previous version, click **Compare** on the Left Navigator and select the version to compare against.



- After reviewing each section, you may select the check box at the bottom to indicate you have reviewed it. This helps you keep track of your progress as you make your way through your review.

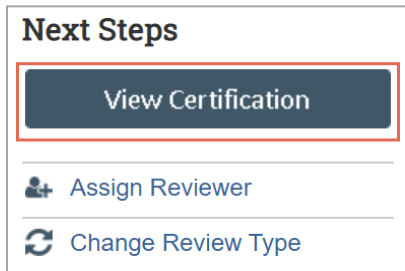


- The section turns green, and a green check mark appears in the Left Navigator. If there are changes to the certification or to the discloser's profile after it has been reviewed, the check mark turns gray and an Edit icon is added, indicating to review that section again.



► To print certification pages

- From the certification workspace, click **View Certification**.



- Click **Print**. The available options are
 - This page - Use this option to print the current page.
 - This project - Use this option to print the entire project.



- Click **Print** at the top of the preview to send it to your default printer.

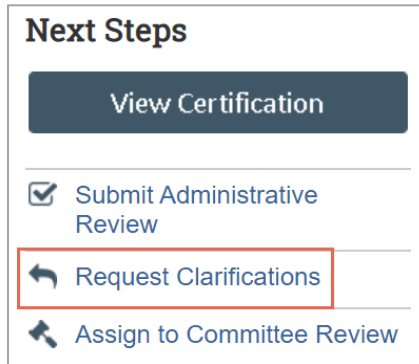
Request Clarification

If you have questions for the discloser, use the Request Clarification activity to send a message. When the discloser submits a response, you will be able to review the response as well as any updates that were made before completing your review.

Note: The Request Clarifications activity is available in certifications, pre-approval requests, and management plans. In management plans the discloser initiates the Request Clarifications activity, the management plan reviewer or management plan creator does not initiate the Request Clarifications activity.

► To request clarification

1. From the project workspace, click **Request Clarifications**.



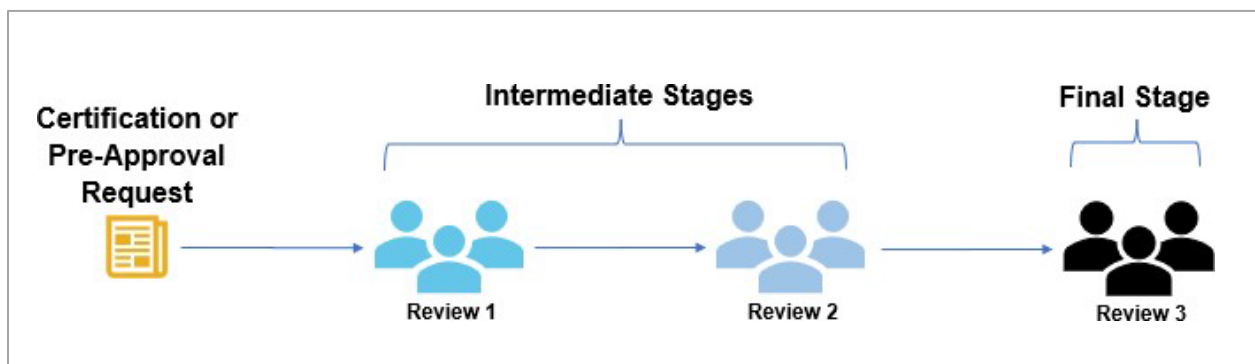
2. Type the details of your clarification request.
3. If required, add supporting documents.
4. Click **OK**.
The discloser will receive an e-mail notification about your request.

Review Workflow

A certification or a pre-approval request can have multiple review stages. A review workflow does not have to include intermediate review stages, but there must be a final stage configured for all reviews.

The reviewers in the intermediate stages provide input that can be used by the reviewer in the final stage. The reviewer in the final stage is responsible for making the determination by referring to the input provided by intermediate reviewers.

For example, a certification or pre-approval request can have two intermediate stages and a final stage of review.



Submit My Review activity is available for intermediate reviewers and Submit Review activity is available for the final reviewer.

On the project workspace, you can view the current review stage, for example Department Review or Central Compliance Office. Additionally, you can view where this review stands in the review progression, for example the image below shows the review is in Review Stage 1 of 3.

CERT00000038: Research certification for Rebecca Simms (pi)-57575

<p>Certification type: Research</p> <p>Assigned reviewer: Fred Smith (coicch)</p> <p>Current review stage: Department Review</p> <p>Review stage: 1 of 3</p>	<p>Discloser: Rebecca Simms (pi)</p> <p>Discloser's employer: Radiology</p> <p>Has significant financial interest: Yes</p> <p>Research project: 57575</p> <p>Research project name: [REDACTED]</p>
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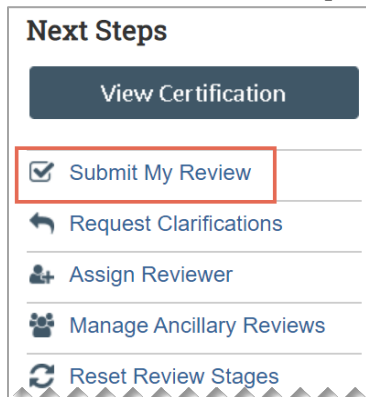
Refer to additional information provided on the Review Information tab.

Submit an Intermediate Review

You may be assigned to perform intermediate review for a certification. After reviewing the assigned certification, you provide your input using the Submit My Review activity. Recording your decision completes your intermediate review and moves the certification forward in the review process.

► To submit an intermediate review for a certification

1. From the certification workspace, click **Submit My Review**.



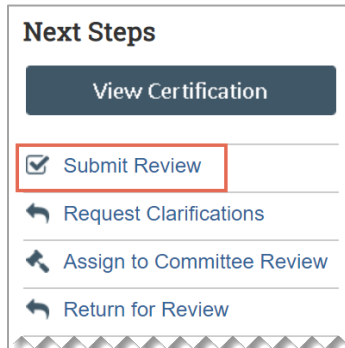
2. Based on your decision, select **Yes** or **No** to the question "Do you recommend?"
Note: The input you provide will be used when making the final determination for this certification.
3. You can explain your recommendation in the Comments section.
4. Under Supporting documents, add any documents related to your review, such as a completed checklist.
5. When finished, click **OK**.

Submit a Final Review

You may be assigned to perform a final review for a certification. After reviewing the assigned certification and the input recorded by the intermediate stage reviewers, you record your decision using the Submit Review activity. Recording your decision completes the final review and moves the certification forward in the workflow.

▶ To submit a final review for a certification

1. From the certification workspace, click **Submit Review**.



2. Complete the page.
Note: Refer to the toolkit worksheet which is available in the activity form to help you make a decision. You can then determine if it is related or not. If related, determine if there is a conflict. And if there is a conflict, add the details of that conflict and assign it to a management plan, or create a management plan as described in Create and Manage a Management Plan on page 19.
3. Under Supporting documents, add any documents related to your review, such as a completed checklist.
4. When finished, click **OK**.

Submit a Research Portfolio Review

A research portfolio review is a type of certification specific to the Research category, which may be created as a discloser's outside activities and interests change over time. The purpose of the Research Portfolio Review is to allow a reviewer to assess a discloser's current outside activities and interests against the research projects that were previously reviewed. The Research Portfolio Review does not result in a relatedness or conflict determination, it simply facilitates another round of review occurring on the projects that the reviewer deems necessary.

Note: The Research Portfolio Review cannot be assigned to committee review.

For example, a discloser may have been added to a research project last year and at that time they disclosed their outside activities and interests and a review was performed. Now, the discloser bought a significant amount of stock in a company and disclosed this in CARA. The system creates a Research Portfolio Review task to facilitate a reviewer to check the current outside activities and interests of the discloser (including the company stock that was bought recently) against the research project that was reviewed a year ago. The reviewer may decide that another relatedness review needs to be performed.

▶ To submit research portfolio review

1. From the Research Portfolio Review workspace, click **Submit Research Portfolio Review**.

Note: You can compare the latest interests of the discloser against all the research projects the discloser is involved in and determine which research projects need another review.

Next Steps

- Review Certification
- Submit Research Portfolio Review
- Assign Reviewer
- Add Comment

2. Complete the SmartForm page.
 - a. Click the ellipsis to select the research projects that require re-review.

Note: You can pick one, or many research projects from the list to generate new research certifications.
 - b. If required, enter comments in the comments section.
 - c. Under Supporting documents, add any documents related to your review.
3. When finished, click **OK**.

The research portfolio review certification moves to the Review Complete state.

Add Comments for Other Reviewers

You may want to add comments for other reviewers to see when they review the project. When you add a comment, it appears in the project's History tab. These comments are viewable by any COI user who can view the project.

You can also add a private comment for pre-approval requests. Private comments are only viewable by assigned reviewers and COI administrators. Private comments do not display on the project's History tab.

Note: The Add Comment activity is available in certifications, pre-approval requests, and management plans.

▶ To add comment to a pre-approval request

1. From My Inbox, click the name of the pre-approval request to open it.
2. From the pre-approval request workspace, click **Add Comment** to add a comment that all COI users can see.
Alternatively, click **Add Private Comment** to add a comment that only assigned reviewers and COI administrators can see.
3. Type your comments.
4. If required, add supporting documents.
5. Select any roles related to this pre-approval request that should receive an e-mail notification.
6. Click **OK**.

▶ To add comment to a certification or management plan

1. From My Inbox, click the name of the project to open it.
2. From the project workspace, click **Add Comment** to add a comment that all COI users can see.
3. Type your comments.
4. If required, add supporting documents.
5. Select any roles related to this project that should receive an e-mail notification.
6. Click **OK**.

Review a Pre-Approval Request

When a pre-approval request is assigned to you for review, it will display in your inbox and you will also receive an e-mail notification.

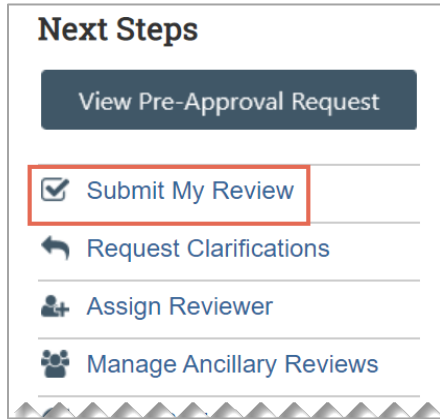
The pre-approval request SmartForm contains the information needed to complete your review. You can click the **View Pre-Approval Request** button to view the pre-approval request. The pre-approval request contains two key pieces of information to use when making a determination - the entity and the activity.

The pre-approval request can have several intermediate stages and a final stage.

▶ To submit an intermediate review for a pre-approval request

1. From My Inbox or the **Pending Requests** tab on the Requests page, click the name of the pre-approval request you want to review.

2. Click **Submit My Review**.



3. Based on your decision, select **Yes** or **No** to the question "Do you recommend ?"
Note: The input you provide will be used when making the final determination for this pre-approval request.
4. If required, type a comment and add supporting documents.
5. When finished, click **OK**.

The pre-approval request moves forward in the review process.