HURON

Huron COI

Reviewer'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.

When an individual discloses interests that exceed the institution's 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 Huron 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.

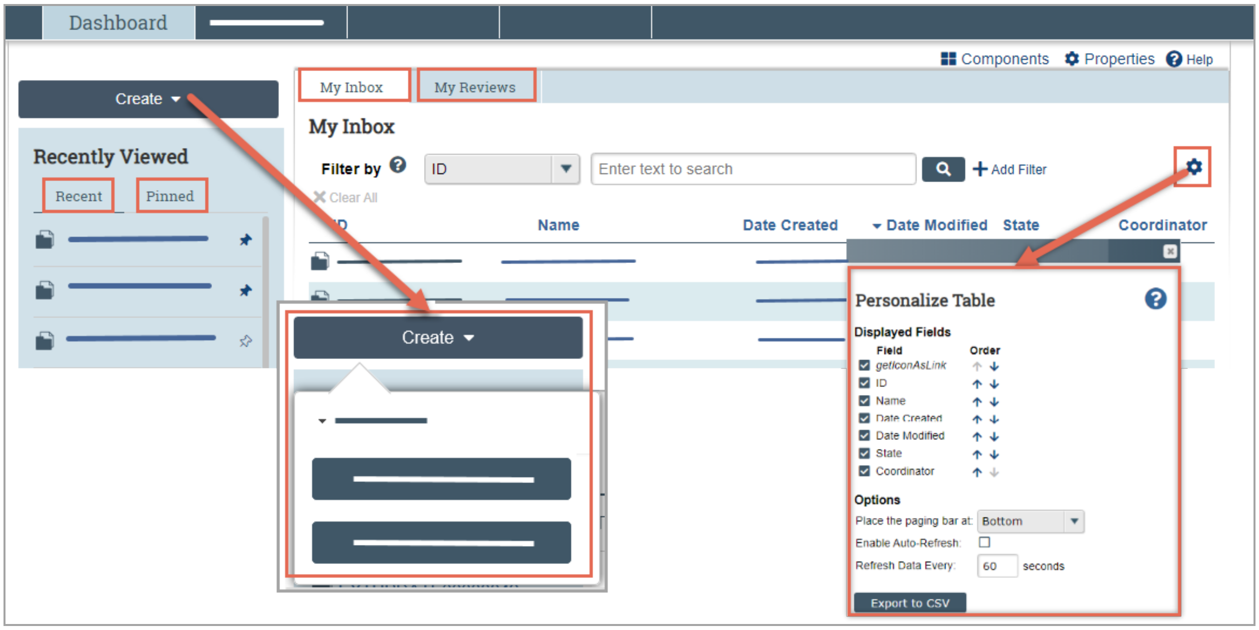
Navigation and Basic Tasks

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

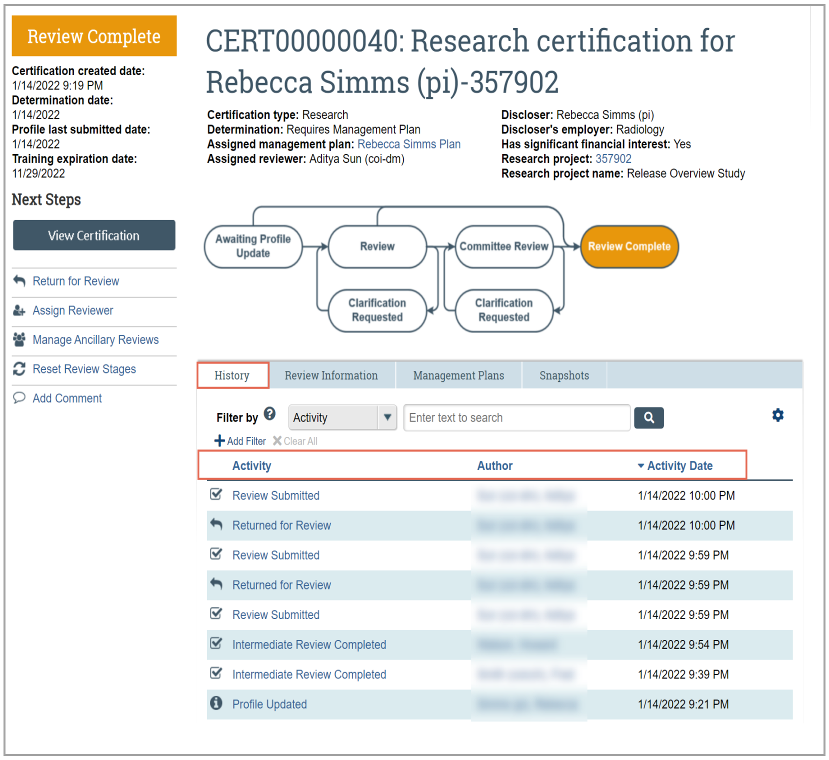
- From My Inbox, or from the Triggering Events page, click the triggering event name.
  The triggering event workspace opens.

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

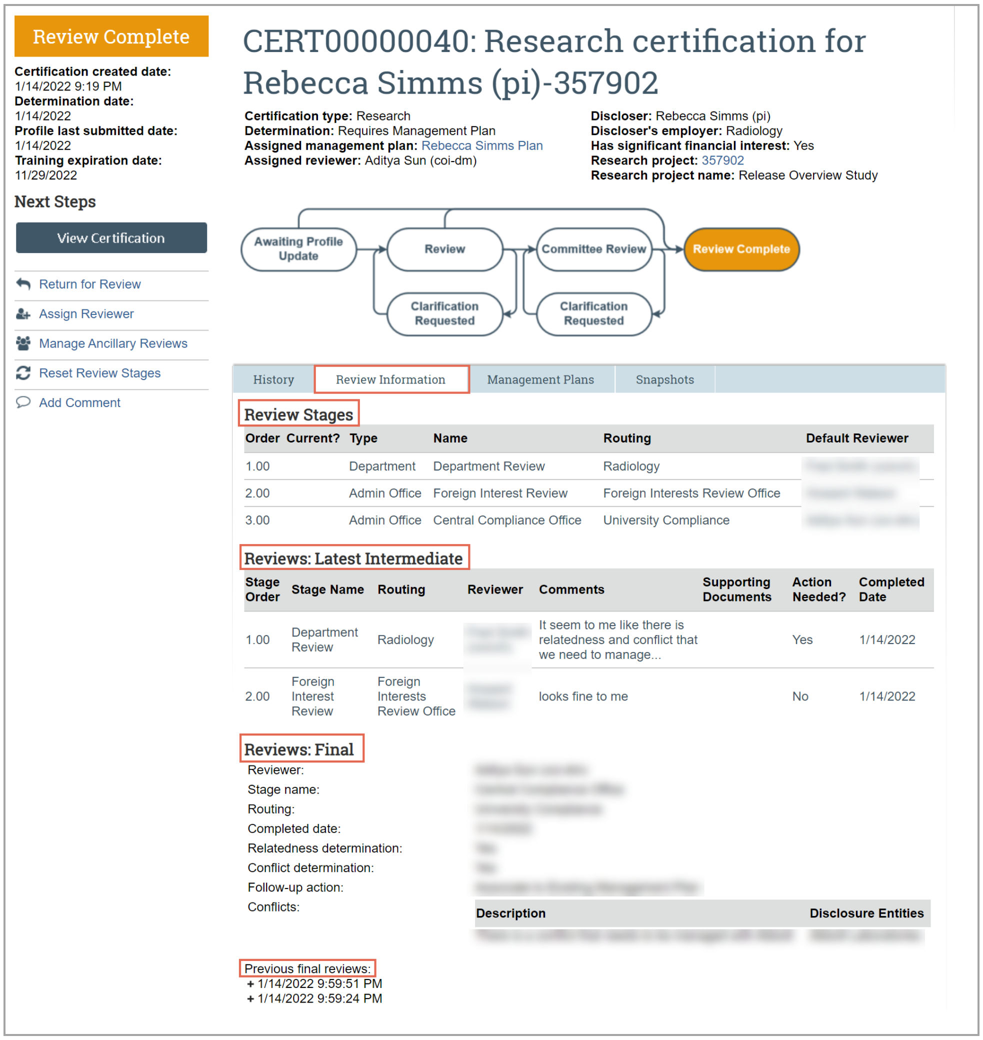
- From the certification workspace, click the **History** tab.



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.



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).

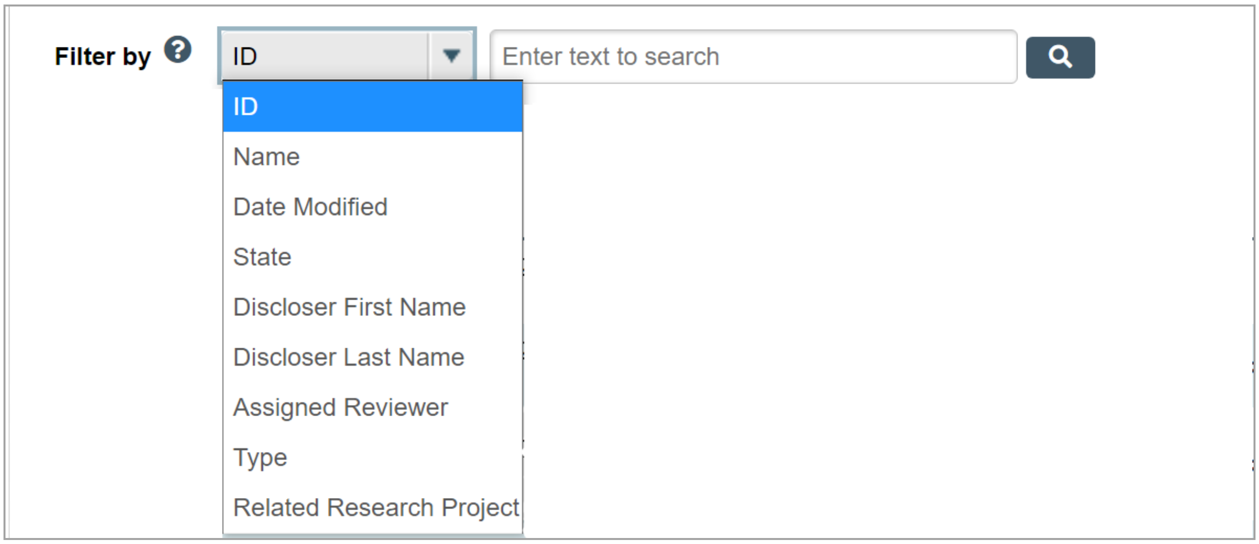
Filter and Sort Data

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

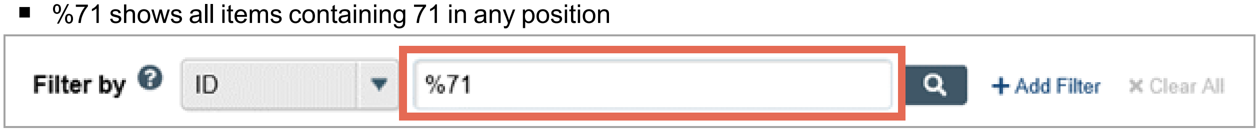
- Filtering reduces the list to only the data that meets the criteria. The advanced filter lets you combine multiple filter criteria together.
- Sorting displays the data in ascending or descending order by a particular column.

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.
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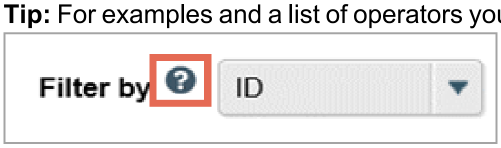
> 
>

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

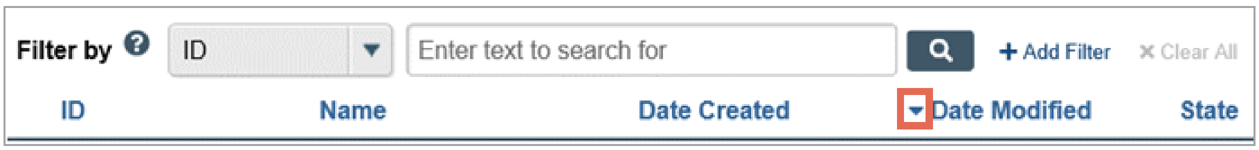
1. In the Filter by area, click **Add Filter**.

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.



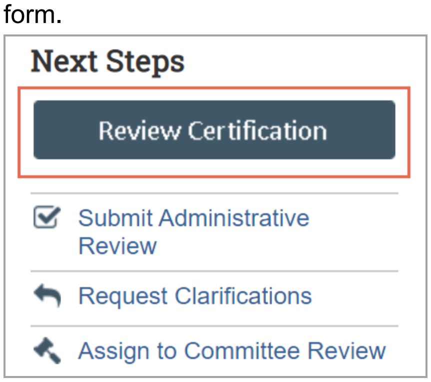
Review a Certification

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

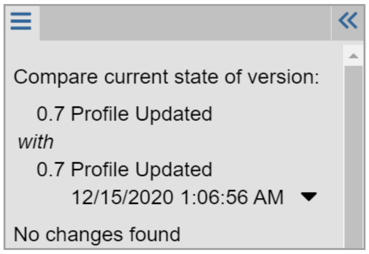
The certification SmartForm contains the information needed to complete your review. The certification contains two key pieces of information to use when making a determination - the interests of the discloser and the research project you are comparing them against.

To review a certification

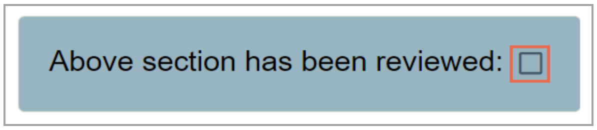
1. From the certification workspace, click **Review Certification**.
   Note: You can scroll through the certification or use Left Navigator to jump to specific sections of the form.



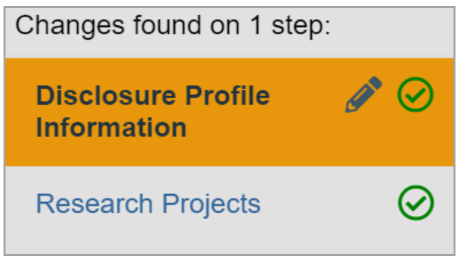
2. To see what changed between this and a previous version, click **Compare** on the Left Navigator and select the version to compare against.



3. After reviewing each section, select the check box at the bottom to indicate you have reviewed it.

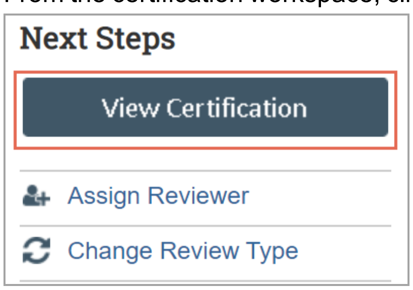


4. The section turns green, and a green check mark appears in the Left Navigator. If there are changes to the certification or to the discloser's profile after it has been reviewed, the check mark turns gray and an Edit icon is added, indicating to review that section again.



To print certification pages

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



2. 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.

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

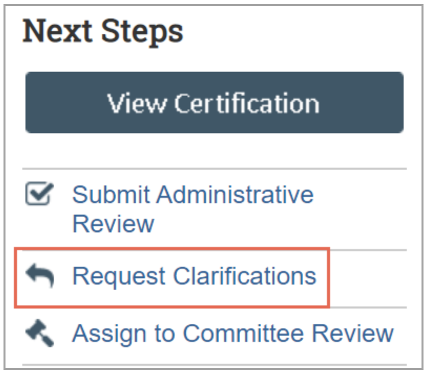
Request Clarification

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**.



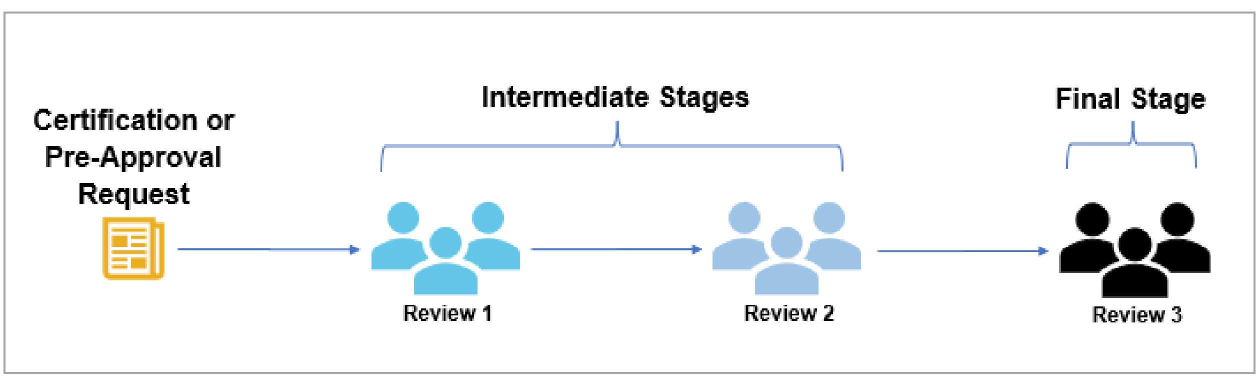
2. Type the details of your clarification request.
3. If required, add supporting documents.
4. Click **OK**.
   The discloser will receive an e-mail notification about your request.

Review Workflow

A certification or a pre-approval request can have multiple review stages depending on your institution's settings. A review workflow can have intermediate and final 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 the where this review stands in the review progression, for example the image below shows the review is in Review Stage 1 of 3.

Refer to additional information provided on the Review Information tab.

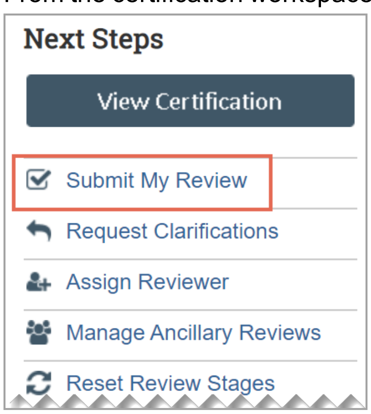
Submit an Intermediate Review

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.

A certification can have a number of review stages depending on your institution's settings.

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**.

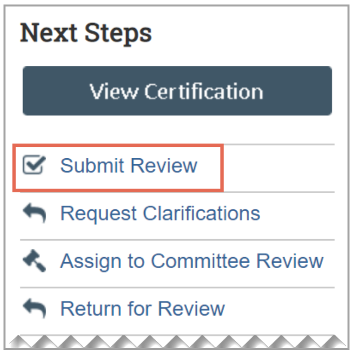
Submit a Final Review

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.

If you feel the submission should be reviewed by the committee, you can use the Assign to Committee activity if available. For details, see Assign to Committee Review on page 12. Committee review is an option that may or may not be available based on your institution's settings.

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.
3. Under Supporting documents, add any documents related to your review, such as a completed checklist.
4. When finished, click **OK**.

Assign to Committee Review

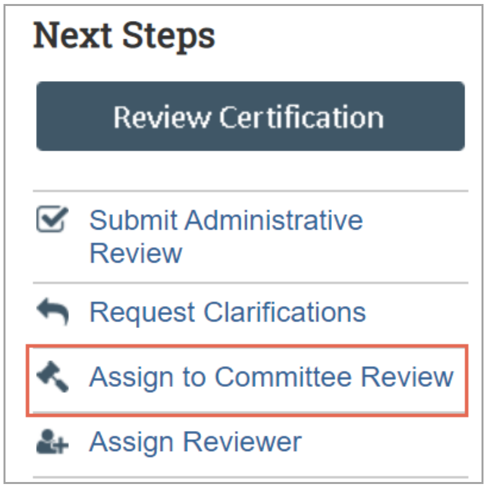
If your institution enables the committee review option, the assigned reviewer can assign the certification to committee review. Committee review is typically used when the assigned final reviewer is unable to make the decision regarding conflict in the discloser's profile. The Assign to Committee Review activity is available only when the certification is in its final review stage.

You can assign a certification to committee review in two ways:

- From Submit a Final Review activity - Use this option if you believe that a committee needs to review the certification, but you want to provide initial input for the committee. The selections that you make in the Submit Review form are pre-populated when the committee reviews the certification.
- From Assign to Committee Review activity - Use this option if you believe you cannot provide any input regarding the certification and need a committee to review it instead.

To assign to committee review

1. From the certification workspace, click **Assign to Committee Review**.



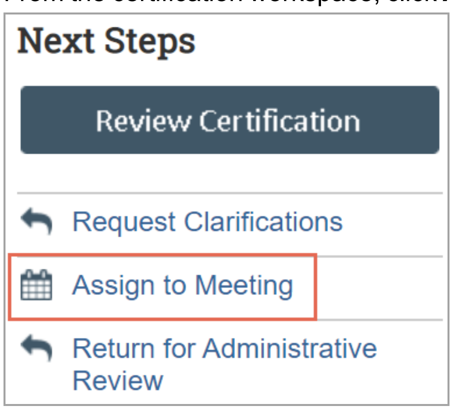
2. If required, add any comments and attach documents related to the review.
3. When done, click **OK**.

Assign to Meeting

You must assign the certification to complete the committee review process.

To assign to meeting

1. From the certification workspace, click **Assign to Meeting**.



2. Select an upcoming COI meeting for the administrative office the certification belongs to.
3. Click **OK**.

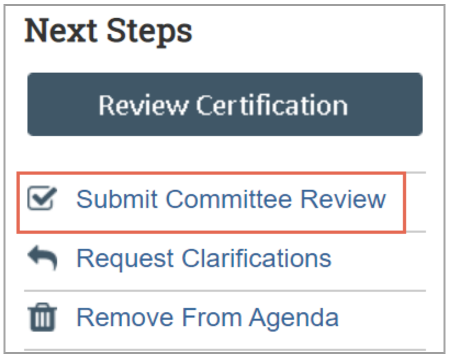
Submit a Committee Review

If the certification went through a committee review, the next step is to record the committee's decision for that certification. You may do this during or soon after the committee meeting. A COI staff member, committee admin, or committee chair can submit the committee review.

To submit a committee review, the certification must already be assigned to a meeting. For information on how to assign a certification to a meeting, see Assign to Meeting on page 13.

To submit committee review

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

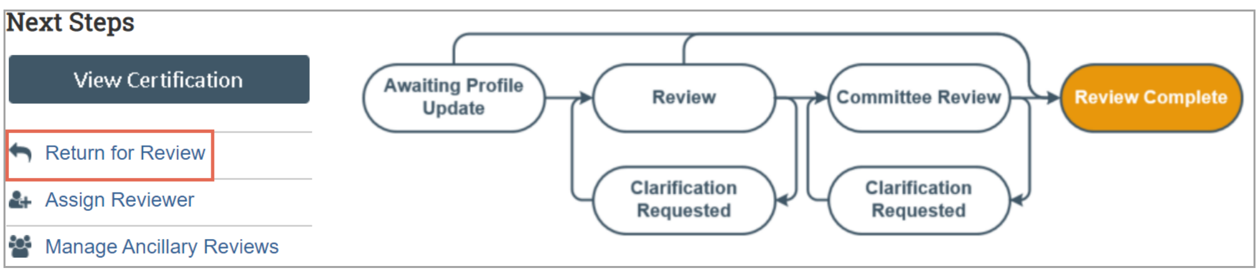


2. Complete the page.
   Note: Refer to the toolkit worksheet which is available in the SmartForm to help you make a decision. You can then determine if it is related or not. If related, determine if there is conflict. And if there is conflict, add the details of that conflict and assign it to a management plan (or create a management plan).
3. Click **OK**.

Return for Review

You can use this option to send the certification back to a prior review stage. For example:

- If there is a mistake that you want to fix in a certification that is in the Review Complete state, you can use this option to bring the certification back to the Under Review state to fix the mistake.
- If there is a change of scope (such as a new drug or a new sponsor) in the research project, you can use this option to review the certification again.

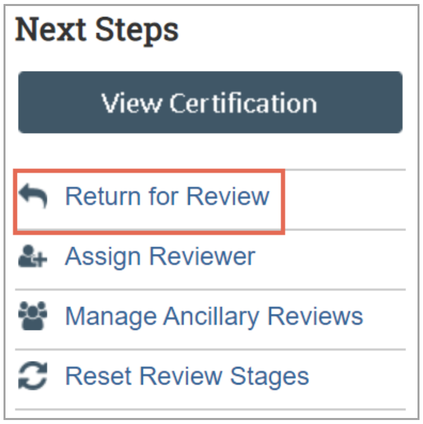


This option is available if the certification is in the following states:

- Under Review
- Committee Review
- No Review Required
- Review Complete

To send the certification back to a prior review stage

1. From the certification workspace, click **Return for Review**.



2. Select the review stage that you want the certification to return to.
3. If necessary, you can add comments and attach documents.
4. When done, click **OK**.

The certification returns to the selected stage and the reviewer for that stage is notified.

Note: If you send a review back to Stage 2 of 5, then stages 2 to 5 will have to complete another review on this task.

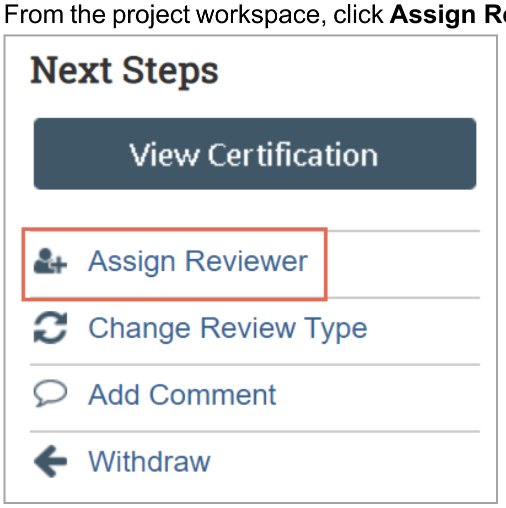
Assign a Reviewer

As a COI Administrator or an eligible reviewer for the current review group, you can assign yourself or another reviewer as the reviewer for a project.

Note: The Assign Reviewer activity is available in certification and pre-approval requests projects.

To assign a reviewer

1. From the project workspace, click **Assign Reviewer**.



2. Select the reviewer using one of the following methods:
   a. In the Assigned reviewer 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.

   The reviewer receives an email notification about the review, and the project appears in the reviewer's inbox.

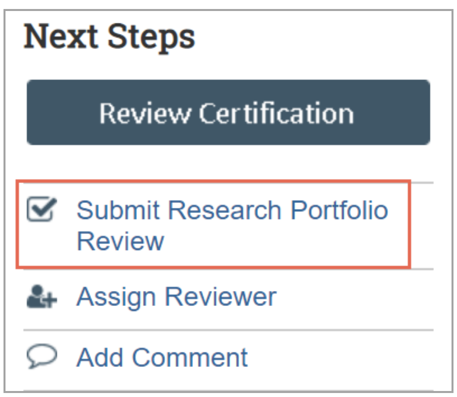
Submit a Research Portfolio Review

A research portfolio review is a type of certification specific to the delivered Research category, which may be created as a discloser's interests change over time. The purpose of the Research Portfolio Review is to allow a reviewer to assess a discloser's current 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 interests and a review was performed. Now, the discloser bought a significant amount of stock in a company and disclosed this in the COI system. The system creates a Research Portfolio Review task to facilitate a reviewer to check the current 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.



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.

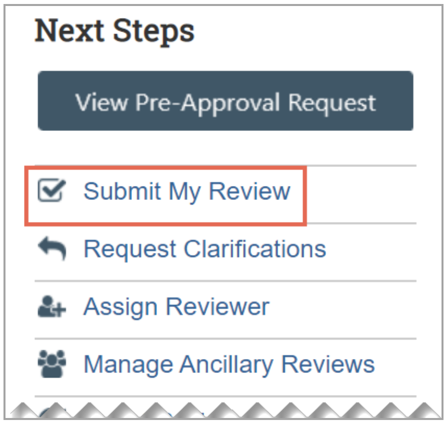
The pre-approval request SmartForm contains the information needed to complete your review. You can click the **View Pre-Approval Request** button to view the pre-approval request. The pre-approval request contains two key pieces of information to use when making a determination - the entity and the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

The pre-approval request can have a series of review stages depending on your institution's settings. 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**.

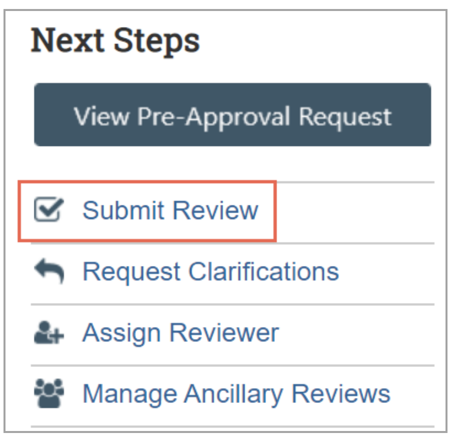


3. Based on your decision, select **Yes** or **No** to the question "Do you recommend.....?"
   Note: The input you provide will be used when making the final determination for this pre-approval request.
4. Based on your institution's settings for an intermediate review stage, you may get an option to disapprove the pre-approval request and skip all later review stages. If you select to skip the final steps, your decision is final and all subsequent review stages will be skipped.
5. If required, type a comment and add supporting documents.
6. When finished, click **OK**.

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

To submit a final 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 Review**.



3. Select your determination for this pre-approval request. The available options are:
   - Approved
   - Disapproved

   Note: If you select Disapproved option, provide a reason for disapproval.
4. If required, type a comment and add supporting documents.
5. When finished, click **OK**.

An e-mail notification is sent to the requestor with the determination.

Create and Manage a Management Plan

A management plan is used to manage a discloser's conflict. The certification reviewer determines whether a conflict exists. If a conflict exists, the reviewer can create a management plan or associate to it an existing management plan. You create a management plan while you are submitting an administrative review or a committee review.

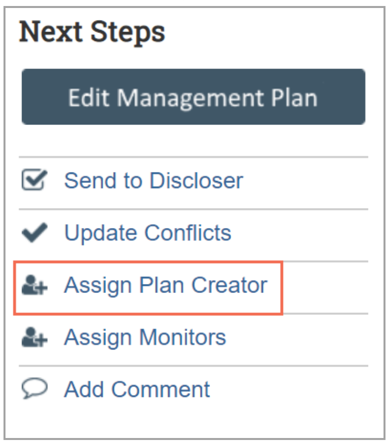
Management plans are configured to manage conflicts as per your institution’s requirements. You can either have one management plan per discloser or allow multiple management plans per discloser.

Assign Management Plan Creator

You can allow a user access to the management plan by assigning the plan creator. The assigned plan creator will receive an email notification regarding the assignment. The assigned plan creator is responsible for drafting or editing the management plan.

To assign a plan creator

1. From the management plan workspace, click **Assign Plan Creator**.



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

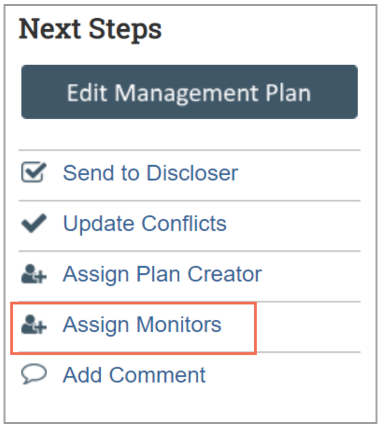
Assign Monitors to a Management Plan

The monitor makes sure that the steps in the management plan are followed throughout the life of the research project. The monitor keeps track of how the management plan is executed and makes changes to the management plan if necessary.

Note: You can assign more than one monitor to a management plan.

To assign monitors

1. From the management plan workspace, click **Assign Monitors**.



2. Select the monitors using one of the following methods:
   a. In the Assigned monitors 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 monitors from the list and click **OK**.
   Note: You can also use the filtering tools to search for a person.

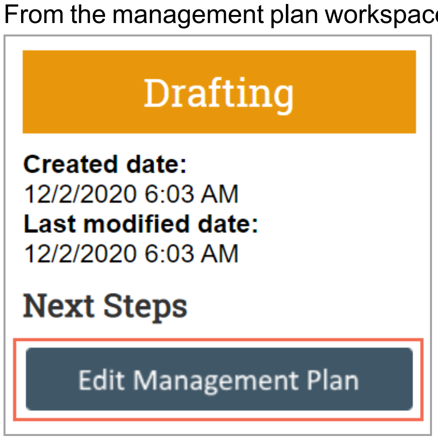
Add the Management Plan Document

If you are the management plan creator or monitor, you can add the management plan document in the SmartForm. You can also use this SmartForm to change the name of the management plan.

Note: Refer to the COI toolkit worksheet to help you in creating a management plan document.

To add the management plan document

1. From the management plan workspace, click **Edit Management Plan**.



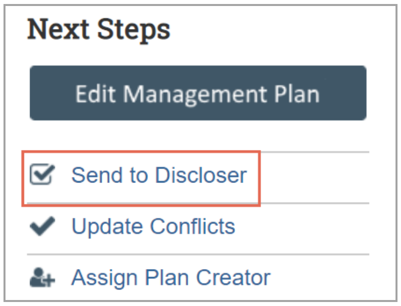
2. Click **Upload** below the management plan question to upload the document.
3. Choose the file to upload and click **OK**.
4. Click **Save** or **Finish**.

Send the Management Plan to Discloser

Once the management plan is created it needs to be sent to the discloser for their review and acceptance. Use the Send to Discloser activity to let the discloser know the management plan is ready for review.

To send to discloser

1. From the management plan workspace, click **Send to Discloser**.



2. If required, add any comments and attach documents related to the management plan.
3. Click **OK**.

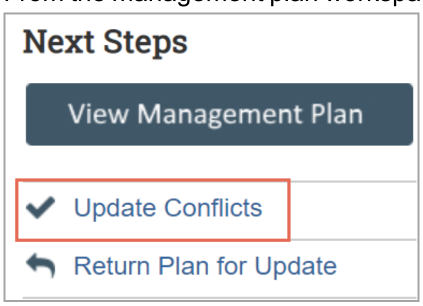
Update Conflicts in a Management Plan

You can update the conflicts to reflect the latest status. If required, you can also update the report due date so that you can report to the research compliance office what you did to manage this management plan.

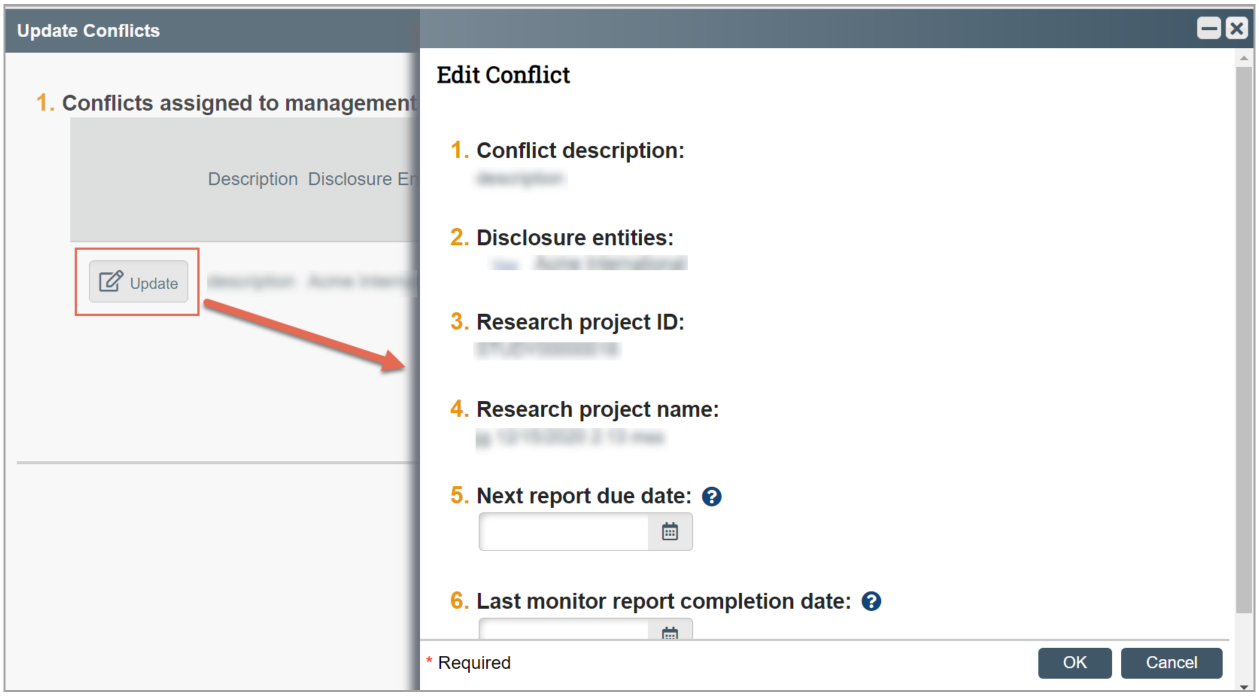
Note: If all conflicts in a management plan move to the state of Conflict Eliminated, the management plan itself transitions to the Satisfied state.

To update conflicts

1. From the management plan workspace, click **Update Conflicts**.



2. Click **Update** next to the description to update any information in the conflict.



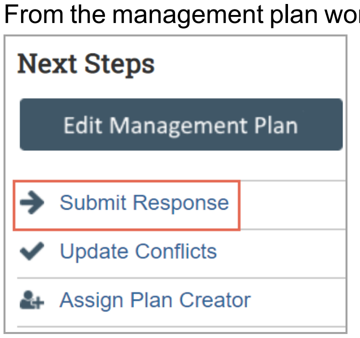
3. Click **OK**.

Submit Response to the Discloser

If the discloser has not accepted a management plan you will receive an email notification that includes their response. Use the Submit Response activity after you have considered the discloser's input and made any changes (if required) to the management plan. The management plan will be in the Clarification Requested state.

To submit a response

1. From the management plan workspace, click **Submit Response**.



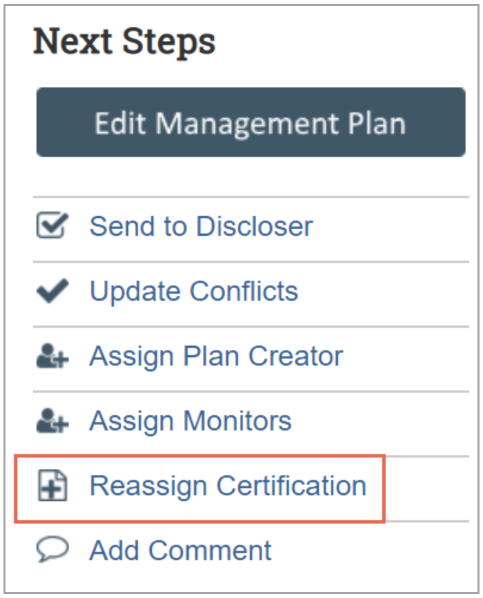
2. Enter your comments for the discloser in response comments section.
3. If required, attach documents related to your response.
4. Click **OK**.

Reassign a Certification to a Different Management Plan

You can reassign a certification to a different management plan if your institution allows multiple management plans for a single discloser.

To reassign a certification

1. From the management plan workspace, click **Reassign Certification**.



2. Select the certifications that you want to reassign to a different management plan.
3. Indicate whether to create a new management plan or associate the certifications to an existing management plan. Based on this selection, you will get further options.
4. When done, click **OK**.

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