OAIR Reviewer Guide

Outside Activity and Interest Reporting System

Table of Contents

Logging In	3
Understanding and Creating Certifications	3
Review Process Overview	6
Locating the Reviewer To-Do List	7
Accessing a Certification	8
Accessing a Disclosure	10
Accessing a Research Project	11
Accessing and Managing Person Information	13
Reviewing a Certification	19
Documenting Management Plans	28
Monitoring and Updating Management Plans	30
Research Project Requirements	33
Generating Reports	34
Notifications	37
Finding More Information	39

Logging In

The Outside Activities and Interest Reporting (OARI) system is secure, which means only authorized individuals have access to it. When you log in to the system, you get a personalized view of the information and possible actions pertinent to you.

To log in:

- 1. Locate your HarvardKey and password
- 2. Navigate to oair.harvard.edu
- 3. Enter your credentials (email address and password) in the appropriate spaces
- 4. Click the Sign In button
- 5. Once authenticated, you will be taken into the OAIR system, to your personal workspace.

If you are unable to log in, contact the OAIR Help Desk at oairhelp@harvard.edu.

Understanding and Creating Certifications

A **certification** is a submission type which contains a confirmation of institutional responsibilities, validation that the information is correct, and if applicable, or one or more disclosures for a particular individual.

A **disclosure** is a single record, indicating the external organization, institution, or entity, along with information about the nature of the relationship such as, any value, payments, time spent providing services, or activities conducted. Disclosures are always created, updated, and reviewed within the context of the certification.

There are three types of certifications in the OAIR system: Annual Certifications, Research Initiated Updates, and Disclosure Updates.

- Annual Certifications A certification that satisfies the university's requirement that the
 designated discloser population must update their reports of outside activities and interests at
 least annually. These certifications are typically created and submitted during a school's annual
 disclosure period but may also be created outside of that time period as needed.
- Research Initiated Updates A certification that satisfies the university's requirement for
 investigators on certain sponsored research projects to disclose their outside activities and
 interests. These certifications may be created for funding proposals and/or projects at an award
 stage and are always created automatically based on project information received in OAIR from
 GMAS.
- Disclosure Updates A certification that is typically created when a discloser has new
 information to report about their outside activities and interests outside the annual disclosure
 period or outside of research project-related requirements. Note: Disclosure Update
 certifications are the only type that can be created by COI Administrators and Disclosers.

Initiating the Annual Disclosure Process

The OAIR System facilitates each school's annual disclosure process. After the school reviews and confirms its current discloser population, the system will be set to automatically create annual certifications for disclosers.

The initiation of the annual process must be completed in coordination with the HUIT Research Administration and Compliance Team. For more information on the annual disclosure process, contact the help desk at oairhelp@harvard.edu.

Creating Ad-Hoc Certifications

If a person needs to complete and submit a non-research related certification outside of the annual disclosure period, COI Administrators have the ability to create a certification for them. For example, if your school's annual disclosure period is in March, but a new faculty member needs to disclose when they are hired in June, you can manually create a certification for them.

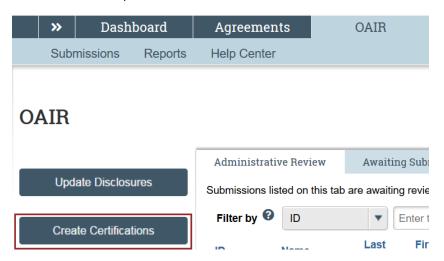
To create a certification:

1. From the Dashboard, click on the Create button and then the Create Certifications button

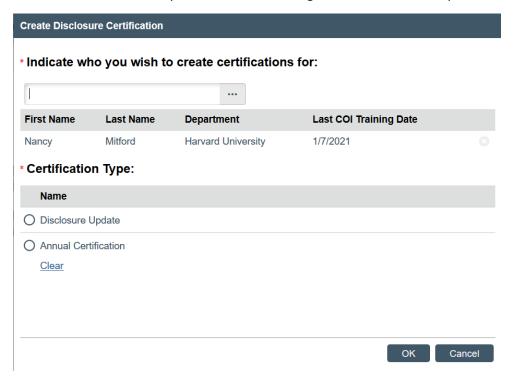


OR

From the **OAIR** tab, click on the **Create Certifications** button.



- 2. In the **Create Disclosure Certification** Activity form, begin typing the name of the person in the search box. A list of matching names appears. Click on the correct name. You may add more than one person at a time. (To **remove a person**, click the **Remove** icon on the right, next to the name.)
- 3. Select a **Certification Type** of either Disclosure Update or Annual Certification. **Tip**: Select **Annual Certification** if they did not disclose during the annual disclosure period.



Note: If you create a certification manually, you will need to email the discloser outside the system because the system does not automatically send a notification. **Tip:** To get a user-friendly link to the certification, highlight the certification name from any of the submission listings and use Ctrl+C to copy the name. Paste the information into an email using Ctrl+V; the name will display with a link to the certification workspace.

Research Certification Creation

Research Initiated Update certifications are created automatically in OAIR based on information received from GMAS. If a project in GMAS includes a requirement for investigators to disclose their outside activities and interests based on the project sponsor and the responsible Harvard school/unit, the creation of research certifications may take place at two points during the sponsored project lifecycle.

- **At proposal**, a certification is created for each investigator who has not otherwise submitted a certification in the OAIR system in the last twelve months.
- **At award,** a certification is created for each investigator who did not have a research certification created at the proposal stage.

Review Process Overview

When Review is Required

When a discloser submits a certification, the system will determine whether the certification requires review. If the criteria for review are not met, the certification will transition to the **No Review Required** status and the process is complete. If the certification needs review, it will transition to the **Administrative Review** status.

Requires Review

- All certifications that include new, updated, or removed disclosure(s)
- Research Initiated Updates that include disclosures
- Disclosure Updates or Annual Certifications submitted when the discloser has new research (defined as projects awarded since the discloser's last certification and for which the discloser was not required to complete a certification)

No Review Required

- Certifications that include no disclosures
- Certifications that include no changes to previously reviewed disclosures.

Administrative Review

If the certification needs review, it will transition to the **Administrative Review** status. While the submission is in the Administrative Review state, you can take the following actions:

- 1. **Assign Reviewer (optional)** If you would like to assign the review of the certification to a specific COI Administrator, you may complete the Assign Reviewer activity.
- 2. **Request Clarifications (optional)** If you have questions for the discloser or need them to revise the certification prior to completing your review, select the Request Clarifications activity. When you do, you will be prompted to record your comments to the Discloser in a pop-up window.
- 3. **Record Administrative Review (required step)** When you have reviewed the certification and associated disclosures, you must complete the Record Administrative Review activity to record the results or your review.
- 4. **Administrative Review Complete (required step)** After you record the results of your review, you must complete this activity to finalize the review and move to the next step in the process.

Management Plans

If the review determination is that a management or mitigation plan is required, the system will display the following activities to facilitate the creation of a management plan and communication with the discloser:

1. **Create or Upload Management Plan (required step)** – When a management plan is required, complete this activity to add the plan document to the system.

- 2. **Prepare Correspondence (required step)** To inform the discloser that a management plan is required and to instruct them on next steps, you must first draft the email to the discloser using this activity.
- 3. **Send Correspondence (required step)** Completion of this activity sends the email to the discloser and makes the management plan document available for them to review in the system.
- 4. **Submit Response Plan (required step)** Either the discloser or the reviewer must complete this activity to accept and finalize the management plan and transition the certification to the plan monitoring phase.

Other Optional Activities

The following activities are available in all states, unless otherwise indicated:

- 1. Withdraw Withdrawing a submission will make a submission inactive, at which point it can no longer be edited or reviewed. COI Administrators can withdraw a submission at any point until the Administrative Review Complete activity has been executed. When completing the Withdraw activity, you will be required to indicate the reason for withdrawal. Note: Withdrawing a certification does not affect any changes made to the associated disclosures through that certification. If the discloser has added new disclosures or modified existing disclosures, the updated disclosure information will be reflected on their next certification.
- 2. Log Comment & Log Private Comment These activities allow you to record notes on your review. "Log Comment" creates a comment visible to COI Staff and the Discloser, whereas "Log Private Comment" creates a comment that is visible only to COI Staff. If you want to add documentation of communications outside the system, you can upload documents to the certification via the Log Comment activities.

Locating the Reviewer To-Do List

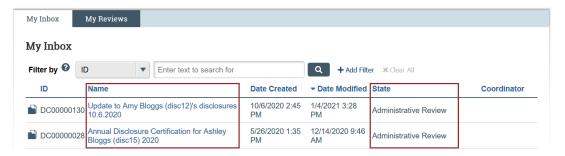
Certifications that are awaiting review or action by a COI Administrator will appear in the **Dashboard** with a link to the submission. To access a submission that does not appear in My Inbox, see Accessing a Certification below.

To access submissions for review:

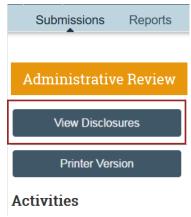
1. Click the **Dashboard** link in the top right navigation header.



2. Open the submission by clicking the link in the Name column. This will open the submission workspace.



3. Click on the View Disclosures button on the left to view the details of the submission.



Accessing a Certification

You may want to go to a specific certification workspace to view it, review it, or take other actions. Note that your access to a certification is based on your role in the system and the role you play in relation to the certification. In addition, the actions you can take on a certification are based on your role.

To view a certification workspace, click the certification name when you find it in a list of submissions.

To find a list that includes the certification name:

 Dashboard (only items that require attention): Click the Dashboard link in the top navigation header. This list displays certifications awaiting review.



OR

 OAIR (all items to which you have access): Click OAIR in the top navigation header and select the All Certifications tab. This list displays links to the workspaces for all submissions in the system that you have permission to view.



Tips:

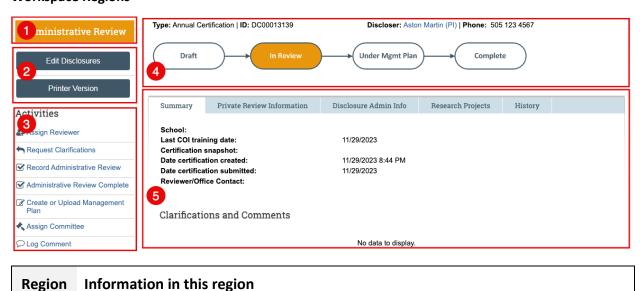
- Try filtering this list by the name of the discloser. Next to **Filter By,** select **Last Name**. Then type the beginning of the name and click **Go.**
- You can also filter by Reviewer. Next to **Filter By,** select **Reviewer/Office Contact**. Then type the last name and click **Go.**
- View the **State** column to see where a submission is in the review process.

Certification Permissions

Permissions on a certification are based on your role in the system and the role you play in relation to the certification. You have access to certifications where you are a COI Administrator for the school/unit with which the discloser is primarily affiliated or where you are a COI Administrator for a school/unit which has been granted guest access to the discloser's information.

Certification Workspace Overview

Workspace Regions



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1	Status Visible in all workspaces, the status region will show the current review status of			
	the certification.			
2	Next Steps Visible in all workspaces, this set of blue buttons allows for:			
	Editing or viewing the current certification SmartForm and			
	 Displaying a printer-friendly version. 			
3	Activities Visible on all workspaces, activity buttons display depending on the status of the			
	certification and your role.			
4	Certification Overview This section displays the following items for reference:			
	The type of certification,			
	The name of the discloser, and			
	An overview of the review process with the current status of the certification			
	highlighted.			
5	Certification Tabs Click the tabs to view:			
	 Summary Information about the discloser's affiliation and COI training, key dates 			
	associated with the certification, and a link to the certification snapshot when			
	applicable. Research certifications will also include information about the			
	associated research project. If a certification is in review, this tab will also display			
	comments and clarifications.			
	Private Review Information The reviewer's determination and associated notes			
	and a list of the discloser's other certifications. For HMS COI Staff, a section			
	including disclosures that require additional review also displays. This tab is visible			
	to COI Staff only.			
	Disclosure Admin Info Information about the discloser's interests and activities.			
	This tab is visible to COI Staff only.			
	Research Projects A list of the awarded projects that have not reached their end			
	date on which the discloser is an investigator. This tab is visible to COI Staff only.			
	History Information about each action taken on a certification and view of			
	comments or activity attachments.			
	The state of the s			

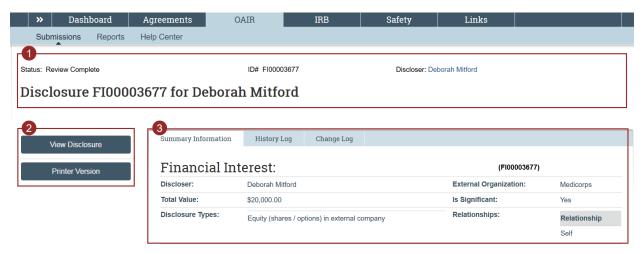
Accessing a Disclosure

Disclosures are normally accessed via certifications during the review process. However, it is possible to view details of a specific disclosure separately. To access a Disclosure Workspace, click on the magnifying glass to the far right of the disclosure record in any of the Disclosure reports available on the Reports page (see Generating Reports below). You can only access the Disclosure Workspace when the disclosure is in a Review Complete or Inactive status. For any disclosure in an Under Modification or Pending Removal status, if you click on the magnifying glass icon for that disclosure, you will be directed to the open certification where the disclosure modification/removal was initiated.

Note that your access to a disclosure is based on your role in the system and the role you play in relation to the associated discloser. You have access to disclosures where you are a COI Administrator for the school/unit with which the discloser is primarily affiliated or where you are a COI Administrator for a school/unit which has been granted guest access to the discloser's information.

Disclosure Workspace Overview

Workspace Regions



Region	Information in this region		
1	Research Project Overview This section displays the following items for reference:		
	The name and status of the disclosure.		
2	Next Steps This set of blue buttons allows for:		
	 Viewing the current certification SmartForm and 		
	 Displaying a printer-friendly version. 		
3	Disclosure Tabs Click the tabs to view:		
	• <u>Summary Information</u> Key Information about the disclosure, including relationship		
	types, disclosure types, and total value.		
	 History Log Information about each action taken on a disclosure and view of 		
	comments or activity attachments.		
	 Change Log Details of changes made to disclosure information. 		

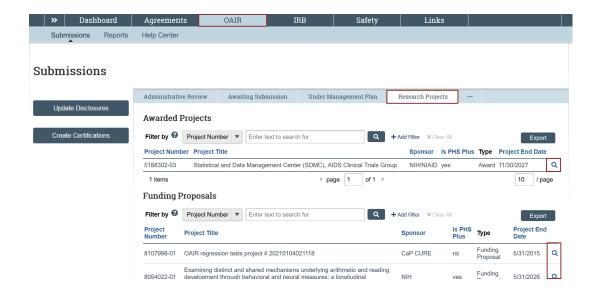
Accessing a Research Project

Summary information about research projects (also called Triggering Events) is available in OAIR. Your access to research project information is based on your role in the system. For full details about a research project, refer to the GMAS system.

To view a research project workspace, click the magnifying glass icon next to the project from the list of projects.

To find a list of projects:

• Click **OAIR** in the top navigation header and select the **Research Projects** tab. This list displays all the projects in the system that you have permission to view.



Tips:

- The listings are grouped by project status, whether they are **funding proposals** or **awarded projects**.
- Try filtering this list by the GMAS Project Number. Next to **Filter By,** select **Project Number**. Then type the number and click **Go.**

Research Project Permissions

Permissions on a research project are based on your role in the system. COI Administrators have access to research projects for the schools/units they are assigned to.

Disclosers do not have access to research projects in OAIR.

Research Project Workspace Overview

Workspace Regions

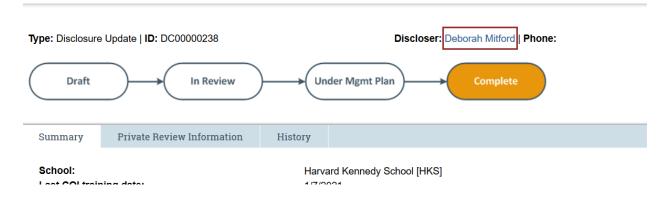


1	Activities Activity buttons displaying actions you can take.
2	 Research Project Overview This section displays the following items for reference: The name and status of the project, The school responsible for the project and its end date, and The sponsor, prime sponsor, and if the project is subject to PHS requirements.
3	 Personnel Information about the investigators associated with the project. Note: project roles, including investigator roles are set in GMAS. Certifications Any research-initiated certifications that have been created to satisfy project requirements. Note: At the funding proposal state, there may not be research-initiated certifications for all personnel. You will only see certifications where you are a COI Administrator for the school/unit with which the discloser is primarily affiliated or where you are a COI Administrator for a school/unit which has been granted guest access to the discloser's information. Details Additional information about the project, including segment and request details, and any documents added to the project via the Add Documents activity. History Information about each action taken on a research project and view of comments or activity attachments.

Accessing and Managing Person Information

To access a person record from a certification:

- 1. Find a certification for the person whose record you want to view following the instructions for Accessing a Certification above.
- 2. In the certification workspace, click on the **discloser's name** to access the workspace for that person record.

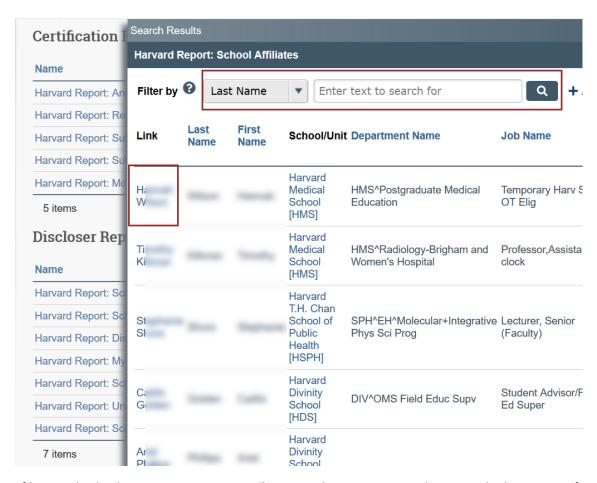


OR

To access a person record via Reports:

- 1. Click **Reports** in the OAIR sub-menu.
- 2. On the Reports page, click the **Harvard Report: School Affiliates** link in the **Discloser Reports** section.

3. In the report, click on the **name of the person** in the **Link** column to access the workspace for that person record.

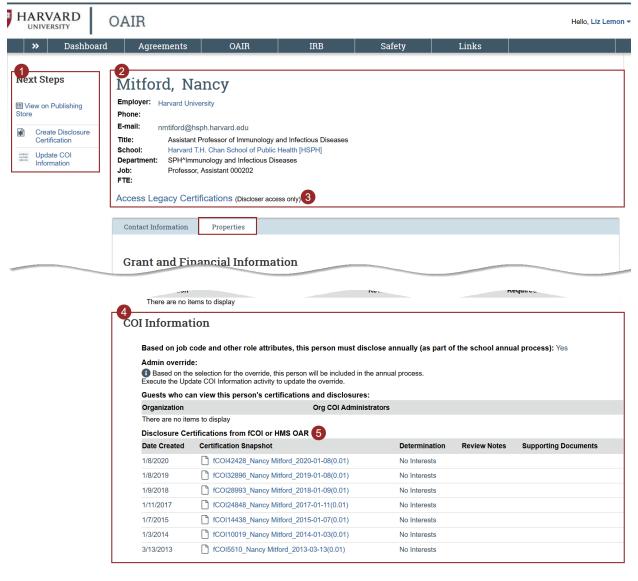


Tips: Try filtering this list by Last Name. Next to **Filter By,** select **Last Name**. Then type the beginning of the name and click **Go.**

Person Record Permissions

Permissions on a person record are based on your role in the system. All COI Administrators have access to all person records. COI Administrators for the person's school of primary affiliation and any COI Administrators with guest access for that person will be able to view additional person information and update certain COI Information.

Person Workspace Overview



Region	Information in this region		
1	Next Steps Activity links displaying actions you can take.		
2	Person Details This section displays the following items for reference:		
	The primary affiliation of the person and		
	 The job name, job code, and FTE of the person's primary job. 		
3	Legacy Certifications for Discloser A link to the discloser's legacy certifications for		
	discloser access only.		
4	Properties Tab This tab_displays the following items at the bottom:		
	 Information about whether the person is required to disclose annually and 		
	 Any organizations with guess access to the person's certifications. 		

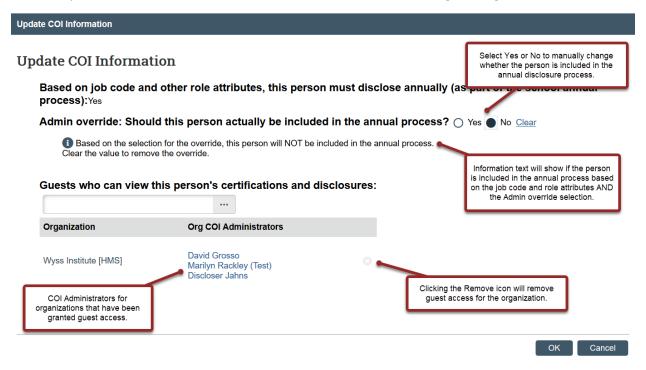
Legacy Certifications for COIAs A list of the discloser's legacy certifications migrated from fCOI and HMS OAR available only to COI Administrators for the person's school of primary affiliation and any COI Administrators with guest access for that person.

Updating COI Information

COI Administrators for the person's school of primary affiliation and any COI Administrators with guest access for that person have permission to update COI information for the person. Click on the **Update COI Information** activity to change the following:

- Admin override The admin override option changes whether the person is included in the annual disclosure process.
 - If the admin override is set to Yes, the person will be included in the annual disclosure process.
 - If the admin override is set to No the person will NOT be included in the annual disclosure process.
- **Guest organizations** The COI Administrators for any schools/units added here will have access to view and review the person's certifications and disclosures.
 - To add a guest organization, begin typing the name of the school/unit in the search box.
 A list of matching organizations appears. Click on the correct name.
 - o To **remove a guest organization**, click the **Remove** icon on the right, next to the name.

Note: Only schools/units with COI Administrators are available to add as guest organizations.



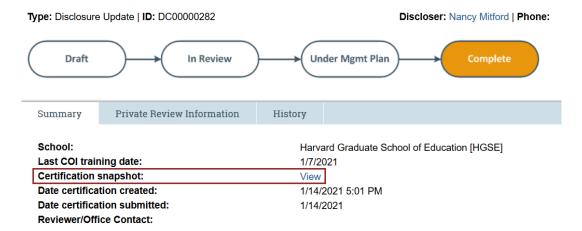
Accessing Historical Disclosure Information

Certifications that are complete remain in the system and are available on the **All Submissions** tab. For more information on accessing these certifications, see the Accessing a Certification section.

Information about a discloser, including information provided by a discloser via a certification SmartForm and information about any research projects the discloser is an investigator on, will continue to be updated during the time that the discloser is active in the system. For example, a discloser may have a relationship with a particular organization over many years that involves different activities and different amounts of compensation and time commitment. Updates may be made to a disclosure for a single organization over multiple certifications.

When a certification is in a review status, information on the certification workspace will reflect the most up-to-date disclosure information and research project information for the discloser in order to facilitate review. Once the certification has transitioned to a complete status, the tabs displaying disclosure details and research projects for the discloser are no longer present on the certification workspace.

To view a certification and the associated disclosure information as it was at the time of review, disclosers and reviewers should view the certification **Snapshot**. The snapshot includes the SmartForm instructions, questions, and responses from the time review was completed, including any changes made during the review process if clarifications were requested. The snapshot is available on the Summary tab of the certification workspace.



Legacy Information from fCOI and HMS OAR

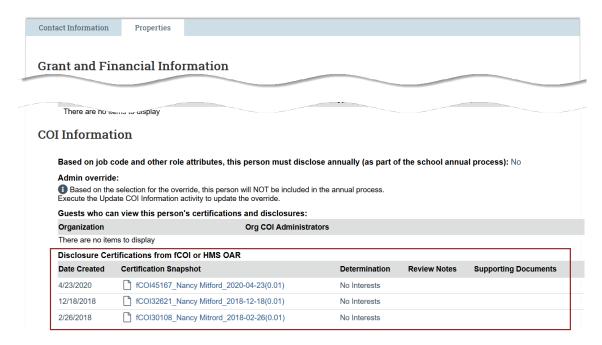
Disclosure reports from fCOI and certifications from HMS OAR are available to the discloser and COI administrators on the person's profile.

To access these legacy reports:

- 1. Navigate to the workspace for the person following the instructions above.
- 2. Click on the **Properties** tab.



3. Scroll to the bottom of the tab to view legacy reports, determination, and administrative review notes. Click on the link to the **Certification Snapshot** to view the full report from fCOI or OAR.



Note: Disclosers are only able to view their own snapshots without the Determination, Review Notes, and Supporting Documents information.

If a discloser has legacy reports but you cannot see them, you will see a message directing you to the OAIR Help Desk for additional information.

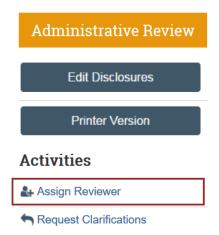
Reviewing a Certification

Assigning a Reviewer

Any COI Administrator with access to a certification is able to complete review activities for that certification. However, if you want to assign the review to a particular person, you may complete the optional Assign Reviewer activity.

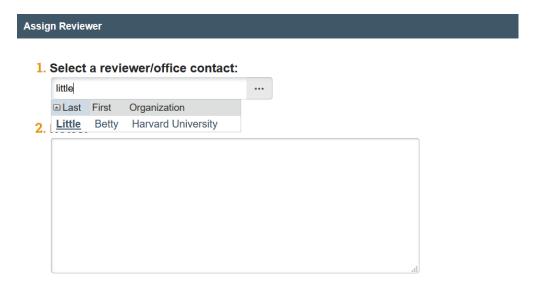
To assign a reviewer:

- 1. Navigate to the certification workspace (see Accessing a Certification for further instructions).
- 2. Click Assign Reviewer on the left.



3. In the **Assign Reviewer** activity form, type the first or last name of the person you want to select into the Select a reviewer/office contact box or click on the ellipsis to see the full list of possible reviewers. Although you may assign any COI Administrator as a reviewer, if that person does not already have access to the submission, assigning them as a reviewer does not give them access.

Note: You may add notes on the activity, but they are not private and will be visible to the discloser.



Note: Assigning a reviewer from another school or unit will not give that person permission to view the certification.

4. Click **OK** to complete the activity.

When you assign a reviewer, that person receives a notification with a link to the certification for review.

Viewing Certification Details

To begin your certification review, you will first need to review the details of the submission.

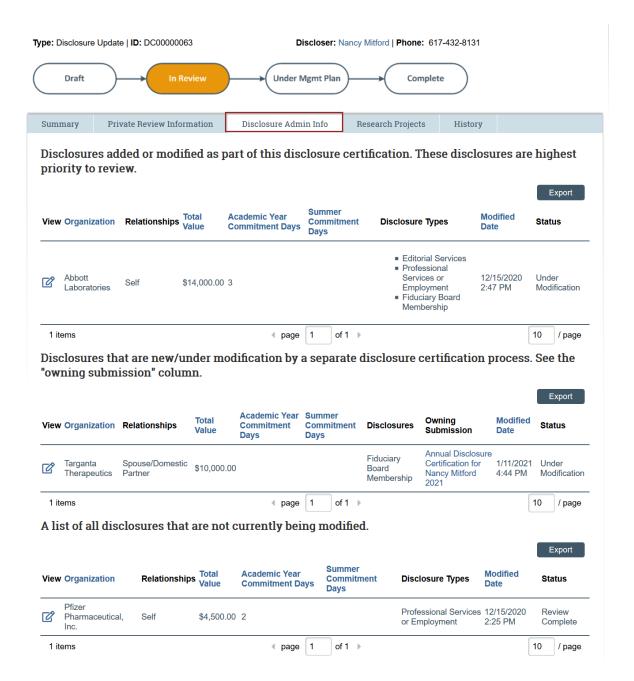
To view the summary information about a certification, related disclosures, and other information about the discloser:

Disclosures – Click on the **Disclosure Admin Info** tab for a list of the discloser's current disclosures. This tab includes three sections:

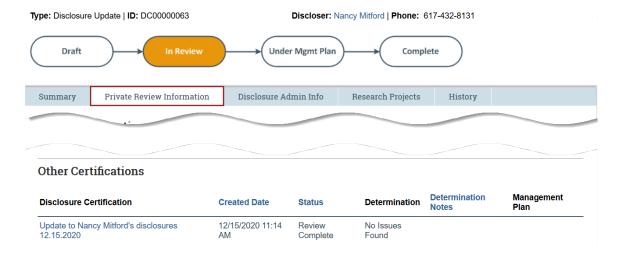
- Disclosures added or modified as part of the certification being reviewed,
- Disclosures added or modified on another certification in draft or review (Note: this situation is not common), and
- Disclosures that have been reviewed on an earlier certification that have not changed on the certification being reviewed.

The status of each disclosure displays next to the disclosure details.

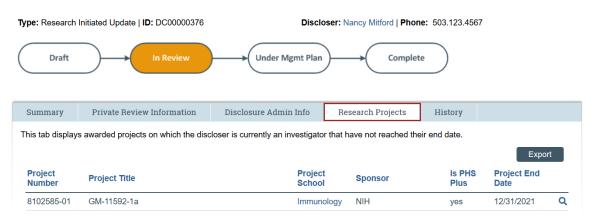
- Under Modification Disclosures that have been added or modified will have a status of Under Modification.
- Pending Removal Disclosures that were removed by the discloser will have a status of Pending Removal. Once the certification review is complete, these disclosures will transition to the Inactive status and will not display on future certifications.
- **Review Complete** Disclosures that have been reviewed on prior certifications will have a status of Review Complete.



Other Certifications – Click on the Private Review Information tab for a list of the discloser's other certifications including determinations and links to the certifications' workspaces for more information.

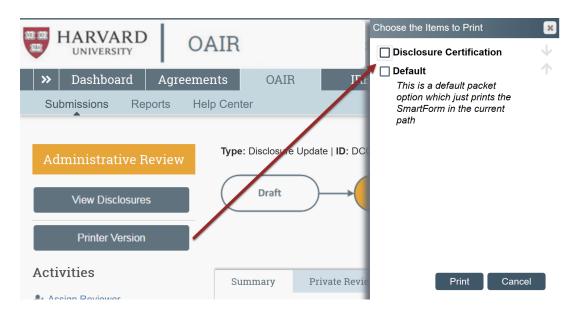


Research Projects - Click on the **Research Projects** tab for a list of awarded projects on which the discloser is currently an investigator.



To view detailed information about a certification and related disclosures:

- To view the SmartForm, page by page, click View Disclosures
- To view the SmartForm as one page, click **Printer Version** and then select the **Default** option
- To view a condensed version of the discloser's responses as one page, click **Printer Version** and then select the **Disclosure Certification** option



Requesting Clarifications on a Certification

During your review, you can request that the discloser provide additional information or make changes to the certification.

Requesting clarifications returns the certification to the discloser so they can edit it and respond to your questions. Requesting clarifications can be useful when:

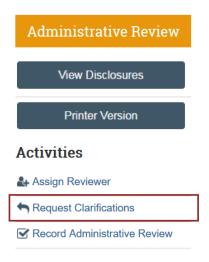
- Required details are missing from the SmartForm.
- There is **inconsistent information** between elements of the SmartForm which need clarification.
- A new item was discovered during review that **needs to be added to the SmartForm**.

The OAIR System is the system of record for faculty and researcher outside activities and interests, so it is important to use this opportunity to ensure the certification is correct and complete during review.

In addition, if a discloser needs to make updates to their disclosures while they have one or more certifications in review, they are only able to update those disclosures if you allow them to edit at least one of those certifications by requesting clarifications. Disclosers may contact a reviewer directly to request the ability to make edits or COI staff may receive a Request for modification of certification notification from the system indicating that the discloser would like to make edits.

To request clarifications:

- 1. Navigate to the certification workspace (see Accessing a Certification for further instructions).
- 2. Click **Request Clarifications** on the left.



- In the Request Clarifications activity form, provide detailed questions or requests for changes.
 Note: You can also attach documents that further explain and/or show suggestions for addressing the request.
- 4. Click **OK** to send the request to the discloser for edits. The certification will transition to the **Administrative Review: Response Pending** status.

You will receive an email notification when the discloser submits a response to your clarification request.

Note: While COI Administrators cannot edit a certification, either the discloser or a COI Administrator can complete the **Submit Clarifications** activity to return the certification to review. If the discloser has made all the appropriate updates but has not submitted their clarifications, the reviewer can submit clarifications on their behalf and should then add any associated correspondence with the discloser to the certification using the **Log Comment** activity.

To view the response submitted for a clarification request:

- 1. Navigate to the certification workspace (see Accessing a Certification for further instructions).
- 2. Click the **History** tab in the Certification workspace.
- 3. View the information about the **Clarifications Submitted** activity, including the response from the discloser, in the History log.



I provided, as requested, an estimate in the percentage of the company of stock which I own. No other changes made.

Note: You may use the Request Clarifications activity as many times as needed during the review process.

Viewing Changes

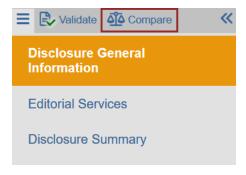
When a new certification is created for a discloser, their current active disclosures are included on the new certification. While the certification is in a Draft state and if clarifications are requested, the discloser has the ability to add, update, and/or remove associated disclosures. If a disclosure has been updated, it is possible to view the changes made to the disclosure since it was originally added.

To View Changes on a Disclosure:

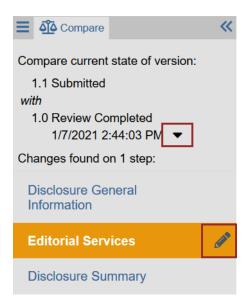
- 1. Navigate to the certification workspace (see Accessing a Certification for further instructions).
- 2. On the **Disclosure Admin Info** tab, view the status and modified date information for disclosures added or modified as part of the disclosure certification under review.
- 3. For a disclosure in the **Under Modification** status, click on the **View** icon to access the disclosure SmartForm. **Note:** If the discloser updated a disclosure as part of the request for clarifications, the **Modified Date** will be updated to reflect the date of the changes.



4. In the SmartForm, click the **Compare** tab on the left navigation.

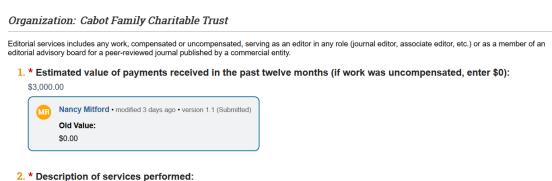


5. Click the dropdown arrow to select a **version** to compare the current SmartForm to.



6. Look for the **pencil icon** next to the page(s) where changes have been made. Click the pencil to jump to the page with changes. The changes since the version you selected will appear with the old values highlighted in a gray box.

Editorial Services



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Completing Your Review

Once all your questions and clarification requests have been answered, you will need to record the outcome of your review and complete it.

- Click on the Record Administrative Review activity and complete the activity form. You will need to fill in or confirm the following:
 - Administrative determination (required) Select No Issues Found if no additional action is necessary; select Management Plan Required if there are activities/interests that will need to be managed.
 - b. **Recommended management/mitigation plan topics** (optional) This prompt will appear if the Administrative Determination is Management Plan Required. The options selected are for statistical/informational purposes only and are NOT communicated to the discloser or automatically added to a management plan.

- c. **Plan monitor:** (optional) This prompt will appear if the Administrative Determination is Management Plan Required. You may select yourself or another COI Administrator as a monitor for the plan. The monitor will receive reminders when a plan review is scheduled.
- d. **Plan review frequency: (in days)** (optional) This prompt will appear if the Administrative Determination is Management Plan Required. Selecting a plan review frequency is required if a plan monitor is chosen. The monitor will receive plan review reminders based on the selected frequency.
- e. **Review/Determination notes** (optional) You may add notes regarding your review and findings. These notes are not visible to the discloser.
- f. **Related attachments** (optional) You may add documents related to your review and findings. These documents are not visible to the discloser.
- g. **Related web links** (optional) You may add links to websites supporting your review and findings. These links are not visible to the discloser.

Click **OK** when you are finished.

2. Click on the **Administrative Review Complete** activity and click **OK** to transition the certification to the next status.

If the **Administrative Determination** is **No Issues Found**, the certification will transition to the **Review Complete** status and a Snapshot will be created. If a management/mitigation plan is required, the certification will transition to **Review Complete: Preparing Correspondence**. Continue with the steps described in the Documenting Management Plans section below.

Note: The system includes an **Assign Committee** activity that allows the reviewer to forward a certification to a committee for additional review. Harvard has not configured committees for use in the system and this activity should NOT be completed.

Forward for Further Review

If a certification has moved to the No Review Required status based on the criteria for review described in the When Review is Required section above, but you determine that review is necessary, you may manually route the certification for review.

To move the certification back for review:

- 1. Navigate to the certification workspace (see Accessing a Certification for further instructions).
- 2. Click Forward for Further Review in the Activities list on the left.
- 3. In the **Forward for Further Review** activity form, you may add notes about why the certification needs review.
- 4. Click **OK** to complete the activity and move the certification back to the **Administrative Review** status.

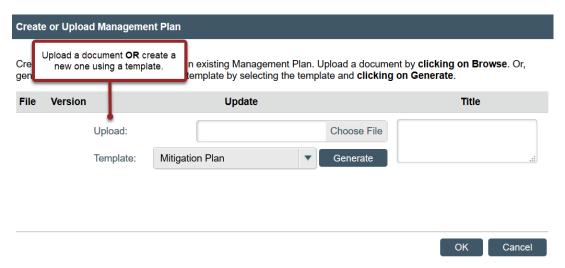
Note: This option is only available when the certification has not already been reviewed. If a review has been completed, it is not possible to move the certification back to the Administrative Review status.

Documenting Management Plans

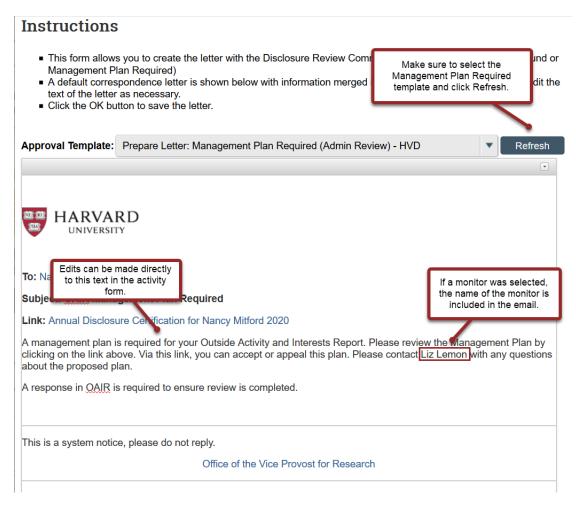
If the discloser's interests and/or activities warrant a management/mitigation plan, you will need to record the management plan on the certification and document communications with the discloser.

- 1. Click on the **Create or Upload Management Plan** activity to upload a management plan drafted outside the system or to create a management plan from the templates available in the system.
 - **To upload a document**, click the **Choose File** button and use the **File Upload** dialog box to browse to the file on your computer. Then click **OK** to complete the activity.
 - To create a document from a template, select the template from the Template
 dropdown and click the Generate button. Note: If you create a document from a
 template, the activity form will close automatically. You can access the management
 plan document on the Private Review Information tab from which it can be
 downloaded and edited.

Tip: This activity can be completed as many times as needed to update the management plan document and ensure that the final version is associated with the certification.



- 2. Click on the **Prepare Correspondence** activity to create and edit the notification to the discloser.
 - In the Prepare Correspondence activity form, from the **Approval Template** dropdown, select the **Prepare Letter: Management Plan Required** option.
 - Click the **Refresh** button to update the notification text that appears below.
 - Edit the notification text as needed.
 - Click **OK** to complete the activity. **Note:** Completing this activity creates the notification to the discloser but does not send it.



- 3. Click on the **Send Correspondence** activity to send the notification to the discloser.
 - In the **Send Correspondence** activity form, you may view the notification to confirm the contents.
 - Click **OK** to complete the activity.
- 4. Click on the **Submit Response Plan** activity to confirm the discloser's acceptance of the management plan. **Note:** This activity may be completed by the discloser or COI staff.
 - In the **Submit Response Plan** activity form, select **Accept** from the dropdown for question 1. You or the discloser may add notes as needed.
 - Click **OK** to complete the activity.

Tip: If you accept the management plan on behalf of the discloser, use the **Log Private Comment** activity to upload any correspondence with the discloser confirming their acceptance of the plan.

Note: If the discloser chooses the **Request Further Clarification** option from the dropdown for question 1, the certification will transition back to the **Administrative Review** status so that the reviewer has the option to update the management plan.

Once the management plan is accepted, the certification will transition to the **Under Management/Mitigation Plan** status and a Snapshot will be created.

Monitoring and Updating Management Plans

While a certification is **Under Management/Mitigation Plan**, the assigned monitor and/or other COI staff has the ability to document management plan compliance and take actions to track management plan requirements.

Monitoring Management Plans

When a management plan review frequency is set during a review, a plan review due date is set in the system based on the review frequency. If a monitor is assigned as well, the monitor will receive reminder notifications fifteen days and one day before the review due date. At any point while the certification is in the Under Management/Mitigation Plan status, COI staff can assign or reassign a monitor.

To Complete the Monitor Report:

- 1. Navigate to the certification workspace (see Accessing a Certification for further instructions).
- 2. Click **Complete Monitor Report** on the left.
- 3. In the **Complete Monitor Report** activity form, indicate whether the discloser is in compliance with the management plan. You can also add notes and attach documents that further detail any plan review activities. **Note:** The information provided in this activity is only available to COI staff.

Complete Monitor Report 1. Management plan monitor report for the discloser: Liz Lemon 2. * Is the management plan on track and in full compliance? O Yes O No Clear Comments and notes regarding this monitor report. If the management plan is not in full compliance, please include the reason(s): Indicating whether the management plan is on track and adding a date the report was completed are Adding notes and/or documents required. is optional. 4. Attach your monitor report and notes: [N ne] 1 Upload 5. * Date report completed: i I hereby confirm that my report is complete and my assessment of management plan compliance is accurate: OK Cancel

4. Click **OK** to complete the report. After the activity is completed, the plan review due date will be reset based on the review frequency established during the review process.

To Assign/Reassign a Monitor:

- 1. Navigate to the certification workspace (see Accessing a Certification for further instructions).
- 2. Click Reassign Monitor on the left.
- 3. In the **Reassign Monitor** activity form:
 - a. To **add a monitor**, begin typing the name of the person in the search box. A list of matching names appears. Click on the correct name.

- b. To remove a monitor, click the Remove icon on the right, next to the name.
- c. To **change a monitor**, remove the existing monitor and add a new monitor.
- 4. Click **OK** to complete the activity.

Note: If the Plan Review Due Date has passed and a Monitor Report has not been completed, the monitor will receive a report overdue reminder notification and the certification will transition to the **Monitor Report Overdue** status.

Documenting Sponsor Reports or Notices

When a certification is in the **Under Management/Mitigation Plan** status, COI Staff can document information reported to the sponsor of a research project regarding the discloser's activities and interests.

To Log a Sponsor Notice:

- 1. Navigate to the certification workspace (see Accessing a Certification for further instructions).
- 2. Click **Log Sponsor Notice** on the left.
- 3. In the **Log Sponsor Notice** activity form, add notes and attach any correspondence/documents that were sent to the sponsor.
- 4. Click **OK** to complete the activity.

Note: This activity is only available while the certification is in the Under Management/Mitigation Plan status. If the plan is marked as satisfied, the Log Sponsor Notice activity is no longer available.

Updating Management Plans

If a management plan for a discloser changes, either because the requirements have been satisfied or because the discloser has new or updated interests or projects, COI Staff should mark the current management plan as satisfied and add a new plan, as appropriate.

To Mark a Plan as Satisfied:

- 1. Navigate to the certification workspace (see Accessing a Certification for further instructions).
- Click Plan Satisfied on the left.
- 3. In the **Plan Satisfied** activity form, add notes and attach documents related to completing the plan.
- 4. Click **OK** to complete the activity.

Once this activity is complete, the certification will transition to the **Management/Mitigation Plan Satisfied** status and will be considered complete.

Note: If the plan is marked as satisfied, the **Log Sponsor Notice** activity is no longer available. Any reports to sponsors should be added before the **Plan Satisfied** activity is completed.

To Update a Management Plan:

A management plan is always associated with a certification in OAIR. When an update to a management plan is required because the discloser has new interests and/or projects on a certification, follow the steps described in the Documenting Management Plans section to upload an updated management plan to the new certification. You do not need to mark the management plan(s) on any prior certifications as

satisfied unless the conflicts associated with the interests and/or projects on those certifications are actually removed.

Research Project Requirements

Research Certifications

Research Initiated Update certifications are created automatically in OAIR based on information received from GMAS. If a project in GMAS includes a requirement for investigators to disclose their outside activities and interests, the creation of research certifications may take place when a funding proposal is created and/or when a project reaches award status.

Funding Proposals

When investigators are added to funding proposals in GMAS, Research Initiated Update certifications are created for investigators:

 If the school/unit responsible for the project is HMS or Wyss and if the investigator has not submitted a certification within the last 12 months

OR

• If the project sponsor is PHS+ and if the investigator has not submitted a certification within the last 12 months.

To ensure that all investigators have up-to-date disclosures on file, if an investigator has a certification on file already, they will receive a notification reminder to update their outside activities and interests if necessary.

Project at Award

When a project reaches the At Award stage in GMAS, Research Initiated Update certifications are created for investigators:

 If the school responsible for the project is HMS and if the investigator has not submitted a certification for that project at the proposal stage

OR

• If the project sponsor is PHS+ and if the investigator has not submitted a certification for that project at the proposal stage.

Note: Investigators who do not have a HarvardKey are not able to disclose in OAIR. See <u>OAIR Guidance</u>-Investigators without a HarvardKey for the options that are available for individuals without a HarvardKey who are required to disclose under Harvard policy.

Reviewing Certifications

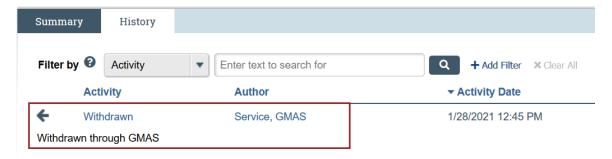
When a project sponsored by your school/unit reaches the At Award stage in GMAS, you will receive a notification from OAIR of the project status update. In order for the award to be set up, all investigators must have submitted a Research Initiated Update certification for the project and these certifications

must be reviewed, if review is required. **Note:** At the funding proposal stage, all investigators must have a recently submitted certification (within the last 12 months), but it is not necessary for those certifications to be reviewed until the project reaches an award stage.

Research Initiated Update certifications should be reviewed following the instructions provided in the Reviewing a Certification section above.

Withdrawn through GMAS

If an investigator was removed from a project in GMAS, their certification will be withdrawn automatically in OAIR, with a note added that the submission was withdrawn through GMAS.



Adding Documents

If there are certifications for the project that were completed outside the system or other documents related to outside activity and interesting reporting and review for project investigators, it is possible to add those documents to the project record in OAIR.

- 1. Navigate to the research project workspace (see Accessing a Research Project for further instructions).
- 2. Click Add Documents on the left.
- 3. In the **Add Documents** activity form, attach any documents related to disclosures for the research project.
- 4. Click **OK** to complete the activity.

Note: Documents are displayed on the **Details** tab on the research project workspace and in the **History** log.

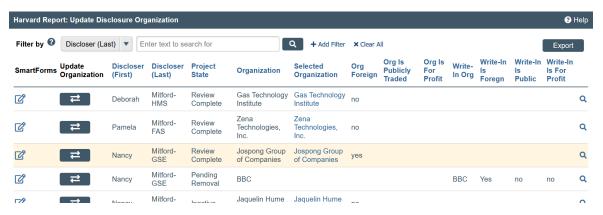
Updating Disclosure Organization Information

In general, reviewers do not have permission to edit disclosure information, with the exception of organization information. Reviewers may update information about the organization associated with a disclosure in the following ways:

- Changing the name or properties of a write-in organization
- Changing a write-in organization to an organization that exists in the system
- Changing the association from an organization that exists in the system to a write-in organization
- Changing the association from one organization that exists in the system to another organization in the system

To update disclosure organization information:

- 1. Click **OAIR** in the top navigator.
- 2. Click **Reports** in the OAIR sub-menu.
- Click the Harvard Report: Update Disclosure Organization report to open the report. The report
 will display relevant organization information for each disclosure. Each disclosure will include
 organization details for either an organization selected from the system or a write-in
 organization.



- 4. To review additional details about a disclosure, click on the SmartForms pencil icon.
- 5. To update the organization information, click the Update Organization button.
- 6. In the activity form, review the existing organization information and update it as appropriate.
 - a. To change the organization selected, click the X next to the organization name and then in the blank organization field, search for and select the correct organization. Type the organization name in the space provided (a list will appear with options from which to select), or you can click the ellipses [...] to search the list of available organizations. Use the "%" symbol to replace portions of a word of which may be unclear or possibly not spelled correctly. This is called a "wildcard" character.
 - b. To remove the write-in organization and add a selected organization, use the search box to search for and select the correct organization (see search tips above). Once you have selected the correct organization, you do not need to change the write-in organization fields; they will be updated automatically when the activity is completed.
 - c. **To remove the organization selected and add a write-in organization,** click the X next to the organization name and then use the fields below to add the organization name and select the organization properties.
 - d. **To edit write-in organization information,** correct the organization name in the text box and change or add any relevant organization properties.
- 7. Fill in the reason you are making the change at the bottom of the form and click OK.
- 8. The Update Disclosure Organization report will automatically refresh and your changes will be reflected.

Replace Organization		
Update the organization associated with this disclosure.		
Current Organization: Gas Technology Institute		
If the organization exists in the database, please select or update it.		
Gas Technology Institute		
or Edit the write-in organization information.		
Organization name:		
Is this organization publicly traded? O Yes O No Clear		
Is this organization for profit? ○ Yes ○ No Clear		
Is this organization a foreign entity, i.e. organized outside the United States?		
* Why are you making this change?		

Notes:

- When updating organization information, the selected organization will always take precedence over write-in organization information. If there is an organization selected on the form, any write-in information will be deleted when the activity is executed.
- Because disclosures are separate from certifications, disclosures can be updated at any time and do not need to be updated during a certification review.
- Reviewers can update disclosures in any status, including Inactive disclosures.
- Any changes made to disclosures will be immediately reflected in certifications that are currently in process for that discloser (i.e. certifications that have not been submitted or are in review).
- To view disclosure history information, including a record of any organization updates you
 made, you can click on the magnifying glass to the far right of the disclosure record in the
 Update Disclosure Information report. For more information on the Disclosure Workspace, see
 the Accessing a Disclosure section above.

- Reviewers cannot update names or associated properties for organizations that exist in the system. Please contact oairhelp@harvard.edu if an existing organization needs to be corrected.
- In some rare cases, a discloser might have selected an organization from the system and written in organization. In these cases, OAIR treats the disclosure as being associated with the selected organization and ignores the write-in organization.

Generating Reports

The OAIR system includes many standard reports to help you access person, certification, and research project records. In addition, reports can help you monitor compliance with requirements and access disclosure details more easily.

The reports provide links to the individual records, as well as sorting and filtering options.

Any user has access to reports, but the data in the reports is limited to the records visible to the individual. For example, a report generated by a discloser will include certifications and disclosures for that person only. COI Administrators will have access to more person data and certifications, disclosures, and research projects for the schools/units they are associated with.

To generate a standard report:

- 9. Click **OAIR** in the top navigator.
- 10. Click Reports in the OAIR sub-menu.
- 11. The list of reports appears. Identify the report you want to generate and click the title. The report will appear, listing the relevant records.
- 12. Report results can be exported to Excel from the results slide in by clicking the **Export** button.

Important! Notes on Exporting Reports

- Click the Export button only ONCE. The system will take a moment to display a pop-up window.
- If the pop-up window doesn't appear automatically, check to confirm that your browser isn't blocking pop-ups.
- If the pop-up displays a message that says, "Waiting to start the export. Your request is enqueued on the server," leave the window open. Your export will begin once the report ahead of it is finished. Closing this window will not cancel your export, it will only limit your access to the export link.
- If no other exports are pending, the pop-up will begin counting items in the anticipated file.
- Once the export is done, a link will appear. Click the link to download the exported list.

Notifications

Notification	Description	Notice Recipients		
Notification	Description	Discloser	COI Admins	Monitor
Annual Certification Notice	Notice sent by the system when a new annual certification is created.	✓		

Reminder of Certification in Draft	Notice sent by the system when a certification has not been submitted.	✓		
Certification Submitted	Notice sent by the system when a certification is submitted.	✓		
Update Certification Submitted	Notice sent by the system when a Disclosure Update certification is submitted and needs review.		✓	
Research Certification Submitted	Notice sent by the system when a Research Initiated certification is submitted and needs review.		✓	
Reviewer Assigned	Notice sent when a reviewer is assigned to a certification.		√ ∗	
Clarifications Requested	Notice sent when reviewer completes Request Clarifications activity.	✓		
Reminder of Clarifications Requested	Notice sent by the system when a response to requested clarifications has not been submitted.	✓		
Clarifications Submitted	Notice sent when discloser responds to requested clarifications and resubmits certification.		✓	
Request for modification of certification	Notice sent when discloser clicks the Create My Certification link on their Profile page AND when they currently have a certification in review.		✓	
Research Initiated Certification Notice	Notice sent by the system when a new Research Initiated Update is created.	✓		
Research Related Update Reminder	Notice sent by the system when a person is an investigator on a funding proposal AND has a disclosure on file in the last 12 months.	✓		
At Award Research Project Notice	Notice sent by the system when the research project reaches an at award status in GMAS.		✓	
Administrative Determination Notice	Notice sent when the certification review determination is Management/Mitigation Plan Required or Changes Required AND Prepare and Send Correspondence activities are completed.	✓		
Management Plan Accepted Notice	Notice sent when the discloser/COI Admin completes the Submit Response Plan activity.			✓
Monitor Report Due Reminders	Notice send when the deadline to submit a monitor report is approaching and when the deadline has passed.			✓

^{*}Notice is sent only to the COI Administrator selected on the Assign Reviewer activity.

Finding More Information

Resource	Description	How to Access It	
Help for a field or page	More information about a question or form.	Click onext to the question or at the top of the form.	
Help system	The full online help system, with search and table of	Click the Help Center sub-menu link at the top of the screen.	
·	contents. The online help contains procedures and information for all users.	>> Dashboard Agreements OAIR Submissions Reports Help Center	
OAIR Discloser Guide	Instructions for submitting a certification.	Click the Help Center sub-menu link at the top of the screen. On the Guides tab, click the name of the guide to open it.	
OAIR Reviewer Guide	Instructions for reviewing a certification.		
OAIR Support	External website with additional information about using the OAIR system	https://ras.fss.harvard.edu/oair	
OAIR Help Desk	Contact for help with access and use	oairhelp@harvard.edu	
OVPR Website	Information about the outside activity and interest reporting process and requirements	Office of the Vice Provost for Research: https://research.harvard.edu/2021/05/18/fcoi/	

This guide was created and edited by Harvard University based on materials originally produced by Huron Technologies, Inc.