Vanderbilt University Medical Center
Conflict Disclosure System
User Guide

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INTRODUCTION

This *Conflict Disclosure System User's Guide* is designed to walk Vanderbilt University Medical Center (VUMC) staff through the process of creating and submitting a conflict of interest disclosure for approval. The guide includes information on creating a disclosure and submitting it for approval, as well as approving a disclosure. A summary of the steps to follow for each process is provided in each section.

If problems are encountered with the Conflict Disclosure System after following the guidelines in this document or if you have suggestions for improvement, please send an email to the following address: coi.vumc@vumc.org.

The Conflict Disclosure System is a web application built specifically for Vanderbilt University Medical Center staff to submit and approve conflict of interest disclosures. Developed initially in 2007, the application allows authorized users to create a disclosure and submit it for approval. It also contains a facility for approvers to review and approve disclosures.

Medical Center staff must complete a disclosure each fiscal year as part of the annual performance evaluation process. If a potential conflict arises during the year, a disclosure can and should be completed as conflicts arise. The Conflict Disclosure System has been created to support this process. Outlined below is a brief summary of the disclosure process the system supports. In addition, a flowchart outlining the process is provided. More details on how to complete each step is provided in the sections that follow.

> **NOTE:** *VUMC employed faculty should not use this system to complete their COI disclosures. COI disclosures for School of Medicine and School of Nursing faculty employed by VUMC are handled through the Office of Faculty Affairs.*

A VUMC ID and Password are needed to use the Conflict Disclosure System.

If you have forgotten your Password, go to the following website and follow the instructions for recovery: https://myidentity.app.vumc.org/forgotpassword/.

If you are using a Microsoft Windows based computer, Internet Explorer version 8.0 or higher, Firefox, or Chrome web browsers are supported. If there is a problem with your web browser, please contact your local technical support person for assistance.

The Conflict Disclosure System's website can be accessed via the following URL: https://coi.app.vumc.org/

Enter your VUMC ID and Password on the log-in page and click *Sign On* to access the system.

PROCESS OVERVIEW:

1. Disclosure Creation and Submission for Approval: VUMC staff are responsible for submitting a disclosure each fiscal year. During the process disclosers complete a disclosure in the Conflict Disclosure System.

- When completing a disclosure, the main Yes/No questions and acknowledgements must be completed on the main disclosure page. If Yes was answered on any of the main Yes/No questions, then additional details about the potential conflict must be provided by completing a conflict details questionnaire. Note that some questions may be private and not visible by the approver.

- Once all disclosure questions are answered, an approver is selected on the ***Select Approver*** pages. Some departments' disclosures are automatically assigned an approver. If the incorrect approver is assigned or no approver is assigned, follow the steps on the ***Select Approver*** pages and select the correct approver.

- The completed disclosure is submitted to the approver for approval. In addition, once a week the system will notify the approver about outstanding disclosures that require approval. When the disclosure is submitted for approval, it is no longer editable by the discloser.

2. Disclosure Approval: when a disclosure is submitted for approval, the approver logs into the Conflict Disclosure System and approves the disclosure through the ***My Approvals*** page.

- If the disclosure does not have any public conflicts the disclosure can be approved directly from the ***My Approvals*** page by selecting the disclosure and clicking the ***Approve Selected Disclosure*** button. Note that private questions are not visible to the approver and not part of the review/approval process for approvers.

- If the disclosure has public conflicts, the approver must review the disclosure details and complete the management plan page for the disclosure. Once the management plan page is created, the disclosure can be approved. After a review of the plan has been completed by the COI Review Committee, the final step for the approver is to acknowledge that the management plan has been put in place.

- The approver also has the option to return a disclosure to the discloser. Upon returning a disclosure, the approver will be required to select a reason for return and has the option to include any additional comments as to why it is being returned. The approver should notify the discloser via email or phone that the disclosure has been returned. In addition, the system notifies the discloser that the disclosure has been returned. The return reason and comments are included in the email and the disclosure for reference.

STEP-BY-STEP GUIDE FOR DISCLOSER:

Outlined below are the steps a staff member should follow to create a disclosure in the Conflict Disclosure System and submit it for approval.

1. Log in to the Conflict Disclosure System. See the Introduction section of this document for information on how to access the log-in page.

   NOTE: If you have not previously created a disclosure, the **My Disclosures** page will be displayed without any disclosures in the list. If a disclosure has been created, it will be displayed on the **My Disclosures** page.

3. Click the **Create Disclosure** button.

   - Note that if you already have a draft or returned disclosure created, then the **Create Disclosure** button will not be displayed on the page. You must complete and submit the disclosure or delete it in order to gain access to the **Create Disclosure** button.

4. If you have previously completed a disclosure you will be prompted to copy information from the last approved disclosure into the new one.

   - Select **Yes** to copy information from the last approved disclosure to the new disclosure. Answers to the main disclosure questions and disclosure detail questions will be copied into the new disclosure. Acknowledgement, approver, and management plan information will not be copied.

   - Select **No** to create a blank disclosure into which you will be able to enter your information.

   - Select **Cancel** to stop and return to the **My Disclosure** page.

5. The new disclosure is displayed on the page.

6. If information was copied from a previous disclosure, the answers to the questions will be defaulted. Confirm that the answer to each question is correct and update answers where needed. If no previous disclosure was copied, answer each of the Yes/No disclosure questions at the top of the page. Note that private questions are not visible to approvers.

7. At the bottom of the page, review the acknowledgements and assignments. Check each one that has been completed. Click on the links provided to view the websites containing the various policies and additional information provided.

8. If **Yes** was answered on any of the main disclosure questions:

   - Click the **Click Here to Provide Details** button to provide more information about the conflict.

   - On the **Disclosure Details Summary** page, click the **Create Conflict Detail** button.

   - Complete all of the information on the **Disclosure Details** page and click the **Back to Details Summary** button to return to the **Disclosure Details Summary** page. If additional detail records need to be provided, use the **Create Conflict Detail** button to create the records. Note that any information related to private questions are not visible to the approver. Use the **Back to Disclosure** button to return to the main disclosure page and continue with the submission process.

9. On the main disclosure page, the **Comments** section can be used to provide information that is not covered in one of the questions. Click the **Add** button in the **Comment** section to add a comment.

   - Enter the comment in the popup provided and click **Add Comment**.

   - The comment will be added to the **Comments** section of the page. The comment can be changed or removed by clicking the **Edit** or **Delete** button, respectively.

10. On the main disclosure page, the **Attachments** section can be used to provide files (Word documents, Excel spreadsheets, etc.) of additional information to your approver or to COI administration. Some example attachments are: the management plan that is already in place, documents explaining what the outside business does, any relevant contracts or business agreements, documents authorizing engagement in activity, etc.

11. Click the **Add** button in the **Attachments** section to add an attachment.

    In the **Add Attachment** window, click the **Browse** button to search for the file attachment on your local computer. Select the file and click **Open**. Click **Attach File** on the **Add Attachment** screen to add the attachment to the disclosure.

    - The following file types can be added to a disclosure: PDF, Word, Excel, Text files, WordPerfect, or Rich Text files.

    - A maximum of 4 attachments can be added to a disclosure.

    - Each attachment must be less than 5 MB in size.

    - The attachment will be added to the **Attachment** section of the disclosure. The attachment can be removed by clicking the **Delete** button. The attachment can be viewed by clicking on the filename or on the icon to the left of the filename.

12. Once the questions on the main disclosure page are completed and conflict details provided (if required), then an approver must be selected. Click the **Continue** button at the bottom of the main disclosure page to continue to the **Select Approver** pages.

13. The **Select Approver** pages are used to search for and select your approver from a list of active staff members. Some COI approvers are defaulted based on the discloser's department. If your approver has been assigned based on your department, the approver will be listed on the first **Select Approver** page. If the approver is correct, click **Continue**, otherwise click the **here** link to go to the search for approver pages. If the approver is not defaulted based on your department, continue to the next step.

14. Review the instructions on the first Select Approver page and click **Continue**.

15. Enter the last name of the approver in the **Last Name** field and click the **Search** button to search for the person.

- If you are not sure how to spell your approver's name, you can enter part of the approver's last name.

- The % symbol can be used as a wildcard.

- If too many search results are returned, enter the first initial of the person's first name and click **Search.** For example, entering a last name of 'jone' and a first name of 'ja' would return a list of all people with a last name starting with 'jone' and a first name starting with 'ja'.
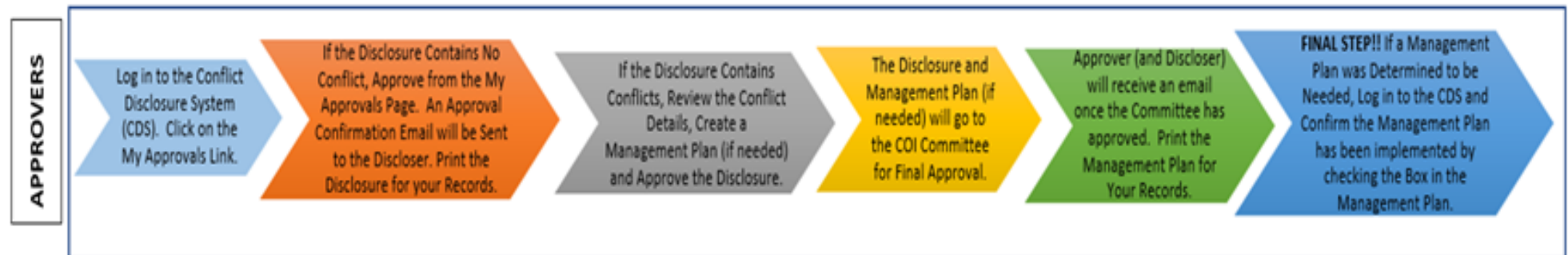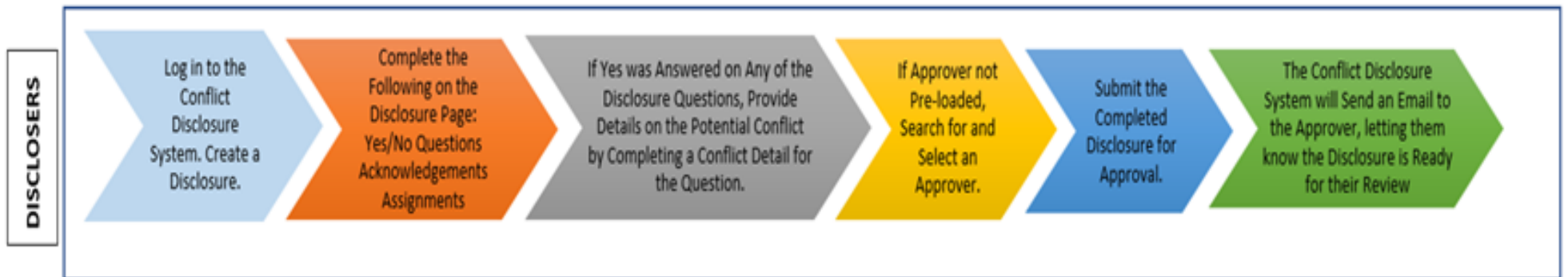
16. A list of active staff that meets the search criteria will be listed. Click the **Select** button next to your approver's name.

17. The selected approver's name will be populated on the next page. If the approver is correct, click **Continue**, otherwise click the **here** link to go back to the search for approver pages.

18. The **Submit Disclosure** page is displayed when you click **Continue** from the **Select Approver** pages. All information must be completed before the disclosure can be submitted for approval. Any missing information will be listed on the **Submit Disclosure** page along with a **Go to Page** button that can be clicked to go directly to the page where the required information is missing. The information that is missing on the page will have an exclamation mark (!) next to it. Complete any missing information and navigate back to the **Submit Disclosure** page using the **Submit Disclosure** button at the bottom of the page.

19. When all information is completed, click the **Submit** button on the **Submit Disclosure** page to make the disclosure available for approval by the approver. The approver should be notified in person or via phone or email that the disclosure is ready for approval. In addition, once a week the system will notify the approver about outstanding disclosures that require approval. When the disclosure is submitted, it is no longer editable by the discloser.

CONFLICT DISCLOSURE PROCESS

DISCLOSERS

Log in to the Conflict Disclosure System. Create a Disclosure.	Complete the Following on the Disclosure Page: Yes/No Questions Acknowledgements Assignments	If Yes was Answered on Any of the Disclosure Questions, Provide Details on the Potential Conflict by Completing a Conflict Detail for the Question.	If Approver not Pre-loaded, Search for and Select an Approver.	Submit the Completed Disclosure for Approval.	The Conflict Disclosure System will Send an Email to the Approver, letting them know the Disclosure is Ready for their Review

APPROVERS

Log in to the Conflict Disclosure System (CDS). Click on the My Approvals Link.	If the Disclosure Contains No Conflict, Approve from the My Approvals Page. An Approval Confirmation Email will be Sent to the Discloser. Print the Disclosure for your Records.	If the Disclosure Contains Conflicts, Review the Conflict Details, Create a Management Plan (if needed) and Approve the Disclosure.	The Disclosure and Management Plan (if needed) will go to the COI Committee for Final Approval.	Approver (and Discloser) will receive an email once the Committee has approved. Print the Management Plan for Your Records.	**FINAL STEP!!** If a Management Plan was Determined to be Needed, Log in to the CDS and Confirm the Management Plan has been implemented by checking the Box in the Management Plan.

STEP-BY-STEP GUIDE FOR APPROVER:

Review & Approve the Disclosure

Outlined below are the steps an approver follows to review and approve a disclosure that has been submitted for approval in the Conflict Disclosure System.

1. Log in to the Conflict Disclosure System. See the Introduction section of this document for information on how to access the log-in page.

2. Click on the *My Approvals* link to access a list of disclosures that have been assigned to you as an approver.

3. The *My Approvals* page lists all disclosures that have been assigned to you for approval. The list can be filtered by *Status* and/or by *Submitted Date.* Click the *Submitted* option next to *Filter by Status* to display disclosures that are ready for approval.

   Outlined below are all *Filter by Status* options along with their definitions:

   - *All* – lists all disclosures assigned to the approver regardless of status.

   - *Submitted* – lists all disclosures that are ready to be approved by you, the approver.

   - *Returned* – lists all disclosures that you, the approver, have returned to the discloser for more information. These disclosures cannot be approved until the discloser resubmits them for approval.

   - *Submitted or Returned* – lists all disclosures that are assigned to you and are in a submitted or returned status.

   - *Approved* - lists all disclosures that have been approved by you, the approver.

   - *Mgt Plans Awaiting Confirmation* – lists disclosures that the COI committee has reviewed and determined that a management plan is needed, and are waiting for the approver to agree to and acknowledge that the management plan has been implemented.

   Use the *Filter by Submitted Date* option to further narrow the *My Approvals* list. Enter a *From* and *End Date* and click the *Filter* button to search for disclosures with a submitted date between the From and End dates entered.

4. The process to approve a disclosure differs depending on whether the disclosure has a potential conflict or not. The *Has Conflicts* column of the *My Approvals* page provides information on whether a disclosure has a potential conflict or not. If the *Has Conflicts* column contains a *No* for the disclosure go to step #5 below for information on how to approve the disclosure from the *My Approvals* page. If the *Has Conflicts* column contains a *Yes* for the disclosure go to step #6 below for information on how to approve the disclosure from the *Management Plan* page.

5. TO APPROVE A DISCLOSURE WITH NO CONFLICTS:

A disclosure that does not have any potential conflicts can be approved directly from the *My Approvals* page. Each disclosure without potential conflicts has a *No* in the *Has Conflicts* column and also has a checkbox next to the name of the discloser. Click the checkbox next to the discloser name and click the *Approve Selected Disclosure* button at the bottom of the page.

- When prompted click *OK* to approve the disclosure. Alternately, click *Cancel* to stop the process.

- The *My Approvals* page is displayed. Click on the *All* filter to confirm that the selected disclosure's status was changed to *Approved*. A message indicating that the disclosure has been approved will be displayed. At this point, the disclosure is approved and the process is completed.

- **NOTE**: You can approve multiple submitted disclosures without potential conflicts at one time by clicking the checkbox next to each name and clicking the *Approve Selected Disclosure* button. You can also automatically select all submitted disclosures without potential conflicts on the page by clicking the checkbox next to the *Name* column heading on the page.

6. TO APPROVE A DISCLOSURE WITH A POTENTIAL CONFLICT(S) & CREATE A MANAGEMENT PLAN, IF NECESSARY:

If a disclosure has potential conflicts, the approver must review the disclosure details, fill out the management plan page for the potential conflict(s), and approve the disclosure from the *Management Plan* page. The disclosure cannot be approved from the *My Approvals* page. Click on the name of the staff member to open the disclosure.

- On the main disclosure page, review the questions with a *Yes* answer.

- The *Comments* section can be used to provide information about the potential conflict that is not covered in one of the questions. Review any comments that have been added by the discloser. The approver can also add comments by clicking the *Add* button in the *Comment* section. The ability to edit or delete a comment you have added is also provided.

- The *Attachments* section can be used to provide files (Word documents, Excel spreadsheets, etc.) of additional information about the potential conflict. Some examples of attachments are: the management plan that is already in place, documents explaining what the outside business does, any relevant contracts or business agreements, documents authorizing engagement in activity, etc. Review any attachments that have been added by the discloser. The approver can also add attachments by clicking the *Add* button in the *Attachments* section. The ability to delete an attachment you have added is also provided.

- Click the *Continue* button at the bottom of the main disclosure page to open the *Disclosure Details Summary*. Alternately, click the *Click Here to View Details* button under a question with a *Yes* answer to access the summary page.

- On the *Disclosure Details Summary* page, click the *Open* button next to the disclosure details record and review the details provided by the discloser about the potential conflict. Click the *Back to Details Summary* page button at the bottom of the *Disclosure Details* to return to the *Disclosure Details Summary* page. Complete these steps for each disclosure detail record that was provided.

Create a Management Plan

- After all detail information provided by the discloser has been reviewed, click the **Continue to Management Plan** button at the bottom of the **Disclosure Details Summary** page.

- On the **Management Plan** page, complete the **Follow Up Process** field and select whether a management action plan is needed in the **Management Action Plan Needed** field.

- If **Yes** is answered on the **Management Plan Needed** question, select the management plans and actions to be followed under "**What actions should be taken to manage this potential conflict?**" Click the checkbox next to the plan you want to select. You will be presented with the **Select Actions** popup where you can select the actions that will be followed to manage the conflict. Select all applicable actions and click **Done** on the **Select Actions** popup. Select additional plans and actions if needed. Note that you can change the actions that were selected by clicking the **Select Actions** button next to the selected plan. You can deselect a plan by un-checking the checkbox next to the plan.

- If none of the standard plans apply or if you believe the conflict may not be manageable, then enter the management plan information in the **Other** field at the bottom of the management plan page. You can also use this field to include additional information about the plan.

- After all information is completed on the **Management Plan** page, click the **Continue** button at the bottom of the page to continue to the **Approve Disclosure** page.

- All management plan information must be completed before the disclosure can be approved. Any missing information will be listed on the **Approve Disclosure** page, along with a **Go to Page** button that can be clicked to go directly to the **Management Plan** page where the required information is missing. The information that is missing on the page will have an exclamation mark (!) next to it. Complete any missing information and navigate back to the **Approve Disclosure** page.

- When all information is completed, click the **Approve** button on the **Approve Disclosure** page to approve the disclosure and complete the process. When the disclosure is approved, the approver no longer has the ability to edit the disclosure. An email is sent to the discloser notifying him/her that the disclosure has been approved.

COI Committee Review

After the approver has created a management plan or determined that a management plan is not necessary, the COI Committee will review the disclosure and any action taken by the approver. After the COI Committee completes the review, an email will be sent out to both the discloser and the approver requiring each of them to review the management plan. **Please note that the COI Committee may determine that a management plan is necessary even when the approver does not, or the COI Committee may determine that additional information needs to be added to the management plan.** After review of the management plan, the approver should discuss the management plan with the discloser to ensure understanding of all requirements of the management plan. After this discussion, the approver should go into the Conflict Disclosure System and acknowledge that the management plan is in place.

Acknowledging a Management Plan (once the notification is received)

1. Log in to the Conflict Disclosure System. See the Introduction section of this document for information on how to access the log-in page.

2. Click on the **My Approvals** link to access a list of your disclosures.

3. Select the **Mgt Plans Awaiting Confirmation** filter to list disclosures that are awaiting management plan acknowledgement. Click on the **View** button in the **Mgt Plan** column to go directly to the Management Plan for the disclosure.

4. Review information in the **COI Review Committee Action** box and the associated management plan. Click the acknowledgement checkbox at the bottom of the page under the **COI Review Committee Action** box to acknowledge the plan.

Returning Disclosures

The Conflict Disclosure System provides approvers the option to return a disclosure to a staff member if, for example, additional information needs to be provided, a potential conflict that has been referenced is not a conflict, or if the incorrect approver was selected. Follow the steps below to return a disclosure.

1. The process to return a disclosure differs depending on whether the disclosure has a potential conflict or not. The **Has Conflicts** column of the **My Approvals** page provides information on whether a disclosure has a potential conflict or not. If the **Has Conflicts** column contains a **No** for the disclosure go to step #2 below for information on how to return the disclosure from the **My Approvals** page. If the **Has Conflicts** column contains a **Yes** for the disclosure go to step #3 below for information on how to return the disclosure from the **Management Plan** page.

2. A disclosure that does not have any potential conflicts can be returned directly from the **My Approvals** page. Click the checkbox next to the discloser name and click the **Return Selected Disclosure** button at the bottom of the page. When prompted, select a reason for the disclosure being returned and enter any additional comments in the **Additional Comments** field that is provided. Click the **Return Disclosure** button in the popup to return the disclosure. Alternately, click **Cancel** to stop the process.

3. A disclosure that does have potential conflicts can be returned from the **Management Plan** page. Click on the name of the staff member to open the disclosure. Click the **View Management Plan** button at the bottom of the main disclosure page to open the **Management Plan** page. Click the **Return Disclosure** button at the top of the **Management Plan** page. When prompted, select a reason for the disclosure being returned and enter any additional comments in the **Additional Comments** field that is provided. Click the **Return Disclosure** button in the popup to return the disclosure. Alternately, click **Cancel** to stop the process.

4. Once the **Return Disclosure** button is clicked, the **My Approvals** page is displayed. The selected disclosure's status will be changed to **Returned**. At this point, an email is sent to the discloser notifying him/her of the return along with the return reason and comments. The disclosure is returned and the discloser can edit the disclosure as needed.
   - Note that if the reason for return is incorrect approver selected, the current approver will be cleared out and the disclosure will no longer Appear on the current approver's My Approvals page.

5. The discloser updates the disclosure as needed and submits the disclosure for approval again.

INFORMATION FOR ALL USERS:

Printing a Disclosure

The Conflict Disclosure System provides options to print a disclosure page or the entire disclosure.

1. A **Print Page** button is in the upper right corner of each disclosure page and can be used to print the current disclosure page.

2. A **Print Disclosure** button is in the upper right corner of each disclosure page and can be used to print the entire disclosure. The **Print** button on the **My Disclosures** and **My Approvals** pages can also be used to print the entire disclosure.

Sorting My Disclosures and My Approvals Listings

The **My Disclosures** and **My Approvals** pages provide users the option to sort the lists by any of the column headers. Click on the column header label to sort the list in ascending order by the column contents. Click the column header label again to sort the contents in descending order.

Viewing Previous Disclosures

The Conflict Disclosure System provides disclosers and approvers the ability to view disclosures that have been previously submitted or approved.

1. A discloser can view a previously submitted disclosure by clicking the **Open** button next to the disclosure from the **My Disclosures** page. A management plan can be viewed by clicking the **View** button next to the disclosure. The **View** button will only be displayed if the disclosure has a management plan.

2. An approver can view approved or returned disclosures by clicking on the name of the staff member from the **My Approvals** page.

Frequently Asked Questions

A list of frequently asked questions is available _here_. A link is also available on the left side of the navigation pane at the Conflict Disclosure System website.

DEPARTMENT REVIEWERS – DISCLOSURE STATUS REPORT (also available to Disclosure Approvers)

Users who have been assigned as department <u>approvers or reviewers</u> in the Conflict Disclosure System have a **Disclosure Status Report** that can be used to view the disclosure status of their assigned department's staff for a given fiscal year. The disclosure status report lists all active people in the selected department(s) who are required to complete a disclosure in the Conflict Disclosure System. For each person listed, if an approved disclosure is found for the selected fiscal year, information about that disclosure is displayed. The report is intended to help approvers and reviewers identify people who still need to complete a disclosure for a given fiscal year.

If you have been set up as a department approver or reviewer in the Conflict Disclosure System, follow the steps below to run the **Disclosure Status Report**.

1. Log in to the Conflict Disclosure System and click on the **Disclosure Status Report** link on the left side of the navigation pane.

2. The **Disclosure Status Report** page will appear and all departments for which you are assigned as an approver or reviewer will be listed on the page.

3. Select the department(s) for which you want to run the report. Select the checkbox next to the departments you want to report on. Alternately, you can use the **Select All Departments** checkbox at the top of the page to select all departments.

4. Select the **Fiscal Year** to report on from the **Fiscal Year** dropdown.

5. Select where to send the report output. You can view the report in Excel by selecting **View Report in Excel.** Alternately, the output can be displayed in a browser window by selecting **View Report on Page.**

6. Complete the selections and click the **View Report** button.

7. If **View Report on Page** was selected, the report will be displayed in a new browser window. From here you can print the report by clicking the **Print Report** link. The report can be exported to Excel by clicking the **Export Report to Excel** link. Note that you can also sort the results by clicking on the column header link for the column that you want to sort by.

8. If **View Report in Excel** was selected, the report will be downloaded as an Excel file.

DEPARTMENT REVIEWERS – DISCLOSURE REVIEW ACCESS

Users who have been set up as reviewers may be provided access to view details of disclosures for his/her department. Outlined below are the steps a reviewer follows to view the details of disclosures for his/her department(s).

1. Log in to the Conflict Disclosure System. See the Introduction section of this document for information on how to access the log-in page.

2. Click on the *Review Disclosures* link to access a list of disclosures for departments in which you are assigned as a reviewer.

3. The *Review Disclosures* page lists all disclosures for departments in which you are a reviewer. The list can be filtered by *Status* and/or by *Submitted Date.*

   Outlined below are all *Filter by Status* options along with their definitions:

   - *All* – lists all disclosures regardless of status.

   - *Submitted* – lists all disclosures that are ready to be approved.

   - *Returned* – lists all disclosures that have been returned to the discloser for more information.

   - *Submitted or Returned* – lists all disclosures that are in a submitted or returned status.

   - *Approved* – lists all disclosures that have been approved.

   - *Mgt Plans Awaiting Confirmation* – lists disclosures that the COI committee has reviewed and determined that a management plan is needed These disclosures are ready for the approver to agree to the management plan and to acknowledge that the management plan has been implemented.

   Use the *Filter by Submitted Date* option to further narrow the *Review Disclosures* list. Enter a *From* and *End Date* and click the *Filter* button to search for disclosures with a submitted date between the From and End dates entered.

   Click on the Name of the staff member to view the disclosure details. You can also print the disclosure if needed.