



How to Respond to Clarifications Requested in eDMS

Once you have submitted your Disclosure Profile and/or Research Trigger Form in eDMS, you may be asked to provide clarifications or make changes to your submitted forms. If a clarification is requested, you will receive an email notification. The email notification will contain a link to directly access your Disclosure Profile, comments/clarifications requested from the COI team, and instructions on how to respond to clarifications.

Sample Email Notification:

Subject: A clarification of your COI Disclosure Profile has been requested

To:	Faculty Member
Link:	Disclosure Profile for Faculty Member (DP0000036)
Requestor:	COI Team Member

A reviewer from Corporate Compliance or the Office of Industry Engagement and Conflicts of Interest (“COI Office”) has requested clarifications regarding your COI Disclosure Profile. Follow the link included in this email to log in and make updates as needed and submit a response to the requestor.

Comments:

Please clarify the following:

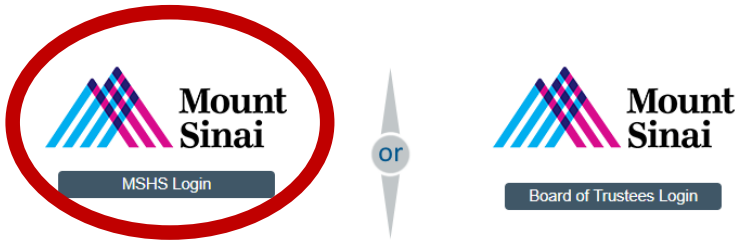
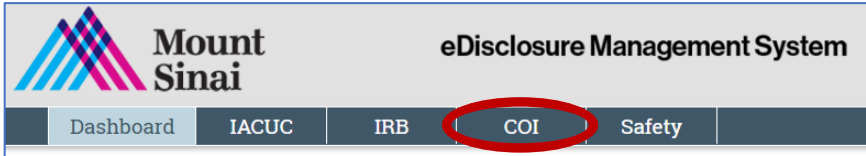

1. *[comments from the COI requestor will be displayed here]*
2. *[comments from the COI requestor will be displayed here]*
3. *[comments from the COI requestor will be displayed here]*

If you have any questions or concerns, please contact the COI Requestor directly or the COI Office at Conflicts.of.Interest@mssm.edu

Supporting Documents:

(any supporting documents, including any instruction documents)

Step-by-Step Instructions:

<p>1. Click on the link in the email to directly go to your eDMS Disclosure Profile OR log into eDMS using your Mount Sinai username and password (https://eDMS.mssm.edu)</p>	
<p>2. Click on the COI tab at top of the page to go to your eDMS Disclosure Profile.</p>	
<p>3. Notice the status of your Disclosure Profile is in an “Action Required” state.</p> <p>Click on “Edit Disclosure Profile” under the Instruction Center to update/complete your eDMS Disclosure Profile.</p>	
<p>4. After reviewing your disclosure and making any edits/clarifications as necessary, check the box in the middle of the Attestation Page.</p>	<p>I attest that this disclosure is an accurate and complete representation of all the outside relationships and related compensation that I and/or my related party (spouse/domestic partner and/or dependent children) have with outside entities. <input checked="" type="checkbox"/></p>
<p>5. To submit your completed eDMS Disclosure Profile, click on Complete Disclosure Profile Update.</p> <p>Clicking on “Finish” will not submit your disclosure profile. “Finish” will only save your changes and exit out of your disclosure profile.</p> <p>Do not click on “Submit Response” if you still need to update/complete your Research Trigger Form (your research project-specific form). If you do not have any Research Trigger Forms to update, skip to Step #8.</p>	<p>Complete Disclosure Profile</p> <p>Click the Complete Disclosure Profile Update button to satisfy the following:</p> <p>Discloser manually updated the disclosure profile</p> <p><input checked="" type="checkbox"/> Complete Disclosure Profile Update</p> <p>Submit Response</p> <p>Exit Save Finish</p>




6. If you are listed on any active research projects, you will be prompted to “update” your open “Research Triggers” at this time.

Click on “**Update**” next to each Research Project to answer questions about relatedness to your disclosed outside financial interests

Complete Disclosure Profile Update

By completing your disclosure profile update you are verifying that all disclosure information is accurate and current to the best of your knowledge.

1. **Open Research Triggers:** When you are listed as an investigator/co-investigator on a submitted research project, it will display below as an “open research trigger”. As part of the review process, you will need to update each “open research trigger” listed in the table below by clicking “Update”. This will bring you to a series of project-specific questions related to disclosed outside financial interests; your answers to these questions are mandatory and will help determine whether there may be a potential financial conflict of interest related to the research project. ?

	Research Project	Event Type	Sponsor	Related Context
	Test Project 3/10/2023	New or Transfer	Icahn School of Medicine at Mount Sinai	
	Test Project 3/12/23	New or Transfer	Abbott	
	Test Project 3/14/23	New or Transfer	Pfizer Inc	

* By checking this box, I certify that all open research trigger information has been updated and provided. All open research triggers must be completed before clicking OK.




OK Cancel

7. Once you are done completing/updating all the Research Trigger Forms for each open research project, **check the box** to confirm that you have updated all your open research trigger information appropriately and click “**OK**” – you will not be able to click “OK” without checking the box

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OK Cancel

8. Click on “**Submit Response**” to submit your response to clarifications requested.

Complete Disclosure Profile

A reviewer has requested clarifications concerning your disclosures. Click the Submit Response button to respond.


Submit Response

9. Click on “**Update**” to indicate your response.

Submit Response

Clarifications have been requested regarding the disclosures on your profile. You can provide a response for each available clarification below.

1. **Pending clarification requests:**

	Request Date	Requestor	Request Source	Response Entered	Supporting Documents
	4/12/2023	COI Team	Research	No	Documents

OK Cancel

<p>10. Answer Questions 6 and 7 (if applicable) in the COI Clarification slide-out window, and click “OK”</p>	<p>6. * Response text:</p> <div style="border: 1px solid #ccc; height: 80px; width: 100%;"></div> <p>7. Response documents:</p> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> + Add </div> <p style="font-size: small; color: #666;">There are no items to display</p> <p style="font-size: small; color: #666;">* Required</p> <div style="text-align: right; margin-top: 10px;"> OK Cancel </div>												
<p>11. Click "OK" and you're done 😊</p>	<p style="background-color: #2c4e64; color: white; padding: 2px;">Submit Response</p> <p style="font-size: small; color: #666;">Clarifications have been requested regarding the disclosures on your profile. You can provide a response for each available clarification below.</p> <p>1. Pending clarification requests:</p> <table border="1" style="width: 100%; border-collapse: collapse; font-size: small;"> <thead> <tr style="background-color: #f2f2f2;"> <th style="width: 10%;"></th> <th style="width: 15%;">Request Date</th> <th style="width: 15%;">Requestor</th> <th style="width: 15%;">Request Source</th> <th style="width: 15%;">Response Entered</th> <th style="width: 20%;">Supporting Documents</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"> Update </td> <td style="text-align: center;">4/12/2023</td> <td style="text-align: center;">COI Team</td> <td style="text-align: center;">Research</td> <td style="text-align: center;">Yes</td> <td style="text-align: center;">Documents</td> </tr> </tbody> </table> <div style="text-align: right; margin-top: 10px;"> OK Cancel </div>		Request Date	Requestor	Request Source	Response Entered	Supporting Documents	Update	4/12/2023	COI Team	Research	Yes	Documents
	Request Date	Requestor	Request Source	Response Entered	Supporting Documents								
Update	4/12/2023	COI Team	Research	Yes	Documents								
<p>12. Your Disclosure Profile should now be in a state of No Action Required</p>	<div style="background-color: #e69d00; color: white; padding: 10px; border-radius: 5px; font-weight: bold; font-size: 1.2em;"> No Action Required </div>												
<p style="color: #2c4e64; text-decoration: underline;"> Click here for more information and step-by-step instructions on How to Complete/Update a Research Trigger Form </p>													

For more details on managing research conflicts of interest, please visit our [COI FAQ page](#).
 For questions please email the [Office of Industry Engagement & Conflicts of Interest](#) at Conflicts.of.Interest@mssm.edu
 For technical help with login issues, usernames, and passwords, please open a Service Now ticket with Research IT via <https://mountsinaihealth.service-now.com/rait>.