

## How to Complete a Research Trigger Form in eDMS

In order to initiate a research project, a Triggering Event (TE) must be completed in eDisclosure Management System (<u>eDMS</u>). Every person listed on the TE will be prompted to review their Disclosure Profile and complete a Research Trigger Form in eDMS through a notification email. <u>Click here for instructions on how to create a</u> <u>Triggering Event (TE) in eDMS</u>.

The Research Trigger Form is used to determine whether any financial interests pose actual or perceived conflicts with a proposed research project. This form is required for every grant and research project/study. The form also requires disclosure of related institutional financial interests. Information on the eDMS Disclosure Profile is imported into this form. <u>Click here for instructions on how to complete/update your eDMS Disclosure Profile.</u>

For more details on research project specific disclosures, please visit our <u>COI FAQ page</u>.



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4.	Please review your Disclosure Profile carefully and make any updates as necessary.	Please note: this is not the Research Trigger Form. You are asked to review your Disclosure Profile and make any changes/updates as necessary. If you already have entities disclosed, please do not select "no" in Question 1, as this will delete all your previously entered information. Please only select "no" if you have nothing to disclose. You will be asked to confirm that you have no financial relationships or outside activities to disclose in the subsequent question before proceeding. Please review the rest of your Disclosure Profile by clicking "Continue" until you reach the Attestation Page.
5.	You will need to <b>check the box</b> on the Attestation Page in order to submit your Disclosure Profile.	Attestation upon Completion of COI Disclosure Profile         If you have an open research trigger, it will display on the following view in the 'Complete Disclosure Profile Update' activity. If applicable, please open your research project(s) in the "open research triggers" table by cilcking "Update".         * By checking the box below, as a staff/aculty member of the lcahn School of Medicine at Mount Sinai and the Mount Sinai Health System,         • I understand that my duties to Mount Sinai cannot be compromised by my (or my related party's) financial interests with, or role at, any outside entity.         • I certify that I have read and understand the relevant institutional policies in the 'aculty Handbook and/or MSHS Code of Conduct including but not limited to, provisions relating to the Use of the Mount Sinai Mane, Business Conflicts of Interest, Financial Conflicts of Interest in Research Policy, Althorship Policy, Intellectual Property, Mount Sinai Mane, Business Conflicts of Interest, Financial Conflicts of Interest in Research Policy, Althorship Policy, Intellectual Property, Mount Sinai Mane, Business Conflicts of Interest, Research Policy, Althorship Policy, Faculty Interaction with Vendors, and Staff Interactions with Vendors and Other Commercial Entities.         • I understand that I am responsible for updating my COI Disclosure Profile throughout the year (within 30 days) if I acquire a new outside financial interest/Justi acativity or if an existing financial relationship changes.         I attest that this disclosure is an accurate and complete representation of all the future relationships and related compensation that I and/or my related party (spouse/domestic partner and/or dependent children) have with outside entitie.
6.	To submit your completed/updated eDMS Disclosure Profile, click on <b>Complete Disclosure Profile Update</b> . Clicking on "Finish" will <u>not</u> submit your disclosure profile. "Finish" will only save your changes and exit out of your disclosure profile. To submit and be taken to your Research Trigger Form, please click on Complete Disclosure Profile Update.	Cick the Complete         Disclosure Profile Update         button to satisfy the following:         Discloser was added to a         research project         Complete Disclosure Profile Update         Discloser manually updated         the disclosure profile

<ol> <li>Click on "Update" next to <u>each</u> Research Project to answer questions about relatedness to your disclosed outside financial interests</li> </ol>	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 is display below as an "open research trigger". As part of the review process, you will need to update <u>each</u> "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 interse related to the research project. Transfer Transfer Transfer About         Image: Test Project 3/12/23 New or Transfer Prizer 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.
<ul> <li>8. Please read the Introduction and complete the Research Trigger Form for each of your open research projects.</li> <li>Tips for Completing the Research Trigger Form:</li> <li>✓ If you find an interest that is related to your research project and is not appearing on your Research Trigger Form, please return to your eDMS Disclosure Profile and enter this entity in the Entity Disclosure Information Table.</li> </ul>	<ul> <li>Introduction</li> <li>You will be asked to review your disclosed financial interests within the context of the current research project in order to identify any possible related financial interests. This is a requirement as per The ISMMS Financial Conflicts of Interest in Research Policy and consistent with Federal Regulations.</li> <li>Please identify any financial interests you (or a related party) have had over the last 12 months or anticipate having in the next 12 months, which may be related to this project.</li> <li>Examples of a related financial interest:         <ul> <li>a. Compensated or uncompensated work for the sponsor or another financially interested company (an entity whose financial interests could be affected by the conduct or outcome of this research project)</li> <li>b. Equity ownership interests, including stock and options, in the sponsor or another financially interested company</li> <li>Intellectual property rights (e.g., patents, copyrights, or royalties from such rights) OR named inventor on a patent with relevance to the sponsor or another financially interested company</li> <li>As a reminder, if you find an interest that is not entered in your Disclosure Profile, please return to the SmartForm, and enter this information before proceeding.</li> </ul> </li></ul>
9. Once you are done completing/updating all the Research Trigger Forms for <u>each</u> open research project, <b>check the box</b> to confirm that you have updated all your open research trigger information appropriately and click " <b>OK</b> " – you will not be able to click "OK" without checking the box	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 ach "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. Project Interest: 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. Transfer I cahn School of Medicine at Mount Sinai         Image: Update       Test Project 3/12/23       New or Transfer       Icahn School of Medicine at Mount Sinai         Image: Update       Test Project 3/12/23       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
10. Your Disclosure Profile should now be in a state of <b>No Action Required</b>	No Action Required

<ol> <li>To check on the completion status of other research personnel on your research projects OR to edit a Triggering Event (TE), click on Triggering Events under the COI tab</li> </ol>	Dashboard         IACUC         IRB         COI         Safety           Disclosures         Requests         Certifications         Plans         Triggering Events         Reports         Meetings         Help Center
12. To search for your Triggering Event, you may search for and select the appropriate TE from the lists or by using the search bar	Open Triggering Events       All Triggering Events         Filter by       ID       Enter text to search       ID       Enter text to search       ID       Add Filter X Clear All       ID         ID       Name       Date Modified       Event Type       Principal Contact       Principal Investigator       Sponsor       Associated Organizations       Estimated End Date         TE 10000536 Test Project 3/14/23       3/13/2023 3/13/2023       New or Transfer       Principal Contact       Pfizer Inc       V         TE 10000536 Test Project 3/12/23       3/13/2023 11:20 AM       New or Transfer       Abbot       V       V         TE 10000533 Test Project 3/10/2023       3/13/2023 10:33 AM       New or Transfer       Icahn School of Medicine at Mount Sinal       Icahn School       Medicine at Mount Sinal       Icahn School
13. To edit a TE, click on "Edit Triggering Event" on the left hand side of the TE Summary Page The PI and PI Designee are able to edit the Triggering Event (e.g., to add or remove research study personnel, to change or make updates to the funding source or study sponsor, etc.) at any time. Once you are done editing/updating your TE, please click on Manage Certifications. <u>Click here</u> <u>for step-by-step instructions on how</u> <u>to edit/create a Triggering Event.</u>	OpenOpenEstimated start date: Estimated end date: Created date: 3/10/2023 1:45 PM Last modified date: 3/13/2023 10:33 AMEstimated start date: Estimated end date: Created date: 3/10/2023 1:45 PM Last modified date: 3/13/2023 10:33 AMNext StepsNext StepsEdit Triggering EventCit Triggering EventActivitiesActivitiesManage CertificationsImage Certifications
<ul> <li>14. To check on the Research Trigger Form completion status of other research personnel on the TE, click on the "Read Only Certifications" tab</li> <li>The Last COI Profile Update column will indicate when the research personnel last updated their Disclosure Profile. The Review Status column will indicate whether the research personnel has completed their Research Trigger Form ("no review required") or if they still need to complete their Research Trigger Form ("awaiting profile update"). The COI Training Complete column will display the date the CITI COI Training has been completed.</li> </ul>	Open       Closed         History       Read-Only Certifications         Name       Date Modified       Discloser Pirst Name       Last COI Last Name       Coll Training Complete       Review Status       Determination         Research certification for Test Discloser 20-TE 10000533       Mon Mar 13 10:33:35 EDT       Test       Discloser 20       21:25:34 EST       Incomplete       Awaiting Profile U2023         Research certification for Test Mon Mar 13 11:28:59 EDT       11:28:57 EDT       Tu Aug 6 11:52:05 EDT       No Review Required         Research certification for Test Mon Mar 13 11:28:59 EDT       10:33:39 EDT       Test       Discloser 21 (disc21)       Tu Can 24 11:28:57 EDT       No Review Required         Research certification for Test Mon Mar 13 2023       Test       Discloser 21 (disc21)       Tu Can 24 24 2023       No Review Required         Research certification for Test Mon Mar 13 2023       Test       Discloser 21 21:25:34 EST 2023       No Review Required         Research certification for Test Mon Mar 13 2023       10:33:39 EDT       Test       Discloser 21 21:25:34 EST 2023       No Review 2023

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.