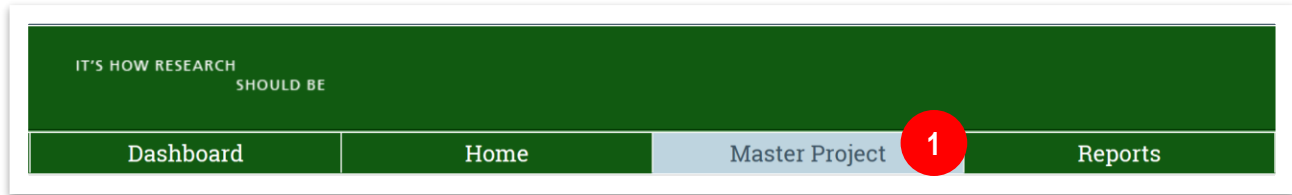


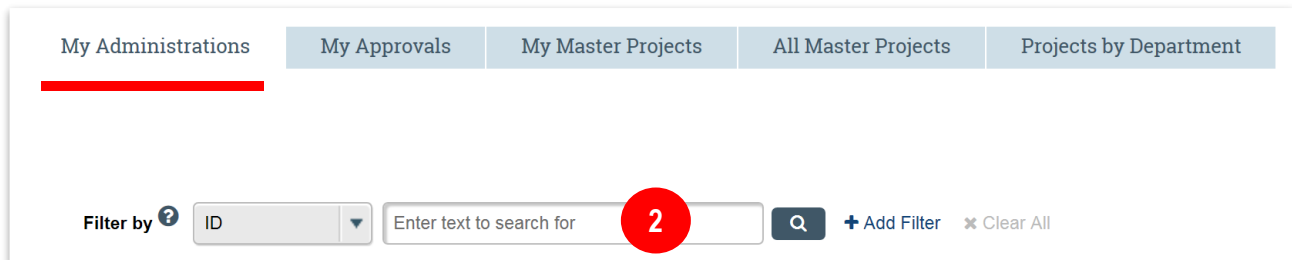
Protocol Specific COI (PSCOI) Disclosure Instructions

To create a PSCOI disclosure, login to RUSH's Research Portal and complete the following steps.

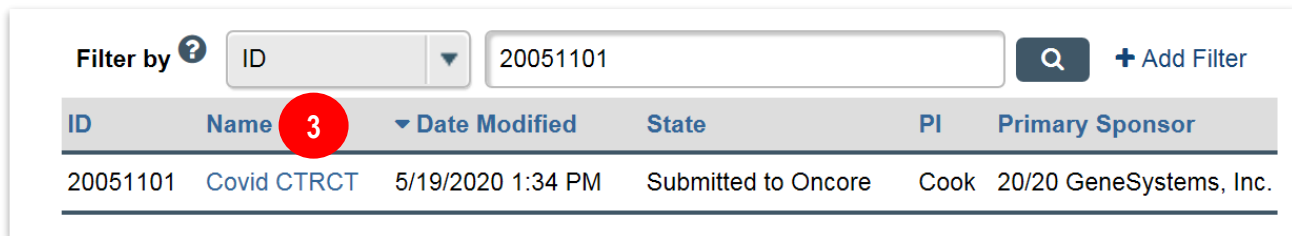
- 1) From the main portal page, click the **Master Project** tab (located at the top green menu bar).



- 2) From the My Administrations page, enter the **ORA number** in the text box shown below and press the **Enter key**. Be sure 'ID' is displayed in the **Filter by** dropdown menu.



- 3) Click the **hyperlink of the ORA study name**. This will take you to the Master Project Summary Workspace page.



- 4) From the **Master Project Summary Workspace** page, scroll down until you reach the **Create** section (located on the left column of the page), and click the **Protocol Specific COI** button.



- 5) From the COI Welcome page begin your disclosure. **Answer all four questions with a red asterisk (*)**. **Note:** A red asterisk (*) indicates a required field and must be answered before moving on to the next page. **After answering each question**, click the **Continue** button along the bottom right corner. This will take you to the COI Role in Study page.

* Is this a new disclosure? Yes No [Clear](#)

* Do you have a financial interest to disclose? Yes No [Clear](#) 5

* Will products be used in the conduct of this research project related directly or indirectly to your external professional relationships? Yes No [Clear](#)

* Is it an update to a previous disclosure submitted to this project? Yes No [Clear](#)

- 6) From the **COI Role in Study** page, **scroll down** until you reach the section **Role in Study** and **choose your role(s)** for that specific study. Example is shown below.

* **Role in Study:** **6**

Statistical Analysis

Data Analysis

Data Collection

- 7) Below the list of study roles, **answer the next required question** then click the **Continue** button along the bottom right. This will take you to the COI Disclosure – Activity page.

* Will the relationship continue into the next 12 months from the date of this disclosure? Yes No **7**

- 8) From the **COI Disclosure – Activity** page, you will have the option to **select one or more activities** to report. **Choose an activity to make a disclosure** by clicking the **+Add** button as shown below.

Sponsored Travel:

+ Add **8**

Organization	Destination	Travel Date	Purpose of Trip
--------------	-------------	-------------	-----------------

- a) A window will appear for you to add an Entity or Sponsor and the related financial or fiduciary activity. After answering all questions, click the **OK** button at the bottom of the page.
- b) If the Entity/Sponsor is not listed in the dropdown list, **Go back** to the **Master Project** main page and **scroll down** until you reached **My Activities** (located on the left column of the page) and click the **'Request New Prime or Direct Sponsor'** button. Provide the requested information and the entity will be added to the 'Sponsor' list.
- 9) After entering the activity information, you will be taken back to the **COI Disclosure – Activity** page where you will see a brief summary of your disclosure. When all activities have been reported, click the **Continue** button. This will take you to the Explanation of the Conflict of Interest page.

Sponsored Travel:

+ Add **9**

Organization	If "Other" Selected, Company Name	Travel Start Date	Destination	Estimated Reimbursed \$	Purpose of Trip
Update	AB Science	2/1/2023	Las Vegas	500	

- 10) From the **Explanation of the Conflict of Interest** page, **explain in detail a) the reason of the activity, b) how the disclosed entity(ies) relates to this research protocol**, and **c) how the financial interest is or may be related to this research protocol**. After entering your explanation in the text box, click the **Continue** button to the COI Financial Submission page.

* Please describe, in the text box below, in what way your disclosed entity relates to this research protocol.

Explanation goes here **10**


- 11) When you reached the **COI Financial Submission & Attestation Page**, review the instructions and click the **Continue** button at the bottom of the page. You will be taken back to your COI disclosure page where you can submit your disclosure.

Submission Instructions **11**

You have come to the last form page within your disclosure. If your information within your disclosure is incomplete or you wish to complete your disclosure at another time, you may continue to update the information within these forms prior to submitting your disclosure.

- 12) **IMPORTANT:** In order to submit your disclosure, you **must** click the **Submit Disclosure** button (located on the left column under **My Activities**). If you miss this step your disclosure will remain in pre-submission and incomplete. If there is no missing information found in your disclosure, you will receive the Attestation Statement.

My Activities

 **Submit Disclosure** **12**

- 13) Review the **Attestation** page and complete the following steps:

- Enter the most recent date of your completed mandatory Financial Conflict of Interest (FCOI) training.
- Review the RUSH COI policies.
- Check the white box to confirm that you have read the policies indicated and that the disclosed information is correct.
- Click **OK** at the bottom of the page. A confirmation will be sent to your email that your PSCOI disclosure was successfully submitted. **End**

Attestation **13**

Prior to receiving HHS/PHS funds, the investigator must complete mandatory financial conflict of interest training and update training as required by Rush. Indicate date of most recent training:

a

Investigator's Affirmation

- The information is true to the best of his/her knowledge.
- He/She has read the Rush's [External Relationship and Financial Conflicts of Interest in Research](#).
- If the disclosed relationship with the external entity is determined by Rush to be a significant financial interest related to the research, question with the research, then the relationship will be reviewed by the Conflict of Individual and Institutional Interest in Research (COIIR) Committee.
- If the relationship is determined to be a Financial Conflict of Interest (FCOI) by the Committee, the investigator must have an approved Management Plan (MP) prior to expenditure of funds and/or IRB approval as it relates to the research project. Management Plans will be issued by the Office of Research Compliance on behalf of the Committee.
- Investigators must acknowledge receipt and adherence to issued MP's.

If research is funded by HHS or PHS:

- If the financial or fiduciary relationship changes during the funding period, the investigator agrees to update this form within 30 days of acquiring or discovering a **new** or a **change** in the Investigator's financial or fiduciary relationship.
- The investigator must disclose sponsored or reimbursed travel (42 CFR 50 605) that meets the \$5000 de minimus within 30 days if not previously reported on this form. The investigator agrees to update this form within 30 days of the travel.
- At the time of the annual continuing review (competitive and non-competitive), the investigator will resubmit this form to the Office of Research Compliance. An additional review by the COIIR may be required if the situation has changed and the management merits revision.
- Please refer to the Rush COI policies below:**

Rush COI Policy and Vendor Guidelines (OP-0359) **b**

Rush External Relationships and Financial Conflicts of Interest in Research (CC-RC-0008)

* I, **c**, certify that I have read the RUSH policy regarding Financial Interests Associated with Individual Research Protocols. I hereby attest that with respect to this research project application that the disclosed information is accurate and complete.

d

NOTE: On the attestation page for **federally funded researchers**, you are required to provide the date of your last FCOI training.