

RESEARCH COMPLIANCE



Research Compliance Awareness: Protocol Specific Conflict of Interest

Need to know: Conflicts of Interest in Research Thresholds	
<i>Financial Interest (in the Previous 12 Months)</i>	<i>What's Required: Human Subjects Research</i>
Anything above 0 dollars to \$5,000 in cash compensation	<ul style="list-style-type: none"> Disclosure
<ul style="list-style-type: none"> >\$5,000 in cash compensation Any ownership interest; equity, stocks (options); A fiduciary role; or Any royalties, license agreement, rights to royalties, "future distribution of compensation" 	<ul style="list-style-type: none"> Disclosure; and A COIIR Review & possible issued Management Plan
	<p><i>Non-Human Subjects Research</i></p> <ul style="list-style-type: none"> Same as above

As of April 24, 2017, the process to submit a **Protocol Specific Conflict of Interest (PSCOI)** has been revised.

There are **two ways** to disclose your outside relationships:

- Rush Annual Conflict of Interest (COI) Survey
This process has NOT changed.
- PSCOI Disclosure
Disclosures are **NOW** created in the Master Project (COI Module) on the main page of the Rush Research Portal.

All Key Personnel listed in the Master Project are required to make a disclosure of Financial Interest whether or not they exist (signed attestation).

Definition of Key Personnel: Any individual who is listed as Key Personnel on a NIH funded study; or studies not NIH funded (e.g. FDA regulated research), Key Personnel are those who contribute to the project in a substantive measurable way, involved in the design, conduct or reporting of the research.

Create

-
-
-
-

If you have questions or need any assistance, please contact the ORA at 312-942-5498

To create a disclosure 'click' on the 'Conflict of Interest' activity button found in the left hand toolbar on the main page of the Master Project. This will bring you to the smartforms to complete your PSCOI disclosure.

My Activities	
	Administration
	Log Public Comment
	Log Private Comments
	Make CA State to null
	Make IRB state Null
	Validate subprojects
	Merge Projects
	Request New Prime or Direct Sponsor
	Issue Required Consent Language
	CA Issued

Troubleshooting: Where's the Sponsor?

When completing a PSCOI, you may not see the Entity or Sponsor listed in the dropdown list. Go back to the Master Project main page and 'click' on the activity button found in the left hand toolbar titled, '**Request New Prime or Direct Sponsor**'. Provide the requested information and the entity will be added to the 'Sponsor' list.

My disclosure is complete- What now?

If there is a disclosure of financial interest made, there is a Disclosure Process to be completed.

Reviews are conducted by Research Compliance & Conflict of Individual/Institutional Interest in Research Committee (COIIR).

Key Elements during Review/Next Steps:

- What is the value of the financial interest?
- What is the scope of the relationship?
- What is the extent of discretion?
- Additional information may be requested by ORC/COIIR
- Proposed management plan to Rush IRB
- IRB reviews plan: approves/rejects management plan
- PI accepts management plan

The MGMT Plan is issued through the Rush Research Portal. Portal notifications are issued via email to all listed study staff.

- *Investigator complies or appeals determination*

The **final steps** when a Management Plan (MGMT Plan) has been issued:

- The researcher receiving the MGMT Plan must **accept or reject** the MGMT Plan within the Rush Research Portal. There is an activity button within the COI disclosure to complete this step.
- If a researcher **rejects** the MGMT Plan, you are asked to complete the smartforms, listing the management plan tool you disagree with, provide a compelling reason for the appeal and describe how you are going to maintain objectivity.

Any questions concerning this process, please contact Mary G. Keller at 312-942-4485 or Mary_G_Keller@rush.edu