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.

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.
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 (COIIIR).

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/COIIIR
- 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