

INVESTIGATOR eCOI DISCLOSURE PROCESS IN INSIGHT/eIRB FREQUENTLY ASKED QUESTIONS

Investigator eCOI Disclosure Process

Investigator Financial Disclosure forms are completed electronically in Insight/eIRB when the study staff sign-off on a protocol that involves an intervention/interaction with research participants. The eCOI form is accessed by clicking on the eCOI disclosure link that appears on the study staff sign off page.

Who must complete the Investigator eCOI Disclosure Form?

The principal investigators (PI), site responsible Investigators (SRI), co-investigators (Co-I) and any other member of the study staff **responsible for the design, conduct, or reporting of the research** (DCR) must complete the eCOI disclosure form.

Of the other members of the study staff, who would be considered responsible for the design, conduct, or reporting of the research?

An individual would be considered a DCR if they conduct activities including, but not limited to, the following:

- Designing or directing research
- Serving as the principal investigator, co-investigator, or sub-investigator
- Enrolling research subjects (including obtaining human subjects' informed consent, if applicable)
- Making decisions related to eligibility to research subjects' enrollment in research
- Analyzing or reporting research data
- Submitting manuscripts concerning the research for publication as a primary author or co-author

How does the system know who is responsible for the design, conduct, or reporting of the research?

A column labeled DCR has been added to the Study Staff grid. DCRs will be indicated by a YES or NO in the column. Principal investigators, site responsible investigators and co-investigators will default to YES. For all others, the submitter must select YES or NO in the DCR column when completing the information required for each member of the study staff – e.g., role on study, permissions (view, edit, manage), contact person.

How do I complete the investigator eCOI disclosure form?

During the sign off step in Insight/eIRB, the study staff person clicks on the eCOI Disclosure link and completes questions related to any companies in which they have reported a Financial Interest in the Partners Disclosure System (Insight COI module) and questions related to any Financial Interest they have, or, to their knowledge, a Family Member has, in any company **related to the study**.

When is a company considered related to the study?

A company is considered related to the study if it:

- Is a sponsor of the study.
- Owns, manufactures or develops any drug, device, or technology that is used in a significant way in the study.
- Is developing products or technology similar to any drug, device, or technology that is being investigated by the study.
- Own, manufactures or develops any drug, device, or technology, the value of which could be influenced by the results of the study.
- Could reasonably be interested in any Intellectual Property (IP) resulting from the study.

Note: Technology used in a significant way includes, for example, imaging equipment that while not the focus of the study, is an important part of the study design and will need to be described and identified in the methods section of a publication. This includes licensed intellectual property such as patents, patent applications, and copyrighted materials.

Can I report new financial interests when completing the eCOI form?

You can navigate to the Partners Disclosure System by clicking [Access Partners Disclosure System](#) on the eCOI page.

Who is responsible for reviewing the eCOI forms?

The Office for Interactions with Industry (OII) will review any disclosed Financial Interests and will make recommendations to the IRB. The IRB is responsible for reviewing the recommendations from OII and for approving the management plan.

How do I complete the Investigator COI Disclosure Form for amendments to add a new industry sponsor or new drug, device or other technology to be studied or used in a significant way?

The eCOI process is incorporated in the sign-off step for new submissions and amendments to add new study staff. Therefore, when submitting an amendment to add a new industry sponsor or new drug, device, or other technology, the principal investigators (PI), site responsible Investigators (SRI), co-investigators (Co-I) and any other members of the study staff responsible for the design, conduct, or reporting of the research (DCR) must complete the word version of the Financial Disclosure Form. The Financial Disclosure Form can be downloaded from the Research Navigator webpage by clicking on Apply/IRB Forms (on the left navigation menu) or by using the link below

[Financial Disclosure Form](#).

How do study staff that do not have a Partners User Name complete the Investigator COI Disclosure Form?

Anyone on the study staff that does not have a Partners User Name must complete the word version of the Financial Disclosure Form. The Financial Disclosure Form can be downloaded from the Research Navigator webpage by clicking on Apply/IRB Forms (on the left navigation menu) or by using the link below

[Financial Disclosure Form](#).

When and how do I report new financial interests?

Complete, sign, scan and email the word version of the Financial Disclosure Form to the Partners IRB Mailbox AND update your financial interests in the Partners Disclosure System using the Insight Conflict of Interest module. The Financial Disclosure Form can be downloaded from the Research Navigator webpage by clicking on Apply/IRB Forms (on the left navigation menu) or by using the link below

[Financial Disclosure Form](#).