

Sponsored Research COI Disclosure Process

Investigator Quick Reference Guide

Overview

Federal regulations and University policies require that researchers' external interests/relationships be assessed relative to each body of research in which they are engaged. This requires ongoing disclosure of external interests/relationships by researchers, and ongoing review by the University with respect to research activities. External interests/relationships are not bad and do not automatically present COI concerns. A COI determination for a particular body of research is made when an external interest/relationship relates to and could directly and significantly impact or bias the research. COIs must be eliminated, reduced or managed. Northwestern's COI in Research Policy is accessible here.

Key points for research-related COI disclosure, review, and management processes

Who must disclose?

Anyone who is an 'Investigator' (an individual responsible for research design, conduct, or reporting) on sponsored research subject to research COI requirements (list of sponsors triggering research COI requirements here). Click here). Click here) for additional guidance on who meets the definition of 'Investigator'.

Where do I disclose?

In the Faculty and Staff Information Service (FASIS) system. Click here to access the COI Portal in FASIS.

What do I disclose?

Significant Financial Interests (SFIs) related to your institutional responsibilities:

- Compensation / payments for service (> \$5,000* from single entity in previous year)
- Equity in non-publicly traded entity (any ownership/equity interests, even if valued at \$0)
- Equity in publicly traded entity (> \$5,000* value)
- Intellectual property interests (> \$5,000* from single entity in previous year)
- Sponsored/reimbursed travel (> \$5,000* from a single entity in previous year)

There are many exceptions for what needs to be disclosed. Click here for details.

*Investigators with primary appointments in FSM have different disclosure thresholds. Click <u>here</u> for details.

When do I disclose?

- Prior to engaging in research;
- Within 30 days of new SFIs; and
- At least annually

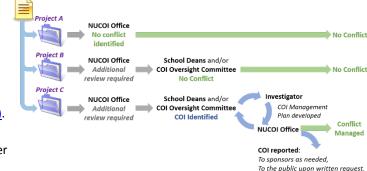
Annual disclosure is <u>not</u> enough if you acquire/receive/obtain new SFIs throughout the year! If you have no new SFIs that arise throughout the year, annual disclosure <u>is</u> sufficient (and required, even if acknowledging no change).

What happens to my disclosure?

Your disclosure is initially reviewed by NUCOI relative to each body of research activity.

If additional review is required, the review is referred to your School's Dean's Office, School-based committees, and/or the Conflict of Interest Oversight Committee (COIOC).

Final disposition for every project on which you are an 'Investigator' is either 'No Conflict' or 'Conflict Managed'.



What happens if a COI is identified?

Your Dean's Office and NUCOI will work with you to reduce, manage, or eliminate any COIs. In most cases, a COI management plan will be implemented to mitigate even the perception of a lack of objectivity in the research due to the COI. The most common strategy for COI management is transparency relative to the relationship/interest through disclosure. Click here for examples of ways to disclose COIs to research teams, research subjects, and in presentations and publications.

If sponsor COI reporting is required, NUCOI handles these requirements and will notify you if and when such reporting occurs.