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General

1. What is a “Financial Conflict of Interest”?

Financial Conflict of Interest (FCOI) means a significant financial interest that the institution reasonably determines could directly and substantially affect, or be affected by the design, conduct, or reporting of funded research or scholarly, educational, procurement, and/or program activities funded under external grants, contracts, or cooperative agreements.

2. When did the PHS FCOI regulation go into effect?

The regulation went into effect on August 24, 2012, and applies to all new awards, proposals, renewals, and no-cost extensions.

3. Which federal agencies are covered by the regulation?

A list of federal and non-federal agencies that have adopted the federal regulation can be accessed on the GMO website: <https://www.inova.org/about-us/grants-management>.

4. Who is covered by the regulation?

The new regulation applies to all Public Health Service (PHS) investigators, which includes the Principal Investigator or Project Director (PI/PD) and any other individual responsible for the design, conduct, or reporting of research funded by the PHS. Inova may designate multiple individuals as PI/PDs who share authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PI/PDs are named, each is responsible and accountable to the applicant organization, or, as appropriate, to a collaborating organization for the proper conduct of the project or program, including the submission of all required reports. The presence of more than one PI/PD on an application or award does not diminish the responsibility or accountability of any individual PI/PD.

5. Who is considered a “Covered Family Member”?

- a spouse or domestic partner.
- a dependent child or stepchild or other dependent, for purposes of determining federal income tax liability during the period covered by the disclosure statement; and a related or non-related, unmarried adult who resides in the same household as the covered individual and with whom the covered individual is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investments.

If the covered individual is in doubt about whether an individual is a covered family member, the covered individual should resolve the doubt in favor of disclosure.

6. Do I need to comply with the regulation if I am not currently receiving PHS funding and have no plans to apply for it?

Yes. Inova’s Conflict of Interest Policy for Research and Public Health Service Funding applies to managing conflicts of interest for researchers, research teams, educators, PI/PDs and grant-funded team members. The policy also fosters compliance with the Public Health Service (PHS) rules on conflicts of interest when implicated for grant-funded projects. Details about FCOI requirements for researchers can be found in Inova’s policy.

7. Does the regulation apply to sub-recipients (e.g., sub-awardees, sub-grantees, sub-contractors, collaborators, or consortium members)?

Sub-recipients, sub-awardees, sub-contractors, and consultants on sponsored awards, contracts or cooperative agreements are required to comply with all aspects of the PHS COI regulations. In order to reduce administrative burden many institutions have certified their COI

compliance with the Federal Demonstration Partnership (FDP) Institutional Clearinghouse <https://thefdp.org/fcoi-clearinghouse/>. If proposed subrecipients are not registered on the FDP Clearinghouse, they must complete a Subrecipient Policy Confirmation form at the time of proposal submission. This form is available on Inova's website: <https://www.inova.org/about-us/grants-management>. In instances that the sub-awardee, sub-contractor, or consultant's organization does not have a federally compliant COI program, they must comply with Inova's COI policies and procedures. Failure to comply with this policy or adhere to a COI Compliance Committee management plan may result in termination of participation in the associated project.

8. What happens if I do not comply with Inova's FCOI policy?

It's important to submit a disclosure form when applying for research funding or conducting a study. If an investigator fails to submit their annual disclosure form to the Grants Management Office, PHS proposal submissions may be delayed. Furthermore, PHS award funds may be frozen until all investigators complete their disclosure form.

Training

9. Do I need to take FCOI training?

All researchers and key personnel involved in the design, conduct, or reporting of research funded by the PHS must complete FCOI training.

10. How do I fulfill the FCOI training requirement?

The CITI Conflicts of Interest training is administered by the Collaborative Institutional Training Initiative (CITI), which is available at <https://www.citiprogram.org>.

11. How often do I need to take FCOI training?

Inova's policy requires investigators to take the training before applying for PHS funding and every four years thereafter.

12. How long does it take to complete the FCOI training?

The **Conflicts of Interest** course is estimated to take approximately 30 minutes.

13. I already took CITI Human Subject Research training; does this meet the FCOI training requirement?

CITI has a **separate** "Conflicts of Interest Course" for the Human Subjects training.

Reporting

14. Who must complete a disclosure form?

All research team members and individuals involved in research are required to complete disclosure forms. This also applies to technical team members who have direct access to research data or human subjects or have non-public information concerning the outcome of such research. Those who are purely advisory or lack independence to influence the design, conduct, or results of the research are excluded from this requirement.

It is the responsibility of the PI/PD to identify which study personnel are required to submit a disclosure form for a particular research project. The PI/PD is also responsible for ensuring that the study personnel are assigned the correct role, so that the Grants Management Office can confirm that disclosure and training requirements have been met.

15. What is meant by "Conduct Research"?

To "Conduct Research" means to perform or otherwise participate in research, including:

- Designing or directing research.
- Enrolling research subjects (including obtaining informed consent).
- Making decisions related to eligibility or risks of participating.
- Collecting, analyzing or reporting data; and/or
- Contributing to manuscripts for publication.

Individuals who participate in any of these activities are required to file an annual financial disclosure form.

16. When must I complete/submit a disclosure form?

Investigators and research team members are required to complete and submit the new COI disclosure form on an annual basis, between January 1st - January 30th. This disclosure must be submitted prior to engaging in research or externally funded educational activities. The disclosure form covers any financial interests that you have held or received in the 12 months leading up to the date of submission, as well as any expected over the next 12 months. This disclosure should be made before submitting proposals for funding or establishing new awards.

17. When must I update my disclosure?

Updates and/or modifications should be entered within thirty (30) days of a newly discovered or acquired significant financial interest.

18. Do I need to file a separate disclosure for my PHS research?

No, the annual disclosure form reflects the new regulatory requirements.

19. How do I submit my disclosure form?

Please complete the disclosure form using the Cayuse Outside Interest portal at <https://www.inova.org/about-inova/grants-management/>. You must send an email to coi@inoa.org to request access to the portal.

What to Report

20. What needs to be disclosed?

You must disclose any financial interests related to your institutional responsibilities, held by you or your family, regardless of the amount.

21. What is meant by "Institutional Responsibilities"?

The term "Institutional Responsibilities" refers to an investigator's professional responsibilities on behalf of the institution. These may include: activities such as research, research consultation, consulting, lecturing, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards, Data and Safety Monitoring Boards, or external advisory boards. Income from, or obligations arising from, any outside activity or commitment that is related to the investigator's institutional responsibilities must be disclosed to Inova.

22. What is meant by "Related to Institutional Responsibilities"?

The phrase "Related to Institutional Responsibilities" includes any external activities associated with your professional expertise or your role at Inova. If you think you are being asked to participate in an external activity because you are a professional in your field at Inova, then it may reasonably be considered related to your institutional responsibilities. Therefore, any consultation related to your area of professional expertise should be disclosed. However, if you have a family business that is unrelated to your profession then you do not need to disclose it. Keep in mind that determining relatedness is not always clear-cut. It's up to your judgment to decide what needs to be disclosed.

23. What are financial interests that must be disclosed?

Financial interests that must be disclosed include:

- Compensation/Remuneration
- Equity Interests
- Royalty Payments
- Special Relationships
- Sponsored Travel
- Other Financial Interests (e.g., certain intellectual property rights)

24. Must I disclose royalty payments?

You must disclose any payments made to you or your family for intellectual property rights that appear to be related to your institutional responsibilities. This includes royalties, license fees, or similar payments. It is essential to include any direct royalty payments received from an outside entity, whether it is a non-profit or for-profit organization, or through Inova, such as through an Inova license agreement. For PHS researchers, it is also necessary to include royalties or any other income received from an independent publishing company that arises from authoring, editing, or reviewing publications, whether in print or electronic format.

25. Do I need to report relationships with non-profit entities?

Financial interests now include remuneration and relationships with non-profit entities, in addition to for-profit entities.

26. What counts as “family” for purposes of disclosure?

When disclosing FCOI, your "family" includes your spouse or domestic partner, dependent children, grown children, grandchildren, parents, and grandparents (but only for financial interests that you are aware of). Additionally, any trust, organization, or enterprise that you control or have a significant interest in, either alone or with your family, must also be disclosed.

Travel

27. Do I need to report travel?

Investigators funded by, or involved in the design, conduct, or reporting of PHS-funded research activities must disclose the occurrence of any reimbursed travel or sponsored travel (i.e., travel that is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities. You may report anticipated travel prospectively in your annual financial disclosure form if it is known at the time. You must update your annual financial disclosure form within 30 days of any undisclosed sponsored travel. Your disclosure should include the purpose of the travel, the identity of the sponsor or organizer, the duration of travel, and approximate value.

28. Must I report all sponsored travel, including that which is reimbursed through my sponsored project?

The disclosure requirement does not apply to travel paid for by Inova and charged to a sponsored project or departmental account, or if it is reimbursed or sponsored by a federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

29. Can I project my future travel?

It is required to report any sponsored travel that is expected to occur in the future on your annual disclosure form, to the extent that it is known at the time of filing. It is recommended that

you list all potential travel in advance on your annual disclosure form to reduce or eliminate the need for filing updates throughout the year.

30. Do I need to update my disclosure whenever I have sponsored travel?

If you have sponsored travel during the year that was not included in your annual disclosure, you must provide an update within 30 days of the end of travel by sending your updated travel information to coi@inova.org or by submitting a new annual disclosure form that includes the new travel information.

After Disclosure

31. What is a “Significant Financial Interest”?

A “Significant Financial Interest” (SFI) is defined as any one of the following:

- Income greater than \$5,000 per year
- An equity stake in a public company greater than 5%, or with a value of more than \$5,000
- Any equity interest in a private company
- All royalties that exceed \$5,000 per year

32. Will my disclosure be made public?

The information provided on your form will be kept confidential unless the FCOI committee decides that it relates to your PHS-funded research. As per the PHS regulation, Inova is obligated to disclose the financial interests of key personnel that are found to be conflicts of interest as defined by the regulations. This information may be accessible to the public.

33. How is an investigator’s FCOI made available to the public?

To comply with the Public Health Service (PHS) requirement for public accessibility, Inova will provide written information about an FCOI to any member of the public who makes a good-faith written request. The request must clearly specify the PHS award and the researcher(s) involved. Inova is obligated to respond to the request within five business days of receiving a request.

Please reach out to the Inova Grants Management Office at coi@inova.org for any inquiries or concerns.

Links:

To learn more, NIH compiled answers to the most frequently asked questions regarding the implementation of the FCOI regulation. Please visit that website:

http://grants.nih.gov/grants/policy/coi/coi_faqs.htm

To review Inova’s FCOI Policy, please visit <https://www.inova.org/about-inova/grants-management/>.