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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 significantly affect the design, conduct or reporting of PHS-sponsored research.

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

The new regulation went into effect on August 24, 2012 and applies to all investigators on new awards, new proposals, non-competing renewals, and no-cost extensions received or submitted on or after August 24, 2012.

3. Do the new reporting requirements affect my PHS awards that predate the new regulation?

The new regulation applies to continuations dated on or after August 24, 2012 only. Any Notice of Award that has an issue date prior to August 24, 2012 is subject to the 1995 FCOI regulation. This also applies to projects extended without funds because even though the project period may be extended past August 24, 2012, the grant award was initially issued prior to August 24, 2012.

4. Which federal agencies are covered by the new regulation?

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry
- Centers for Disease Control (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Office of Global Affairs
- Office of the Assistant Secretary for Health, including
 - Office of Minority Health Resources Center (OMH)
 - Office of Population Affairs (OPA)
 - Office of Research Integrity (ORI)
 - Office of Research on Women’s Health (OWH)
- Office of the Assistant Secretary for Preparedness and Response, including
 - Biomedical Advanced Research and Development Authority (BARDA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

A list of non-federal agencies who have adopted the federal regulation can be accessed on the GMO website: <http://inovonet.net.inova.org/grantsmanagementoffice>

5. Who is covered by the new regulation?

The new regulation applies to all PHS investigators, which includes the Project Director or Principal Investigator (PI) and any other individual who is responsible for the design, conduct, or reporting of research funded by the PHS.

6. Who is 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.

7. Does the new regulation apply to me if I don't currently have PHS funding and don't plan to apply for any?

No. Inova's FCOI policy applies to all researchers who have active PHS funding or plan to apply for PHS funding. Details about FCOI requirements specific to PHS-funded research can be found in the Inova policy.

8. Does the regulation apply to subrecipients (e.g., subawardees, subgrantees, subcontractors, collaborators or consortium members)?

Yes. The regulation applies to subrecipients on PHS-funded awards. Many institutions have certified their compliance through the Federal Demonstration Partnership (FDP) Institutional Clearinghouse (http://sites.nationalacademies.org/PGA/fdp/PGA_070596). If proposed subrecipients are not registered on the FDP Clearinghouse, they must complete a mandatory Subrecipient Policy Confirmation form at the time of proposal submission. This form is available on Inovanet: <http://inovanet.net.inova.org/grantsmanagementoffice>. Additional forms may also be required, depending on whether the proposed subrecipient already has its own conflict of interest policy in compliance with the PHS regulations, or whether it commits to having such a policy before any subaward is made. In rare cases, an exception may be made through Inova that would bring the proposed subrecipient under Inova's Policy on Financial Conflicts of Interest and Research. Such exceptions may only be granted by the Grants Management Office.

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

Research funding and study review will be delayed when there is a failure to submit a disclosure form. PHS proposals will not be submitted until all investigators have submitted an annual disclosure form to the Grants Management Office. PHS award funds may be frozen until all investigators have completed a disclosure form.

Training

10. Do I need to take FCOI training?

All investigators involved in the design, conduct, or reporting of research funded by the PHS must complete FCOI training.

11. How do I fulfill the FCOI training requirement?

The FCOI training is administered through Collaborative Institutional Training Institute (CITI). Login with your CITI username and password at: <https://www.citiprogram.org/Default.asp?>. At the Main Menu choose "**Add a course or update your learner groups for Inova Health System**" in order to add the **Conflicts of Interest** training course and complete the certification. Step-by-step instructions on how to access the training are available on Inovanet: <http://inovanet.net.inova.org/grantsmanagementoffice>. A completion report will automatically be sent to the Grants Management Office and included in your file.

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

Inova's policy requires investigators to take the training prior to submitting an application for PHS-funding and every four years thereafter.

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

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

14. 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

15. Who must complete a disclosure form?

Disclosure forms are required of all research staff or others involved in research. This includes technical staff who:

- have direct access either to research data or to human subjects
- are in a position to influence the design, conduct or results of the research and/or have non-public information as to the outcome of such research.

Individuals who are purely advisory or are not sufficiently independent to be in a position to influence design, conduct or results of the research are not included.

For any particular research project, the PI is responsible for identifying which study personnel are required to complete and submit a disclosure form. The PI is responsible for ensuring that study personnel are assigned the correct role so that the Grants Management Office can confirm that disclosure and training requirements have been completed.

16. 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.

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

Any individual who conducts research at Inova must complete/submit an annual financial disclosure form upon hire and each subsequent year. Your annual disclosure covers your financial interests held or received in the 12 months preceding the date of your disclosure and those expected over the following 12 months. The annual disclosure must be submitted to the Grants Management Office before proposals are submitted for funding or new awards are established.

18. When must I update my disclosure?

You must update your disclosure throughout the year whenever your financial interests change. PHS researchers must update their financial interest report within 30 days of a new financial interest.

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

No, the annual disclosure form reflects the new regulatory requirements. However, after August 24th, the Grants Management Office will not submit new PHS proposals for funding or set up new awards or continuations until all Investigators on the project have submitted a new disclosure form.

20. How do I submit my disclosure form?

Disclosure forms are located: <http://inovanet.net.inova.org/grantsmanagementoffice>. You may also request a form by sending an inquiry to gmo@inova.org.

Forms may be submitted by:

- a. Sending the form (in PDF format) to the Grants Management Office **via email** to gmo@inova.org with “**FCOI Review—CONFIDENTIAL**” in the subject line, or
- b. Sending the form **via USPS or interoffice mail** in a sealed envelope to: **ATTN: FCOI REVIEW—CONFIDENTIAL**, Grants Management Office—TDI Building, 5580 Port Royal Road, Springfield, VA 22151

What to Report

21. What needs to be disclosed?

You must disclose financial interests *of any amount* that are related to your institutional responsibilities, and that are held or received by you or your family.

22. What is meant by “Institutional Responsibilities”?

The phrase “Institutional Responsibilities” is understood to mean all of the activities that you are required to perform in fulfilling your obligations to Inova, including your sponsored activities (such as sponsored research or service projects), teaching, Inova administrative duties, clinical practice, and other Inova activities.

23. What is meant by “Related to Institutional Responsibilities”?

Included in what is meant by “Related to Institutional Responsibilities,” are outside activities associated with your area of professional expertise or related to your role at Inova. Ask yourself, “Am I being asked to participate in this outside activity because I am a professional in my field at Inova?” If the answer is “Yes,” then it may reasonably appear that the requested activity is related to your institutional responsibilities. By this measure, any consultation in your area of professional expertise should be disclosed. On the other hand, if, for example, you are an orthopedist with a family business that imports rugs, that would not need to be disclosed. Keep in mind that relatedness is not always a bright-line determination. You should use your judgment when deciding what needs to be disclosed.

24. 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)

25. Must I disclose royalty payments?

You must disclose any payments to you or your family from intellectual property rights that reasonably appear to be related to your institutional responsibilities, such as royalties, license fees, or similar payments. Be sure to include royalty payments received either directly from an outside entity, which includes non-profit as well as for-profit entities, or through Inova (such as through an Inova license agreement). PHS researchers must also include royalties or other income received from an independent publishing company arising out of authoring, editing or reviewing publications (print or electronic).

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

Yes. In a change from previous requirements, under the new regulation, financial interests now include remuneration from, and other relationships with, non-profit as well as for-profit entities.

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

With regard to FCOI disclosure, your “family” includes: your spouse or domestic partner; your dependent children; your grown children, grandchildren, parents and grandparents (but only for those financial interests that are known to you); and any trust, organization or enterprise over which you, alone or together with your family, exercise a controlling or significant interest.

28. Do I need to report travel?

If you are funded by the PHS or plan to apply for such funding, you must disclose all reimbursed or sponsored travel that reasonably appears to be related to your institutional responsibilities. You may report anticipated travel prospectively in your annual financial disclosure form to the extent it is known at the time. You must update your annual financial disclosure form within 30 days of any undisclosed sponsored travel. Your disclosure must include: the purpose of the travel, the identity of the sponsor or organizer, the duration of travel and approximate value.

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

No. You should *not* report travel that is funded through Inova and charged to a sponsored project or through a departmental account, nor should you report travel that 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 that is affiliated with a U.S. institution of higher education.

30. Can I project my future travel?

Any anticipated sponsored travel must be reported *prospectively* on your annual disclosure form, to the extent it is known at the time. To the extent possible, listing all potential travel prospectively on your annual disclosure will reduce or eliminate the need to file updates throughout the year.

31. 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 gmo@inova.org or by submitting a new annual disclosure form that includes the new travel information.

After Disclosure

32. What does Inova do with my disclosure?

Your disclosure form remains in a confidential file in the Grants Management Office, where access is restricted. The Grants Management Office reviews any reports that disclose financial interests related to your research. If a reported financial interest exceeds specific thresholds, it is considered a Significant Financial Interest and must be reviewed by the Conflict of Interest Committee.

33. 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

34. Will my disclosure be made public?

The information on your form is kept confidential, unless the FCOI committee determines that an FCOI relates to your PHS-funded research. Under the PHS regulation, Inova is required to make accessible to the public information about key personnel’s financial interests that are found to be conflicts of interest as defined by the regulations.

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

To meet the PHS requirement for public accessibility, Inova will provide written information about FCOI to members of the public who make a good-faith written request. The request must specify the PHS award and the researcher(s) in question. Inova must respond within five business days of receipt of the request.

For additional questions or concerns regarding Financial Conflicts of Interest (FCOI), please contact Inova Grants Management Office at gmo@inova.org or (703) 764-5532.

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: <http://www.inova.org/upload/docs/about-Inova/grants-management-policy.pdf>