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General

1. 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 that date.

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

Yes. The revised regulation applies to PHS award *continuations* as of the award's next renewal date on or after August 24, 2012.

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

The new regulation applies to individuals with funding from any PHS agency including:

- National Institutes of Health (NIH – including all individual Institutes and Centers)
- Centers for Disease Control and Prevention (CDC)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

4. Who is covered by the new regulation?

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

5. Are Postdocs and Grad Students covered by the new regulation?

Yes, if the postdoc or grad student meets the definition of an “Investigator,” which includes the Project Director or Principal Investigator and *any other individual who is responsible for the design, conduct, or reporting of research funded by the PHS*. 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.

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

For consistency and simplicity, some of the new PHS FCOI requirements have been integrated into Columbia's FCOI policy. The [Columbia University Policy on Financial Conflicts of Interest and Research](#) applies to all researchers. Details about FCOI requirements specific to PHS-funded research can be found in [Appendix 2: Compliance with Revised Public Health Service Regulations](#).

7. Does the regulation apply to subawardees?

Yes, the regulations flow down to subawardees and subcontractors on PHS-funded awards. Many institutions have certified their compliance through the Federal Demonstration Partnership (FDP) Institutional Clearinghouse. If a proposed subawardee is not registered on the FDP Clearinghouse, at proposal submission the subawardee must complete a mandatory Subrecipient Policy Confirmation form, available on the [SPA website](#). Additional forms may also be required, depending on whether the proposed subawardee 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 which Columbia would bring the proposed subrecipient under Columbia's Policy on Financial Conflicts of Interest and Research. Such exceptions may only be granted by the Executive Vice President for Research.

Training

8. Do I need to take FCOI training?

All PHS Investigators must complete training on financial conflicts of interest and research prior to engaging in PHS-funded research, and every four years thereafter. This includes any individual who is responsible for the design, conduct, or reporting of research funded by the PHS.

9. How do I fulfill the FCOI training requirement?

A short course that satisfies the new regulation is available in Rascal: [TC1450 - Financial Conflicts of Interest for PHS Researchers](#). Alternatively, as of July 16, 2013, the Rascal course TC0087 – Human Subjects Protection Training, also satisfies the PHS training requirement; human subjects researchers who complete the course (Basic or Refresher) on or after that date, do not need to complete TC1450.

10. How often do I need to take training?

FCOI training is required prior to engaging in PHS-funded research and every four years thereafter. If you conduct human subjects (HSP) research, your FCOI training will be renewed when you complete HSP continuing education every three years.

11. If I have previously completed other FCOI training at Columbia, such as Rascal TC0091 - Financial Conflicts of Interest and Research, do I need to take additional training?

Yes, prior to engaging in PHS-funded research, all PHS-funded Investigators need to complete Rascal course [TC1450 - Financial Conflicts of Interest for PHS Researchers](#), or have completed Rascal course TC0087 – Human Subjects Protection Training on or after July 16, 2013.

General Reporting

12. Who must file a Financial Interest Report?

Financial Interest Reports (sometimes referred to as “annual disclosure forms”) are required of all Officers of Instruction, Research, or Libraries, students, fellows, research staff or others involved in research. This includes technical staff who:

- have direct access either to research data or to human subjects; and
- 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. Under some circumstances, external consultants may be required to file a Financial Interest Report (see question 14 below).

For any particular research project, the Principal Investigator is responsible for identifying which study personnel are required to file a Financial Interest Report. For example, the PI is responsible for ensuring that study personnel are assigned the correct role in Rascal Proposal Tracking so that SPA can confirm that disclosure and training requirements have been completed.

13. Are students required to file Financial Interest Reports?

Students in some circumstances may act with sufficient independence as to be required to file Financial Interest Reports. It is the PI's responsibility to identify such students as "Student-Investigators" in Rascal Proposal Tracking.

14. Are consultants required to file Financial Interest Reports?

No, provided that the consultant is serving in a purely advisory role, or is not sufficiently independent to be in a position to influence design, conduct or results of the research.

Any consultant listed as key personnel on a Columbia PHS-funded sponsored project is required to file a Financial Interest Report. At the time of proposal, the consultant may file a paper form (available from SPA upon request). At the time of just-in-time notification, a Columbia UNI should be obtained for the consultant so that he/she can file an electronic form in Rascal before any funds are expended on the award.

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
- Contributing to manuscripts for publication

Individuals who participate in any of these activities are required to file an annual Financial Interest Report.

16. When must I file a Financial Interest Report?

Any individual who conducts research at Columbia must file an annual Financial Interest Report 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 filed in Rascal before SPA will submit proposals for funding or set up new awards.

17. 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.

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

No, the annual disclosure form in Rascal has been updated to reflect the new regulatory requirements. However, after August 24, 2012, SPA will not submit new PHS proposals for funding or set up new awards or continuations until all investigators on the project have filed a new disclosure using the updated form in Rascal.

What to Report

19. 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.

20. 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 Columbia University, including your sponsored activities (such as sponsored research or service projects), teaching, University administrative duties, clinical practice, and other University activities.

21. What is meant by “related to institutional responsibilities”?

To understand what is meant by “related to your institutional responsibilities,” you should think about your outside activities that are associated with your area of professional expertise, or that are related to your role at the University. Ask yourself, “Am I being asked to participate in this outside activity because I am a professional in my field at Columbia University?” 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; but when in doubt, err on the side of transparency.

22. 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)

23. 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 not-for-profit as well as for-profit entities, or through the University (such as through a University 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).

24. 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, not-for-profit as well as for-profit entities.

25. 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.

Travel

26. 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 Interest Report, to the extent it is known at the time. You must update your annual financial interest report 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.

27. 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 the University 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.

28. Can I project my future travel?

Any anticipated Sponsored Travel must be reported *prospectively* in your annual Financial Interest Report, 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.

29. 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 TravelUpdate@columbia.edu or by filing a new annual Financial Interest Report in Rascal that includes the new travel information.

After Disclosure

30. What does the University do with my disclosure?

Your Financial Interest Reports remain in the confidential Rascal system where access is restricted. The Office of Research Compliance and Training 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 Financial Conflict of Interest Committee.

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 on your form is kept confidential, unless the FCOI committee determines that an FCOI relates to your PHS-funded research. Under the PHS regulation, the University 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.

33. How are an Investigator's FCOI made available to the public?

To meet the PHS requirement for public accessibility, the University will provide written information about FCOIs 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. The University must respond within 5 business days of receipt of the request.