

**APPENDIX 2:
COMPLIANCE WITH REVISED
PUBLIC HEALTH SERVICE REGULATIONS**

This Appendix to the Columbia University Policy on Financial Conflicts of Interest and Research (the “Policy”) documents the policies and procedures adopted by Columbia University for compliance with the revised Public Health Service regulations, entitled *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought*, 42 CFR Part 50 Subpart F (“PHS Regulations”), effective Aug. 24, 2012.

Like the Policy, this Appendix 2 is University-wide and applies to all Individuals who propose or Conduct Research funded by the Public Health Service (“PHS Investigators”). The Public Health Service (“PHS”) includes the following agencies:

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

The University is implementing the PHS Regulations through this Appendix 2 on a project-by-project basis sequentially, on the award date of each project.

1. Definitions

This Appendix employs the same Definitions set forth in the Policy. In addition, the following definitions apply for purposes of compliance with the PHS Regulations:

- a. **Financial Conflict of Interest (“FCOI”):** a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-funded research.
- b. **Institutional Responsibilities:** all professional activity for which an individual is compensated by Columbia University, including sponsored activities (e.g. sponsored research or service projects), teaching, University administrative duties, private practice, and other activities.
- c. **PHS Award:** a University sponsored project funded by the Public Health Service and subject to the PHS Regulations. For purposes of this Appendix, and consistent with the PHS Regulations, Phase I SBIR/STTR awards are excluded from this definition.

- d. **PHS Investigator:** the Project Director/Principal Investigator and any other individual, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding.
- e. **PHS Research:** Research conducted pursuant to a PHS Award.
- f. **Sponsored Travel:** Travel related to a PHS Investigator's Institutional Responsibilities that is (i) reimbursed to the PHS Investigator, or (ii) paid on behalf of the PHS Investigator. Sponsored Travel does not include travel funded through the University and charged to a sponsored project or departmental account, which is subject to the University's Travel Policy.

2. Training

All PHS Investigators must complete training on financial conflicts of interest and research prior to engaging in PHS Research and at least every 4 years after that.

Under certain circumstances, training must be completed immediately, as follows:

- a. PHS Investigators who are new to the University must complete training no later than 30 days after their start date;
- b. PHS Investigators who are found to be in noncompliance with the Policy must complete training with 5 days of being notified of such noncompliance;
- c. In the event that the University revises this Policy in any manner that affects PHS Investigator requirements, PHS Investigators must complete training regarding the revisions within 30 days of their effective date.

The training requirement may be fulfilled by completion of:

- a. the Rascal stand-alone course entitled [TC1450 - Financial Conflicts of Interest for PHS Researchers](#); or
- b. Such other trainings as the University shall identify, including departmental or school trainings, other on-line trainings, or other mechanisms.

3. Disclosure

- a. **Annual Disclosure:** As set forth in the Policy, PHS Investigators must disclose all Financial Interests at least annually. Disclosures are filed in Rascal at www.rascal.columbia.edu.
- b. **Updates within 30 days:** In the event that a PHS Investigator acquires or discovers a new Financial Interest, he or she must update his or her annual disclosure within 30 days.

- c. **Sponsored Travel Disclosure:** PHS Investigators must disclose all Sponsored Travel, except for travel sponsored or reimbursed by:
- i) a Federal, state or local government agency;
 - ii) a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education

Disclosures must include at a minimum the identity of the sponsor/organizer, as well as the purpose, destination, and duration of the travel. Additional information may be requested on a case-by-case basis.

PHS Investigators must disclose Sponsored Travel prospectively in the annual Financial Interest Report, to the extent it is known. In addition, PHS Investigators must provide Sponsored Travel updates through an approved University mechanism. Such mechanisms include:

- i) emailing the updated information to TravelUpdate@columbia.edu;
- ii) filing a new annual Financial Interest Report that includes new travel information; or
- iii) such other mechanism that the University establishes for reporting sponsored travel updates.

4. Relatedness Review

With respect to each PHS Award, prior to expenditure, the University shall review the annual Financial Interest Reports for all participating PHS Investigators to assess whether any disclosed Significant Financial Interest is related to the PHS Research (“Relatedness Review”). A Significant Financial Interest is related to the PHS Research when it: (a) could be affected by the relevant PHS Research; or (b) is in an entity whose financial interest could be affected by such Research.

Factors that indicate relatedness include but are not limited to whether the SFI is in an entity (an “Interested Business”) that:

- a. funds the PHS Research in whole or in part, whether through a research agreement, gift, or other arrangement;
- b. supplies drugs, devices or other goods that are the subject of such Research, or services or other deliverables in connection with the research, pursuant to a material transfer agreement, a research agreement or otherwise;
- c. holds an Investigational New Drug application or Investigational Device Exemption for a Technology being investigated in such Research;
- d. owns, licenses or has any other contractual interest in a Technology being investigated in such Research;

- e. acts for or on behalf of another Interested Business, directly or indirectly. Depending on the relationship, this could include some medical education companies and other similar entities; or
- f. Could otherwise be affected by the PHS Research.

As set forth in Section 12 below, the Office of Research Compliance and Training (RCT) has primary responsibility for the Relatedness Review; in conducting such review, RCT may call upon subject-matter experts as needed with respect to any particular project, such as members of the Financial Conflict of Interest Committee (“FCOI Committee”), department chairs, division chiefs, and others with relevant expertise.

5. Sponsored Travel Initial Review

Initial review of Sponsored Travel disclosures shall be by RCT, in accordance with the following guidelines:

- a. RCT will review Sponsored Travel disclosures and assess whether additional information is required for further review.
- b. No further information is required for travel to attend Gordon Research Conferences or other professional conferences sponsored by an academic or professional society.

The FCOI Committee may establish criteria for when particular categories of Sponsored Travel disclosures do not require FCOI Committee review.

6. FCOI Review

Where a Significant Financial Interest has been found to relate to PHS Research, the FCOI Committee shall determine whether the Significant Financial Interest is a Financial Conflict of Interest, i.e., whether the SFI could directly and significantly affect the PHS Research. Factors to consider may include, but are not limited to:

- a. The nature of the PHS Investigator’s SFI and its relationship to the PHS Research.
- b. The design of the PHS Research, including, *e.g.*, the size and scope of the Research; the outcome measures being studied; the statistical analysis plan; and other design elements that affect whether the PHS Research is susceptible to bias.
- c. The role of the PHS Investigator who has the SFI in question.
- d. Whether there are additional researchers who will work on the PHS Research, and if so: (i) their roles on the project; and (ii) whether they are subordinate to the PHS Investigator in question.
- e. Whether the results of such Research have limited potential to directly and predictably benefit the Interested Business.
- f. Such other factors as the FCOI Committee shall determine consistent with the Policy and PHS Regulations.

7. Management and Reporting to PHS Awarding Component

Any FCOI shall be managed in accordance with the Policy as set forth Section G. Such management plans shall include, among other things, how the management plan will be monitored to ensure Investigator compliance.

In unusual circumstances, and depending on the nature of the SFI, the Chair of the relevant FCOI Subcommittee, with appropriate consultation with RCT, Office of the General Counsel, and members of the FCOI Committee, may conduct an expedited, interim FCOI review and implement an interim management plan if needed, provided that such expedited determinations shall be subsequently and timely reported to the full FCOI Subcommittee and reviewed as appropriate.

In the event that any Financial Conflict of Interest is found with respect to a particular PHS Award, the University shall submit a report of the FCOI (“FCOI Report”) to the PHS Awarding Component. Such report must include the following:

- a. Project number;
- b. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- c. Name of the Investigator with the financial conflict of interest;
- d. Name of the entity with which the Investigator has a financial conflict of interest;
- e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- f. Value of the financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- g. A description of how the financial interest relates to the PHS-funded research and the basis for the University’s determination that the financial interest conflicts with such research; and
- h. A description of the key elements of the Institution's management plan, including:
 - i) Role and principal duties of the conflicted Investigator in the research project;
 - ii) Conditions of the management plan;
 - iii) How the management plan is designed to safeguard objectivity in the research project;
 - iv) Confirmation of the Investigator's agreement to the management plan;
 - v) How the management plan will be monitored to ensure Investigator compliance; and
 - vi) Other information as needed.

FCOI Reports will be submitted in the following instances:

- i. **New PHS Awards:** Prior to expenditure of any funds under a new PHS Award, the University shall submit any required FCOI Report(s). No FCOI Report is

required or shall be submitted in cases in which the FCOI is eliminated prior to the expenditure of funds under the PHS Award.

- j. **Existing Awards, New Investigator or Newly Acquired Interest:** For a PHS Investigator who is newly participating in a PHS Award, or for a PHS Investigator who discloses a new SFI during the period of PHS Award, the University shall, within 60 days: (i) conduct a Relatedness Review; (ii) if the SFI is found to be related to a PHS Award, determine whether it constitutes an FCOI; and (iii) if so, implement a management plan on at least an interim basis. The University shall submit an FCOI Report to the PHS Awarding Component within 60 days after any determination that an FCOI exists.
- k. **Untimely Disclosure/Review:** whenever a PHS Investigator does not disclose timely a previously existing SFI or the Institution fails to review a previously existing SFI during an ongoing PHS Award(s), the University shall, within 60 days: (i) conduct a Relatedness Review; (ii) if the SFI is found to be related to a PHS Award, determine whether it constitutes an FCOI; and (iii) if so, implement a management plan on at least an interim basis. The University shall submit an FCOI Report to the PHS Awarding Component within 60 days after any determination that an FCOI exists. Finally, the University shall also conduct a retrospective review of the PHS Research as described below, within 120 days of the University's determination of non-compliance.
- l. **Annual Updates:** For any FCOI previously reported to the PHS Awarding Component, the University shall provide an annual FCOI update. Such update shall address the status of the financial interest and any changes to the management plan. Annual updates shall be submitted for the duration of the project, including no-cost extensions, at the same time as when the University is required to submit the annual progress report.

8. Retrospective Review for Bias and Mitigation Reports

- a. **Retrospective Review for Bias:** In the event of untimely disclosure or review, as described above, and where the SFI at issue is found to be an FCOI, the University shall conduct a retrospective review of the PHS Research at issue. The purpose of such retrospective review is to determine whether any PHS Research, or portion thereof, conducted during the period of noncompliance, was biased in the design, conduct or reporting of such Research. The review must include and document at least the following key elements:
 - i) Project number;
 - ii) Project title;
 - iii) PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - iv) Name of the Investigator with the FCOI;
 - v) Name of the entity with which the Investigator has a financial conflict of interest;

- vi) Reason(s) for the retrospective review;
 - vii) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - viii) Findings of the review; and
 - ix) Conclusions of the review.
- b. **Reporting to the PHS Awarding Component:** Based on the results of the retrospective review, the University shall, if appropriate, update the previously submitted FCOI Report, specifying the actions that will be taken to manage the FCOI going forward.
- c. **Mitigation Report:** If the retrospective review determines that the PHS Research was biased, the University shall promptly notify the PHS Awarding Component and submit a mitigation report that includes the key elements of the retrospective review, a description of the impact of the bias on the research project, and the University's plan of action or actions taken to eliminate or mitigate the effects of the bias.

9. Public Disclosure

The University shall provide written information about FCOIs held by Senior/Key Personnel on a PHS Award to members of the public who make a written request. The written request must specify the PHS Award and personnel in question.

Senior/Key Personnel include the Principal Investigator/Project Director and any individual listed as Key Personnel on the PHS funding application.

The University's response will be postmarked or dated within 5 business days of receipt of the request by the Office of Research Compliance and Training (RCT), unless a reasonable extension is granted.

10. PHS Award Subrecipients

For any PHS Award that includes a subaward to another institution ("PHS Subaward"), the written agreement between the University and subrecipient shall establish whether the FCOI policy of the subrecipient shall apply to the subrecipient's PHS investigators and include time periods to meet disclosure and/or FCOI reporting requirements.

If the FCOI Policy of the subrecipient shall apply to the subrecipient's PHS Investigators, the subrecipient shall certify as part of the written agreement between the University and the subrecipient that its FCOI Policy complies with the PHS Regulations.

Subrecipients must report identified FCOIs to the University 15 days before any PHS reporting deadline for the University, in order to enable the University to meet the PHS reporting deadline. For example, in the event that the subrecipient identifies a new FCOI after a PHS Subaward has begun, the subrecipient must report the FCOI to the University

within 45 days of its determination, to enable the University to report to the PHS Awarding Component within the 60 days prescribed by the PHS regulations.

In the event that the subrecipient is unable to apply its own FCOI policy, the University may choose to award the subaward to a different subrecipient, or, in rare circumstances, apply the University's Policy to the subrecipient.

11. Record Retention

The University shall maintain records relating to all Investigator disclosures of financial interests and the University's review of and response to such disclosures (whether or not such disclosure resulted in a determination of an FCOI) and all actions under the Policy and this Appendix for at least three years from the date the final expenditures report is submitted to the PHS or such other date as is required by law.

If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

12. Institutional Official

The Executive Vice President for Research (EVPR) is the Institutional Official with overall responsibility for compliance with the PHS Regulations. The EVPR has delegated the responsibility for Relatedness Review to the Office of Research Compliance and Training, and for determinations as to whether a particular SFI constitutes an FCOI to the FCOI Committee.