

CUNY’s Procedures for Complying with 2011 Public Health Service (PHS) Regulations: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR 50, Subpart F)

I. Applicability

These procedures apply to all PHS research funding by means of a grant or cooperative agreement.

EXCEPTION: These procedures DO NOT apply to Phase I Small Business Innovation Research or Small Business Technology Transfer applications.

<p>Applicable to all PHS authorized research, including:</p> <ul style="list-style-type: none"> - Research grants - Cooperative agreements - Career development grants - Center grants - Individual fellowship award - Infrastructure award - Institutional training grant - Program project - Research resources award - Conference grants - Minority Biomedical Research Support - Subrecipients, subgrantees & collaborators 	<p>PHS Agencies include:</p> <ul style="list-style-type: none"> - Agency for Toxic Substances & Disease Registry (ATSDR) - Center for Disease Control & Prevention (CDC) - Food & Drug Administration (FDA) - Health Resources and Services Administration (HRSA) - Indian Health Service (IHS) - National Institutes of Health (NIH) - Office of the Assistant Secretary for Preparedness and Response (ASPR), including Biomedical Advanced Research and Development Authority (BARDA) - Office of Global Affairs (OGA) - Substance Abuse & Mental Health Services Administration (SAMHSA) <p>Source: US DHHS Organizational Chart</p>
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II. Definitions

- a. *College Conflicts Officer (CCO)* means the individual at each College designated by the College President to perform the functions described in Section 4.4.1 of CUNY Conflict of Interest Policy.
- b. *Financial Conflict of Interest (FCOI)* means a Significant Financial Interest that could directly and significantly affect the design, conduct, reporting, or regulatory review of PHS-funded research at CUNY.
- c. *Institutional Responsibilities* means an Investigator’s professional responsibilities on behalf of CUNY, performed in the course of and within the scope of the Investigator’s appointment or employment by CUNY, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards.

- d. *Investigator* means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of a research project at CUNY that is funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants, whether or not such project director, principal investigator, or other person is employed by CUNY or the CUNY Research Foundation.
- e. *Significant Financial Interest (SFI)* means:
- i. One or more of the following financial interests of an Investigator (and the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 1. With regard to any **publicly traded entity**, if the total of (A) the salary and any payment for services not otherwise identified as a salary (for example, consulting fees, honoraria, paid authorship) received from the entity in the 12 months preceding the disclosure, AND (B) the value of any equity interest in the entity (including any stock, stock option, or other ownership interest) as determined through reference to public prices or other reasonable measures of fair market value as of the date of the disclosure, exceeds \$5,000.
 2. With regard to any **non-publicly traded entity**, if (A) the total of the salary and any payment for services not otherwise identified as a salary (for example, consulting fees, honoraria, paid authorship) received from the entity in the 12 months preceding the disclosure exceeds \$5,000, OR (B) any equity interest, regardless of value, in the entity (including any stock, stock option, or other ownership interest).
 3. Intellectual property rights and interests (for example, patents and copyrights), upon receipt of income related to such rights and interests.

The occurrence of any reimbursed travel or sponsored travel (i.e., travel paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) that is related to the Investigator's Institutional Responsibilities, provided that the disclosure requirement does not apply to travel that is reimbursed or sponsored by:

- A Federal, state, or local government agency;
- An institution of higher education;
- An academic teaching hospital;

- A medical center; or
- A research institute that is affiliated with an institution of higher education.

ii. A Significant Financial Interest DOES NOT include the following:

1. Salary, royalties, or other remuneration paid by CUNY to the Investigator if the Investigator is currently employed or otherwise appointed by CUNY, including intellectual property rights assigned to CUNY and agreements to share in royalties related to such rights;
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
3. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
4. Income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or

III. Training

Prior to engaging in research related to any PHS-funded grant or cooperative agreement, all Investigators are required to complete the CITI training in conflicts of interest prior to engaging in such research. All CCOs are also required to complete this training. Additionally, the CCO may require other individuals at their respective college to complete this on-line training. Individual training requirements may be based on such considerations as the nature of an existing conflict; non-compliance with the CUNY Conflict of Interest Policy or other CUNY policies; non-compliance with a conflict of interest (COI) management plan; or non-compliance with applicable laws and regulations or sponsor requirements. Training is valid for four years. Detailed requirements and instructions are available at <http://www.cuny.edu/research/compliance/training-education/citi-training.html>.

IV. Subrecipients

If CUNY carries out PHS-funded research through a subrecipient (for example, subcontractors or consortium members), the CUNY Research Foundation shall

obtain written documentation that any subrecipient Investigator complies with 42 CFR 50.604(c), by, for example, requiring the subrecipient to certify in the written agreement that its investigators will abide by the CUNY Conflict of Interest Policy.

V. Disclosure

All investigators, as defined in section II above, who are planning to participate in PHS-funded research at CUNY must complete the [CUNY Significant Financial Interest \(SFI\) Disclosure Form for PHS Funded Research](#) and submit it to the college Grants Officer and CCO at the time that the Principal Investigator submits a grant proposal or application. In addition, all Investigators must update their SFI Disclosure Forms, and Investigators who join an ongoing PHS-funded research project at CUNY must complete the SFI Disclosure Form, as set forth in section VII below.

VI. Review Process

Every positive disclosure of a SFI shall be reviewed in accordance with the following procedures:

- a. The CCO shall complete a FCOI Determination Report, setting forth his or her determination:
 - i. Whether the Investigator's SFI is related¹ to PHS-funded research; and, if so,
 - ii. Whether the SFI constitutes a Financial Conflict of Interest, as defined in section II above.
- b. Whether or not the CCO determines that a FCOI exists, the CCO shall promptly forward the SFI Disclosure Form for PHS Funded Research, the SFI Supplement Form for PHS Funded Research and a completed FCOI Determination Report to the University Director for Research Compliance, the College Provost, the Investigator and the Legal Department of the Research Foundation.
- c. The Chair of the Conflicts Committee shall review the FCOI Determination Report and indicate whether s/he concurs with the CCO's determination. If the Chair determines that a FCOI exists, the FCOI will be reviewed as follows:
 - i. The University Director for Research Compliance shall promptly schedule a meeting (either in-person or via teleconference) of the Conflicts Committee.
 - ii. The Conflicts Committee shall decide on the requirements of a conflict management and oversight plan that specifies the actions required to

¹ An Investigator's SFI is related to PHS-funded research when the CCO determines that the SFI could be affected by the PHS-funded research, or is in an entity whose financial interest could be affected by the research.

manage the FCOI. **A conflict management and oversight plan must be developed and implemented prior to the expenditure of any related PHS funds.** Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to, the following:

- Public disclosure of the FCOI (for example, when presenting or publishing the research);
 - For research projects involving human subjects research, disclosure of the FCOI directly to participants;
 - Appointment of an independent monitor capable of taking measures to protect the design, conduct, reporting and review of the research against bias resulting from the FCOI;
 - Appointment of a Conflicts Overseer in accordance with the CUNY COI Procedures for Oversight of Research by a Conflicts Overseer;
 - Modification of the research plan;
 - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - Reduction or elimination of the SFI (for example, sale of an equity interest); or
 - Severance of relationships that create the FCOI.
- iii. The Conflicts Committee Administrator shall document the Committee's determinations in a formal conflict management and oversight plan and promptly distribute it to all affected parties, including the CCO, the College Provost, the Investigator, the college Grants Officer, and the Legal Department of the Research Foundation.
- If the PHS funds in question are supporting research involving human subjects, the Conflicts Committee Administrator shall also notify the appropriate Institutional Review Board (IRB).
 - If the PHS funds in question are supporting research involving animal subjects, the Conflicts Committee Administrator shall also notify the appropriate Institutional Animal Care and Use Committee (IACUC).
- iv. Whenever the Conflicts Committee develops and implements a management and oversight plan, the Office of the Vice Chancellor for Research, with the assistance of the CCO, shall monitor the Investigator's compliance with the plan on an ongoing basis until the completion of the research project.

VII. Disclosure Updates

All Investigators are required to submit an updated SFI Disclosure Form for PHS Funded Research to the CCO (with a copy to the Grants Officer at their College) at the following times:

- a. Annually, prior to submission of annual progress reports.
- b. Within 30 days of any material change in the previously disclosed SFI or discovering or acquiring a new SFI.
- c. When the Investigator joins an ongoing PHS-funded research project at CUNY.

VIII. Reviews of Updated Disclosures

The CCO shall promptly review an updated SFI Disclosure Form and determine whether an FCOI exists. If so, the review process shall proceed in accordance with the procedures outlined in section VI above. The Conflicts Committee shall implement a management and oversight plan, on at least an interim basis, within 60 days of the CCO's receipt of the disclosure.

IX. Noncompliance

- a. The Chair of the Conflicts Committee must be notified immediately upon the discovery of a SFI that an Investigator who is participating in an ongoing PHS-funded research project did not disclose in a timely manner or that the Conflicts Committee, for whatever reason, did not previously review. Within 60 days of the Chair's receiving this notification, the Conflicts Committee, working with the CCO as needed, must determine if the SFI is related to the PHS-funded research, whether an FCOI exists, and if so, implement, on at least an interim basis, a management and oversight plan.
- b. Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI that is later determined to be a FCOI, failure by the college or others to review or manage such FCOI, or failure by the Investigator to comply with an FCOI management and oversight plan, the CCO, the Conflicts Committee, and others as appropriate, shall, with the guidance of the University Director for Research Compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The retrospective review shall be documented in accordance with 42 CFR 50.605(a) (3) (ii)(B).
- c. Whenever an Investigator fails to timely disclose an SFI or otherwise comply with the CUNY Conflict of Interest Policy, CUNY may consider whether disciplinary action against the Investigator or others, consistent with the University's Collective Bargaining, is appropriate. In addition, any failure by an investigator to comply with the requirement to disclose a SFI or with a management and oversight plan regarding a FCOI may lead to a loss and/or

withdrawal of grant funding or support, ineligibility to submit grant applications to research sponsors or to participate in research on behalf of CUNY, and/or ineligibility to supervise the work of other investigators in research projects.

X. Reporting to PHS

The Grants Officer, with assistance from the CCO and the University Director for Research Compliance, shall report to the PHS funding agency in accordance with 42 CFR 50.605(b) as follows:

- a. An initial FCOI report regarding any FCOIs prior to CUNY's expenditure of any PHS funds. If the FCOI is eliminated prior to the expenditure of PHS funds, a report is not required.
- b. An FCOI report within 60 days of identifying any conflicting SFIs subsequent to the initial FCOI report during an ongoing PHS-funded research project.
- c. Annual FCOI reports on previously reported FCOI regarding ongoing PHS-funded research projects that address the status of the FCOIs and any changes to the management and oversight plan.
- d. A mitigation report with a corrective action plan in the case of an Investigator's failure to comply with CUNY's FCOI policies and procedures or a management and oversight plan, and the Conflicts Committee determines that such failure has biased the design, conduct or reporting of the PHS-funded research.

XI. Record Keeping

CCOs, Grants Officers and the Conflicts Committee Administrator shall retain all records relating to all Investigator disclosures of SFIs, the reviews and responses to such disclosures (whether or not the disclosures resulted in a determination of an FCOI), and any resulting management and oversight plans for at least three years from the date the final expenditure report is submitted to the PHS.