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.

<table>
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<th>Applicable to all PHS authorized research, including:</th>
<th>PHS Agencies include:</th>
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<td>- Research grants</td>
<td>- Agency for Toxic Substances &amp; Disease Registry (ATSDR)</td>
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<td>- Cooperative agreements</td>
<td>- Center for Disease Control &amp; Prevention (CDC)</td>
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<td>- Career development grants</td>
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<td>- Center grants</td>
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<td>- Individual fellowship award</td>
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<td>- Infrastructure award</td>
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<td>- Institutional training grant</td>
<td>- Office of the Assistant Secretary for Preparedness and Response (ASPR), including Biomedical Advanced Research and Development Authority (BARDA)</td>
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<td>- Program project</td>
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<td>- Conference grants</td>
<td>Source: <a href="#">US DHHS Organizational Chart</a></td>
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<td>- Minority Biomedical Research Support</td>
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<td>- Subrecipients, subgrantees &amp; collaborators</td>
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II. Definitions

a. *College Conflicts Officer (CCO)* means the individual at each College designated by the College President to receive disclosures of Significant Financial Interests, review such disclosures to determine whether a Financial Conflict of Interest exists, and refer such FCOIs to the University’s Conflicts Committee for further review.

b. *Financial Conflict of Interest (FCOI)* means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

c. *Financial Interest* means anything of monetary value, whether or not the value is readily ascertainable.

d. *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.

e. *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 research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

f. *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. Involving a **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 of the date of the disclosure, exceeds $5,000.

2. Involving a **non-publicly traded entity**, if (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 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) that is related to the Investigator’s Institutional Responsibilities.

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;

5. 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.

III. Training
All Investigators engaging in research related to any PHS-funded grant or contract, and all CCOs are required to complete the CITI training in conflicts of interest prior to engaging in such research and are required to re-take the training at least every 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 Research Foundation shall obtain written documentation that any subrecipient Investigator has complied with 42 CFR 50.604(c), by, for example, requiring the subrecipient to certify in the written agreement that its investigators will abide by CUNY’s financial conflicts of interest policy.
V. Disclosure and Review Process

The following procedures shall be followed for all PHS funding applications covered under the aforementioned regulations:

a. Investigators must submit a completed SFI Disclosure Form to their CCO (with a copy to the College Grants Officer at their College) no later than the time of their application.

b. The CCO shall determine:
   i. Whether the Investigator’s SFI is related\(^1\) to PHS-funded research; and, if so,
   ii. Whether the SFI constitutes a Financial Conflict of Interest\(^2\), as defined in Section II above.

c. If the CCO finds that the SFI is related to PHS-funded research and constitutes an FCOI, s/he shall promptly forward the SFI Disclosure Form to the University Director for Research Compliance. The CCO will at the same time inform the College Grants Officer and the Legal Department of the Research Foundation in writing that s/he has taken this action.

d. Upon receipt of the SFI Disclosure Form, the University Director for Research Compliance, or his/her designee, shall promptly schedule a meeting (either in-person or via teleconference) of the University’s Conflicts Committee to review the FCOI.

e. The Conflicts Committee shall review the FCOI and proceed as follows:

   i. Determine whether it agrees with the CCO’s assessment that the SFI is related to PHS-funded research and constitutes an FCOI.

   ii. If the Conflicts Committee disagrees with the CCO’s assessment, the Committee’s assessment and justification for this assessment will be documented in the Committee’s meeting minutes, and the case will be closed. The Conflicts Committee Administrator shall inform all affected parties, including the Legal Department of the Research Foundation, of this determination.

   iii. If Conflicts Committee agrees with the CCO’s assessment, then the Committee shall decide on the requirements of a conflict management

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\(^1\) An Investigator’s SFI is related to PHS-funded research when the CCO reasonably 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.

\(^2\) An FCOI exists when the CCO determines that there is a reasonable basis to believe that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
and oversight plan that specifies the actions that have been and shall be taken to manage the FCOI. 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, and reporting of the research against bias resulting from the FCOI;
- 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 FCOI (for example, sale of an equity interest); or
- Severance of relationships that create the FCOI.

iv. 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 College Grants Officer and the Legal Department of the Research Foundation.

f. A conflict management and oversight plan must be developed and implemented prior to the expenditure of any related PHS-funds.

g. If the PHS funds in question are supporting research involving human subjects, the Conflicts Committee Administrator shall communicate with the appropriate Institutional Review Board (IRB), as follows:
   i. Upon receipt of the SFI Disclosure Form by the Conflicts Committee, inform the IRB that a potential conflict exists.
   ii. Upon completion of the Conflicts Committee's review, provide a copy of any management and oversight plan to the IRB.

VI. Disclosure Updates

It is the responsibility of the CCO to ensure that all Investigators submit an updated SFI Disclosure Form 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 discovering or acquiring a new SFI.
   c. When the Investigator is new to participating in an ongoing PHS-funded research project.
VII. **Reviews of Updated Disclosures**  
Within 30 days of receiving an updated SFI Disclosure Form, the CCO shall review the disclosure and determine whether an FCOI exists. If so, the review process shall proceed in accordance with the procedures outlined in V.c-g 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.

VIII. **Noncompliance**  
a. Whenever CUNY identifies an SFI that was not disclosed in a timely manner by an Investigator, or was not previously reviewed by the CCO and, if necessary, by the Conflicts Committee during an ongoing PHS-funded research project, the review of the SFI shall be completed and a management and oversight plan, if required, shall be implemented on at least an interim basis within 60 days.

b. Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI that is determined by CUNY to constitute an FCOI, failure by CUNY to review or manage such FCOI, or failure by the Investigator to comply with an FCOI management and oversight plan, the CCO and the Conflicts Committee shall, within 120 days of determination of noncompliance, 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, CUNY may consider whether disciplinary action in accordance with the University’s Collective Bargaining Agreement against the Investigator or others is appropriate.

IX. **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.

X. **Record Keeping**
CCOs, Grants Officers and the Conflicts Committee Administrator shall retain all records relating to all Investigator disclosures of financial interests, 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.