Key Conflict of Interest Terms

- **Research**: A systematic experiment, study, evaluation, demonstration or survey, in any academic field, designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, causes, functions or effects.

- **Sponsored Projects**: Project activities that include research, creative activity, and training. It includes instruction or service undertaken within or on behalf of the University pursuant to funding or other support from an external source.

- **Investigator**: The project director, principal investigator, co-principal investigator, students, and any other person, regardless of title of position, who is responsible for the design, conduct, or reporting of a University Sponsored Project, which may include, for example, collaborators or consultants, whether or not such individual is employed by the University or the Research Foundation.
Institutional Responsibilities: An investigator's professional responsibilities on behalf of the University, performed in the course of and within the scope of the Investigator's appointment or employment by the University, which may include, for example, activities such as research, research consultation, teaching, professional practice, institutional administration, committee memberships, and service on panels such as Institutional Review Boards, Institutional Animal Care and Use Committees or Institutional Biosafety Committees.

Conflicts of Interest: A conflict of interest exists when two or more contradictory interests relate to an activity by an individual or an institution. The conflict lies in the situation, not in any behavior or lack of behavior of the individual. That means that a conflict of interest is not intrinsically a bad thing. (Office of Research Integrity)

College Conflicts Officer – Appointed by the College President, the CCO is responsible for receiving and reviewing all Financial Disclosure Forms from Investigators at the College. The CCO determines whether or not any disclosed Significant Financial Interest is related to the proposed Sponsored Project, and if so, whether or not a Financial Conflict of Interest exists and if so, whether a Significant Financial Interest is related to the Sponsored Project. The CCO assists in the implementation and monitoring of any management and oversight plans developed by the Conflicts Committee.
CUNY’s Conflict of Interest policy and procedures are designed to ensure, to the extent possible, that any financial interests and/or conflicts of commitment are managed in a manner that prevents bias in the design, conduct, reporting, or regulatory review of research.

https://www.cuny.edu/research/research-compliance/conflict-of-interest/

**Purpose in Sponsored Projects**

- To promote integrity by establishing standards and procedures to ensure, to the extent possible, that any Significant Financial Interest (as defined in Section 8.19) that could directly and significantly affect the design, conduct or reporting of a Sponsored Project at the University (each, a “Financial Conflict of Interest” or “Financial Conflict”) does not bias the design, conduct or reporting of the Sponsored Project.
Each College within CUNY appoints a College Conflicts Officer (CCO) who is appointed by the President or their designee, and serve as the first level of review. CCNY’s CCO works collaboratively with our Office of Research Compliance and Ethics (RCE) and CUNY Office of Research staff, to implement CUNY COI Policy, for promoting the need to disclose significant financial interests to faculty and staff at their College, and for reviewing all disclosures in accordance to this policy.

- Conflicts related to the Researcher’s commitment should be disclosed to the Research Integrity Officer (RIO).
- Conflicts related to research involving human subjects should be disclosed to the Human Research Protection Program (HRPP);
- Conflicts related to research involving animal subjects should be disclosed to the Institutional Animal Care and Use Committee (IACUC).

CCNY’s CCO

Dr. Maria Lima, Medical Professor, Molecular Cellular and Biomedical Sciences
Associate Dean for Research/Chief Research Officer mlima@med.cuny.edu

March 22, 2023
A Significant Financial Interest (SFI) is determined when:

- 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

Equity Ownership and Intellectual Property (CALCIP) Disclosure

- Each CUNY investigator who has become aware of a Company's acquisition or intention to acquire ownership of or a license to investigator developed, created or discovered intellectual property must also complete the CUNY Acquisition of or License to CUNY Intellectual Property Form (CALCIP)

Currently, researchers are expected to disclose any Financial Conflicts of Interest (FCOI) using the significant interest financial disclosure and supplement forms. Completed and signed PDF forms are then returned to the Office of Research Compliance and Ethics (RCE) via email.
INITIAL PUBLIC HEALTH SERVICES FORM

SFI Disclosure Forms (Current method)

SUPPLEMENT PHS FORM

Please provide requested details regarding your positive responses made on the SFI Significant Financial Interest Disclosure Form and, if necessary, use additional Supplement Forms.

1. Salary and any payment for other services (for example, consulting fee, honorarium, paid authorship) received from a publicly traded entity in the past 12 months to include:
   - Name of person or persons (and relationship to self) to whom the salary or payment was made
   - Name of publicly traded entity

2. Equity interest (including any stock, stock options, or other ownership interest) in a publicly traded entity:
   - Name of person or persons (and relationship to self) who hold(s) the equity interest
   - Name of publicly traded entity
   - Type of equity interest
   - Current value of equity interest

3. Relationship to your institutional responsibilities

Please refer to the SOPN Significant Financial Interest Disclosure Form for additional information, or contact your departmental office for assistance.
PHS Agencies

- 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)

Source: US DHHS Organizational Chart
Procedure for complying with PHS Requirements

- Revised regulations issued by The Department of Health and Human Services (HHS) issued in regards to *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought in 2011*.

- **Applicable** to all PHS authorized research, including Research grants, Co-op agreements, Career Development and Center grants, fellowship and Infrastructure awards, Institutional training grant, Program project, Research resources award, Conference grants, Minority Biomedical Research Support, Subrecipients, subgrantees & collaborators.

- **Not applicable** to Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (SBTT) applications

- **Publicly traded entity** - In 12 months if total of salary and any payment for services received from the entity, **AND** value of any equity interest in the entity exceeds $5,000. Same threshold for **Non-Public Traded entity**, however either salary **OR** Equity Interest exceeds $5,000.

- Upon income received for *Intellectual Property or Rights*

- The occurrence of any reimbursed travel or sponsored travel
Training Requirements for Recipients of PHS Funding

- The Collaborative Institutional Training Initiative (CITI Program) training in Conflicts of Interest is required of all Investigators PRIOR to engaging in research related to any PHS-funded grant or cooperative agreement.

- Additionally, the CCO may require other individuals at CCNY 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/research-compliance/training-education/citi-training
Introducing Outside Interest (OI)

OI is an online platform where CCNY Researchers, using their Single Sign-On (SSO) credentials, can securely submit their Significant Conflict of Interest Financial Disclosures for review by the Conflicts Of Interest Committee.
Submit your new COI Financial Disclosure Form at the time of the Annual Campaign and when submitting a new proposal with the Office of Grants and Sponsored Programs (GSP).

The Annual Campaign is conducted at the beginning of the calendar year
- Emails for the Annual Campaign will be sent to Researchers.
- They notify Researchers of the annual period and the task to complete the Annual Disclosure.

Click on the link to the OI portal during the campaign period and complete Annual Disclosures for both Public Health Services (PHS) and Non-PHS research.
TWO TYPES OF FCOI DISCLOSURE IN OI

ANNUAL DISCLOSURE
The Annual Disclosure is the master form where all relationships with any external organization are captured. It must be updated yearly and whenever there is a change in relationship. The Annual Disclosure must be updated prior to completing the Research-Based Disclosure.

RESEARCH-BASED DISCLOSURE
A Research-Based Disclosure is required when submitting a proposal, with responses specific to the proposed activities of that proposal.
Submitting a New COI Financial Disclosure

1. Go to upper right-hand corner under your name, click on My Profile

2. Click on COI Disclosures

3. In the upper right-hand corner click + New Disclosure
OI HELP

Click on the Question Mark in the lower right of your screen, and step-by-step instructions will appear to guide you through the process of submitting a new disclosure form.
FCOI Responses

When you answered an YES to a question, additional questions would appear dynamically for you to answer.

How to add a new relationship?
You would need to select the entity (external organization) that this potential conflict is associated with

1. Search for the External Organization
2. If not found, + Request New External Org
3. Enter the name and Save
FCOI Workflow

How would a disclosure be reviewed and processed?
Rollout Timeline

FEBRUARY –
Internal testing period by the implementation team

MARCH –
Finalize form design and testing with Vendor

APRIL (early) –
Campus rollout starting with the Division of Science

MAY – JUNE –
Phased-in rollout with the entire campus
Demonstration Notes

The following pages are not to be presented, but a note on the demonstration procedures
Go to My Profile -> COI Disclosure
Briefly explain the annual and research-based disclosures
Show how the HELP works
New Disclosure

Explain Sections
- PHS vs Non-PHS
- CALCIP
- Document Section and when to use it
- FAQ’s purpose
- Certification

Explain Question Numbering
- 1, 2, 3…. vs. NP1, NP2, etc.
- S1, S2, S3…
Demonstration Notes

- Reporting a relationship that might be of FCOI concern
  - External Org
  - What if you cannot find it on the list?
  - Add new ones

- Document Section
- Being returned -email
Questions?
Contact us at research@ccny.cuny.edu