

Conflict of Interest Guidance: Identifying 'Investigators'

Overview of Significant Financial Interest Disclosure Requirement

Per <u>CUNY Conflict of Interest (COI) Policy and Procedures</u>, Principal Investigators (PI) must submit the CUNY Significant Financial Interest (SFI) Disclosure Form(s) to the college Grants Officer (GO) and College Conflicts Officer (CCO) before a proposal or application is submitted to an external sponsor. All other investigators must submit Significant Financial Interest Disclosure Form(s) prior to the expenditure of any awarded funds or support.

In the case of sponsored projects involving multi-year funding or support, all investigators must disclose any previously undisclosed SFIs and must provide updated information regarding any previously disclosed SFI annually throughout the period of award.

In addition, each investigator (including the PI) is required to submit an updated CUNY SFI Disclosure Form to the GO and the CCO within 30 days of any material change in the previously disclosed SFI, discovery or acquisition of a new SFI, or when the investigator joins an ongoing sponsored project at CUNY.

Who Are Considered Investigators?

<u>CUNY Conflict of Interest (COI) Policy and Procedures</u> define *investigator* as the project director, the PI, any co-PIs, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of a University research project, 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 Research Foundation.

An *employee or agent*¹ of CUNY would generally be considered an investigator when they are engaged in any of the following activities:

- Planning, decision-making, direction, supervision of a sponsored project;
- Making a significant contribution to the design of the sponsored project;
- Recruiting, enrolling, or consenting research subjects;
- Recording primary study data in a system without quality control measures;
- Independently operating laboratory or technical equipment;
- Analyzing, interpreting, or manipulating data;
- Manuscript writing and authoring publications;
- Presenting research outcomes and results at conferences or the public, etc.;
- Submitting annual progress reports, reporting adverse events, unanticipated problems, non-compliance, or any other official update to an agency or sponsor;

AND operate in a significantly independent manner when carrying out these activities.

Version dated: May 7, 2020

¹ For the purposes of this document, *employees or agents* refers to individuals who: (1) act on behalf of CUNY; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. *Employees or agents* can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.



An *employee or agent** of CUNY would generally not be considered an investigator if they are **only** engaged in the activities listed below.

- Drafting or editing informed consent documents, protocol applications, recruitment materials, and other study materials if the content decisions and final approvals are made by an investigator;
- Recording study data in a system with quality control mechanisms such as random data checks or duplicate entry;
- Assisting with laboratory tasks under the direction of an investigator;
- Administrative tasks like scheduling research meetings, subject appointments, or tracking project expenditures

Title/Role in Research	CUNY Investigator Status	Guidance
Principal Investigator	Yes	
Co-Investigator	Yes	
Graduate or Postdoctoral Fellows on paid fellowships	Yes	
Collaborators at another institution	No	If CUNY is the prime awardee and assuming overall responsibility and compliance for the project, obtaining confirmation or assurance for the collaborator that COI disclosures for investigators have been made in accordance with the policies of the funding agency or sponsor is strongly encouraged.
Collaborators at other CUNY campuses/institutions	Yes	CUNY collaborators who meet the definition of investigator should submit SFI disclosure forms to the GO and the CCO at the campus where they are employed/hold their primary appointment.
Collaborators not affiliated with CUNY or any institution	Yes	If a collaborator meets the definition of investigator and is affiliated with CUNY or any other institution then CUNY must take responsibility for the investigator and the collaborators must submit SFI disclosure forms to the GO and the College CCO at the campus where the PI is employed/holds their primary appointment
Consultants	Maybe	Consultants are typically paid a fee in exchange for expert opinion and advice to researchers. They are not usually responsible for the design, conduct or reporting of research, but an analysis must be done to make this determination.

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