

CUNY Conflict of Interest Disclosure, Oversight and Management Procedures For Research NOT Funded by the Public Health Service

I. Applicability

These procedures apply to all research at CUNY, EXCEPT for research that is funded by means of a grant or cooperative agreement from the Public Health Service (PHS). For conflict of interest (COI) procedures related to PHS funded grants and cooperative agreements, please refer to [CUNY's Procedures for Complying with 2011 PHS Regulations](#).

II. Research Defined

For the purposes of these procedures, research means 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.

If an investigator or a Grants Officer is in doubt regarding whether an activity constitutes research, the College Conflicts Officer (CCO), in consultation with the college's Research Integrity Officer (RIO) and the University Director for Research Compliance, will make the final determination.

III. Training

All CCOs are required to complete the on-line CITI training in conflicts of interest. In addition, the CCOs may require certain researchers at their respective colleges 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 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. Disclosure

Each investigator (as defined in section 6.14 of the [CUNY Conflict of Interest Policy](#)) must complete the [CUNY Significant Financial Interest \(SFI\) Disclosure Form](#) for Research Projects Not Funded by the Public Health Service and submit it to the college Grants Officer and CCO at the time that the Principal Investigator submits a grant proposal or application, and each investigator must submit and updated Form to the college Grants Officer and CCO at the time the Principal Investigator submits an annual progress report.

In addition, each investigator is required to submit an updated CUNY SFI Disclosure Form to the college Grants Officer 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 research project at CUNY.

V. Review Process

Every positive disclosure of a SFI (as defined in Section 6.16 of the CUNY Conflict of Interest Policy) shall be reviewed in accordance with the following procedures:

1. The CCO shall complete a FCOI Determination Report, setting forth his or her determination:
 - a. Whether the investigator's SFI is related¹ to the investigator's research; and, if so,
 - b. Whether the SFI constitutes a Financial Conflict of Interest (FCOI)², as defined in section 6.12 of CUNY Conflict of Interest Policy.
2. Whether or not the CCO determines that a FCOI exists, the CCO shall promptly forward the SFI Disclosure Form, the SFI Supplement Form, and a completed FCOI Determination Report to the University Director for Research Compliance, the College Provost, the investigator, and if the case involves a sponsored project administered through the CUNY Research Foundation, the Legal Department of the Research Foundation.
 - a. The Chair of the Conflicts Committee shall review the FCOI Determination Report and indicate whether or not 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 manage the FCOI. **A conflict management and oversight plan must be developed and implemented prior to the expenditure of any related research 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);

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

² An FCOI exists when the CCO determines that the SFI could directly and significantly affect the design, conduct, reporting or review of 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 College Provost, the investigator, the college Grants Officer and, if the case involves a sponsored project administered through the CUNY Research Foundation, the Legal Department of the Research Foundation.
- If the research in question involves human subjects, the Conflicts Committee Administrator shall also notify the appropriate Institutional Review Board (IRB).
 - If the research in question involves animal subjects, the Conflict 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.

VI. Non-Compliance

Any failure to comply with the provisions of the CUNY Conflict of Interest Policy may result in disciplinary sanctions consistent with applicable collective bargaining agreements, up to and including termination of employment. 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.