



New York Institute of Technology

Policy on Conflicts of Interest in Research

Effective August 24, 2012

New York Institute of Technology
Policy on Conflicts of Interest in Research

Table of Contents

I. PURPOSE.....1
II. APPLICABILITY AND PROHIBITION.....1
III. DEFINITIONS.....2
IV. INVESTIGATOR DISCLOSURE REQUIREMENTS.....3
V. TRAINING.....4
VI. INSTITUTIONAL RESPONSIBILITIES AND PROCEDURES.....4
VII. RECORDS.....6
VIII. VIOLATIONS OF THIS POLICY.....6

Appendix A: Special Rules Applicable to PHS-Funded Research

Appendix B: Financial Interest Disclosure Form

I. PURPOSE

The purpose of this policy is to promote objectivity in research by establishing standards and procedures to ensure that there is no reasonable expectation that the design, conduct, or reporting of research will be biased by any conflicting financial interest of the investigator.

This policy is intended to comply with the requirements of federal regulations, including the following:

42 CFR Part 50, Subpart F	Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought
45 CFR Part 74	Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments
45 CFR Part 94	Responsible Prospective Contractors
34 CFR Part 74	U.S. Department of Education Administration of Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations
NSF Grants Policy Manual	Chapter V, Section 510 Conflict of Interest Policies
21 CFR Part 54	FDA Financial Disclosure by Clinical Investigators

II. APPLICABILITY AND PROHIBITION

- A. This policy applies to all research at NYIT whether supported by external or internal funding, sponsored or unsponsored, and to all research to be carried out at other sites in the name of NYIT.
- B. No Investigator, faculty member or administrator at NYIT may participate in Research in which s/he or the Investigator’s Family has a Conflict of Interest unless approved in advance in writing in accordance with this policy.
- C. No Investigator, faculty member or administrator at NYIT shall assign any student, post-doctoral fellow or other trainee or subordinate to any Research project in which that

person has a Conflict of Interest unless approved in advance in writing in accordance with this policy.

III. DEFINITIONS

- A. “Conflict of Interest” means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research.
- B. “Equity Interest” includes stocks, stock options and other ownership interests, but does not include income from investment vehicles, such as mutual funds and retirement accounts, provided the Investigator does not control the investment decisions made in these vehicles.
- C. “Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of NYIT, including teaching, research, administrative functions and committee memberships.
- D. “Investigator” means the principal investigator and any other person who is responsible for the design, conduct or reporting of Research, including faculty, the attending physicians, interns and residents sponsored by NYIT, research scientists, clinical fellows, nurses, technicians and others engaged in Research, whether as employees or volunteers. “Investigator” does not include advisors, persons who provide technical support or clinical trial participants, who have no responsibility for design, conduct or reporting of the Research.
- E. “Investigator’s Family” means the Investigator’s spouse and dependent children.
- F. “Key Personnel” means the Principal Investigator or Project Director, and any other person identified as senior or key personnel in the grant application or in other institutional reports to the grantor.
- G. “NYIT” means New York Institute of Technology and all of its schools, departments, centers, and affiliates.
- H. “Remuneration” means salary or any other payment for services, including consulting fees, honoraria and paid authorship.
- I. “Research” means a systematic investigation designed to develop or contribute to generalizable knowledge, including behavioral and social science research. It encompasses both basic and applied research and product development.

J. “Significant Financial Interest” means:

1. Any interest of monetary value of the Investigator or the Investigator’s Family that reasonably appears to be related to the Investigator’s Institutional Responsibilities, consisting, in the aggregate, of one or more of the following:
 - i. In the case of a publicly traded entity, Remuneration and/or the value of any Equity Interest together totaling in excess of \$5,000 during the preceding twelve months;
 - ii. Remuneration from any non-publicly traded entity in excess of \$5,000 during the preceding twelve months, or any Equity Interest in a non-publicly traded entity;
 - iii. Intellectual property rights and interests in the Research (e.g. patents and copyrights) and the right to receive royalties therefrom;
2. Remuneration affected by the outcome of the Research—for example, compensation that is higher for a favorable outcome than for an unfavorable outcome;
3. Remuneration from the sponsor of the Research to the Investigator, or payments to NYIT to support activities of the Investigator, which remuneration or payments are over and above the costs of conducting the current Research project;
4. Position as a director, officer, manager, employee or consultant to an entity with a Significant Financial Interest in the Research.

“Significant Financial Interest” does not include the following:

- a. Remuneration paid to the Investigator by NYIT, including any share in royalties related to intellectual property rights assigned by the Investigator to NYIT, provided that the Investigator is currently employed or otherwise appointed by NYIT;
- b. Income from seminars, lectures or teaching engagements sponsored by a government agency, institution of higher education or affiliated research institute, academic teaching hospital, or medical center;
- c. Income from service on advisory committees or review panels for a government agency, institution of higher education or affiliated research institute, academic teaching hospital, or medical center.

IV. INVESTIGATOR DISCLOSURE REQUIREMENTS

- A. Investigators are required to disclose, in accordance with the procedures set forth in Section IV. B below, the following:
1. Any Significant Financial Interest; and
 2. Any travel related to the Investigator's Institutional Responsibilities, which is reimbursed or sponsored by any entity other than a government agency, institution of higher education or affiliated research institute, academic teaching hospital, or medical center. In connection with any such travel, the Investigator is required to disclose the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- B. Investigators are required to submit to the Institutional Official, in accordance with Sections VI. B and VI. C below, a completed and signed NYIT Financial Interest Disclosure Form (attached hereto as Appendix B). The Financial Interest Disclosure Form must be submitted as follows:
1. The Financial Interest Disclosure Form must be submitted with any Research proposal, and prior to the submission of any proposal to the sponsor, any Institutional Review Board, or any other outside entity.
 2. A new Form must be submitted annually thereafter during the pendency of the Research project; and
 3. A new Financial Interest Disclosure Form must be submitted within 30 days of the Investigator's discovering or acquiring a new Significant Financial Interest during the pendency of the Research project.
- C. It is the responsibility of the Principal Investigator on any Research to ensure that all Investigators involved with the Research (as defined in Section III. D. above) submit the required Financial Disclosure Forms.

V. TRAINING

- A. NYIT recommends that all Investigators complete a Conflicts of Interest training program selected from time to time by the Institutional Official. The Institutional Official may in his or her discretion require that training be completed in certain circumstances, including, for example, if an Investigator is found to be non-compliant with the Policy or for Investigators new to NYIT.

- B. Investigators conducting PHS-Funded Research must comply with the training requirements set forth in Appendix A, Section 1.

VI. INSTITUTIONAL RESPONSIBILITIES AND PROCEDURES

- A. NYIT shall designate an institutional official (the “Institutional Official”) who shall be responsible for identifying Conflicts of Interest and taking action to manage, reduce or eliminate such Conflicts. The currently-designated Institutional Official is the Assistant Provost, Research and Director of Sponsored Programs and Research.
- B. Each proposal for external funding shall be submitted for review, together with a Financial Interest Disclosure Form, to the Institutional Official. If the Institutional Official determines that a Significant Financial Interest exists, the Institutional Official shall comply with the regulations of the funding agency with regard to reporting and managing any potential conflicts. (See Appendix A hereto for specific policies applicable to PHS-funded research.)
- C. Review of Research that is funded internally shall be carried out by the academic deans.

The dean shall have the Investigator complete and sign a Financial Interest Disclosure Form and provide it to the Institutional Official for review and action in accordance with this policy.

- D. In the event that the Institutional Official determines that a Conflict of Interest exists for any Investigator involved in proposed Research, s/he shall advise the Investigator on mechanisms designed to manage, reduce or eliminate the Conflict of Interest. These may include, but are not limited to, the following:
 - 1. Public disclosure of the Significant Financial Interest whenever and as often as reasonably necessary to ensure objectivity of the Research.
 - 2. Monitoring of research by independent reviewers, such as independent peer review or audits of data.
 - 3. Modification of the research plan, such as using a double-blinded protocol where appropriate, ensuring that subjects are randomly selected or excluding the Investigator from the portion of the research that may be affected by the Significant Financial Interest.
 - 4. Divestiture of the Significant Financial Interest.
 - 5. Severance of the relationships that create actual or potential Conflicts of Interest as a result of the Significant Financial Interest.

- E. The Institutional Official shall sign the Financial Interest Disclosure Form when s/he is satisfied that there is no Conflict of Interest or that the Conflict of Interest has been appropriately managed, reduced, or eliminated.
- F. NYIT shall establish a Committee on Objectivity in Research. In the event that the Institutional Official and the Investigator do not agree on either the existence of a Conflict of Interest or on procedures that will insure that a Conflict of Interest is managed, reduced, or eliminated, the Institutional Official shall refer the matter to the Committee on Objectivity in Research. The Committee shall make a decision after reviewing the research proposal and the Financial Interest Disclosure Form, and, if the Committee sees fit, after meeting with the Investigator. In the event that the Committee determines that a Conflict of Interest does not exist or has been appropriately managed, reduced, or eliminated, the Chair of the Committee shall indicate so in writing to the Institutional Official and Investigator.

VII. RECORDS

- A. The Institutional Official shall make and maintain records of the steps to which the Investigator has agreed to ensure that Conflicts of Interest are managed, reduced, or eliminated.
- B. The Institutional Official shall maintain Financial Interest Disclosure Forms and all records of action taken for not less than 3 years after the latest of:
 - 1. Conclusion of the Research
 - 2. Submission of the final expenditure report to a sponsor.
 - 3. Disposition of property and equipment provided by a sponsor.
 - 4. Final resolution of any litigation, claim, or audit arising out of the research.

VIII. VIOLATIONS OF THIS POLICY

The Committee on Objectivity in Research shall have authority to take any of the following actions upon a determination that any Investigator, faculty member, or administrator has violated this policy:

- A. Issue a written reprimand that may be placed in the offender's employment file.
- B. Recommend that the offender be disciplined, up to and including termination.
- C. Terminate the Research that is associated with the Conflict of Interest.
- D. Bar the offender from Research for a specific period of time.
- E. Report the violation to any sponsors, bodies, or individuals as may be required by federal regulations, laws or contracts.

Special Rules Applicable to PHS-Funded Research

Any Research for which an Investigator is applying for Public Health Service funding (“PHS-Funded Research”) must comply with the NYIT Policy on Conflicts of Interest in Research (the “Policy”), and must additionally comply with the Special Rules set forth in this Appendix A.

D) Training

Each Investigator engaged in PHS-Funded Research must complete the training requirements specified by the Institutional Official as follows:

- a) The Investigator must complete the training before commencing the Research and the training must be repeated every four years during the pendency of the Research.
- b) Any Investigator who is found to be non-compliant with the Policy will be required to immediately complete the designated training.
- c) The Institutional Official may direct that Investigators complete the designated training in other instances, including in the case of changes to the Policy or for Investigator new to NYIT.

II) Management and Reporting of Conflicts of Interest

A. Public Disclosure of Policy: The NYIT Policy on Conflicts of Interest in Research, including this Appendix A, is publicly available on the NYIT website, at www.nyit.edu/ospar.

B. Public Disclosure of Conflicts of Interest: NYIT will respond within five business days to any request for information regarding Conflicts of Interest held by Key Personnel associated with any PHS-Funded Research. For any Conflict of Interest which has been disclosed and determined to exist in accordance with this Policy, NYIT’s response will include the following information: the Key Personnel’s name, title and role in the research project, name of the entity in which the Significant Financial Interest is held, the nature of the Significant Financial Interest, and the approximate dollar value of the Significant Financial Interest or a statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. The response will note that the information provided is current as of the date of the correspondence and is subject to updates on an annual basis and within 60 days of NYIT’s identification of a new Conflict of Interest, which should be requested subsequently by the requestor.

C. Reporting to NIH:

- i. Prior to NYIT’s expenditure of funds in connection with any PHS-Funded Research, NYIT will provide a report to the PHS Awarding Component regarding any Conflict of Interest of an Investigator which has been determined to exist in accordance with this policy (and has not been eliminated). The report will include information regarding the management plan which NYIT has implemented.

**Policy on Conflicts of Interest in Research
Appendix A**

- ii. In the event that during the course of an ongoing PHS-Funded Research project, a new or newly-discovered Significant Financial Interest is disclosed, the Institutional Official shall within 60 days determine whether a Conflict of Interest exists, and if so, the Institutional Official shall implement an interim management plan, subject to further institutional review. The new Conflict of Interest and management plan will be reported to the PHS Awarding Component.

- iii. Any report under (i) or (ii) above will provide sufficient information for the PHS Awarding Component to understand the nature and extent of the financial conflict and to assess the appropriateness of NYIT's management plan, including:
 - a. Project number and contact information;
 - b. the Investigator's name, title and role in the research project, name of the entity in which the Significant Financial Interest is held, the nature of the Significant Financial Interest, and the approximate dollar value of the Significant Financial Interest or a statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
 - c. a description of how the financial interest relates to the Research and the basis for NYIT's finding of a Conflict of Interest; and
 - d. a description of the key elements of the management plan, how it will safeguard objectivity, confirmation of the Investigator's agreement to the management plan, and how the plan will be monitored to ensure Investigator compliance.

- iv. In the event that NYIT makes any report as provided above, NYIT will provide the PHS Awarding Component annual update reports throughout the period of the project, addressing the status of the Conflict of Interest, including whether it still exists and is being managed, and any changes to the management plan.

D. Retrospective Review: In the event that a Conflict of Interest in connection with any PHS-Funded Research is not identified or managed in a timely manner including failure by the Investigator to disclose a Significant Financial Interest which is determined to be a Conflict of Interest, failure of the institution to review or manage the Conflict of Interest, or failure by the Investigator to comply with a Conflict of Interest management plan, then the Institutional Official shall, within 120 days of the institution's determination of non-compliance, complete a retrospective review of the Investigator's activities 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 Institutional Official shall document the retrospective review, including:

- a. Project number and contact information;
- b. the Investigator's name, title and role in the research project, and name of the entity in which the Significant Financial Interest is held;
- c. reasons for the retrospective review and detailed methodology of the review process; and

**Policy on Conflicts of Interest in Research
Appendix A**

- d. findings and conclusions of the review.

Based upon the results of the retrospective review, if appropriate, NYIT will update the previously submitted Conflicts of Interest report, specifying the actions which will be taken to manage the Conflict of Interest going forward. If bias is found, NYIT will promptly notify the PHS Awarding Component and submit a mitigation report, including the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and NYIT's plan of action or actions taken to eliminate or mitigate the effect of the bias. NYIT will update this report at least annually.

III) Subrecipient Awards

In the event that a portion of any NYIT PHS-Funded Research is carried out by a subrecipient, then the agreement between NYIT and the subrecipient institution must include the following provisions:

- i. The subrecipient Investigators must comply with this policy or the subrecipient must certify that its own research conflicts policy complies with all legal requirements.
- ii. The subrecipient Investigators must report any Significant Financial Interests to NYIT so that NYIT may make any required disclosures and reports.

Policy on Conflicts of Interest in Research

Appendix B is on next page

Financial Interest Disclosure Form

Investigator: _____ Department: _____ Phone: _____

Proposal Title: _____ Sponsor: _____

Please indicate below any **Significant Financial Interests** (as defined on page 2 of this Form) held by you or members of your immediate family (spouse and dependent children):

	I have Financial Interests to disclose		A member(s) of my Immediate Family has Financial Interests to disclose	
	YES	NO	YES	NO
Monetary Consideration (salary and/or other payments)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intellectual Property Rights	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Equity Interests	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (position as director, officer, manager, employee, or consultant)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If you have checked any of the “YES” boxes above, please provide a description of the nature and amount of the Interest on an additional page in a sealed envelope marked “Confidential.” Attach the envelope to this form and submit it with your proposal to the Office of Sponsored Programs and Research.

Travel (any travel reimbursed or sponsored by any entity other than a government agency, institution of higher education or affiliated research institute, academic teaching hospital, or medical center).

Purpose of the trip _____

Sponsor/Organizer _____

Destination _____

Duration _____

I have read and agree to abide by the New York Institute of Technology Policy on Conflicts of Interest in Research.

Signature

Date

Please do NOT write in this space. For office use only.

Disclosure statement was reviewed: no conflict of interest determined.

Conflict of Interest appropriately managed, reduced, or eliminated.

Refer to Committee on Objectivity in Research.

Signature: _____

**Policy on Conflicts of Interest in Research
Appendix B**

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 - i. In the case of a publicly traded entity, Remuneration and/or the value of any Equity Interest together totaling in excess of \$5,000 during the preceding twelve months;
 - ii. Remuneration from any non-publicly traded entity in excess of \$5,000 during the preceding twelve months, or any Equity Interest in a non-publicly traded entity;
 - iii. Intellectual property rights and interests in the Research (e.g. patents and copyrights) and the right to receive royalties therefrom;
2. Remuneration affected by the outcome of the Research—for example, compensation that is higher for a favorable outcome than for an unfavorable outcome;
3. Remuneration from the sponsor of the Research to the Investigator, or payments to NYIT to support activities of the Investigator, which remuneration or payments are over and above the costs of conducting the current Research project;
4. Position as a director, officer, manager, employee or consultant to an entity with a Significant Financial Interest in the Research.

“Significant Financial Interest” does not include the following:

- a. Remuneration paid to the Investigator by NYIT, including any share in royalties related to intellectual property rights assigned by the Investigator to NYIT, provided that the Investigator is currently employed or otherwise appointed by NYIT;
- b. Income from seminars, lectures or teaching engagements sponsored by a government agency, institution of higher education or affiliated research institute, academic teaching hospital, or medical center;
- c. Income from service on advisory committees or review panels for a government agency, institution of higher education or affiliated research institute, academic teaching hospital, or medical center.