

NOVA SOUTHEASTERN UNIVERSITY POLICY
Office of Grants and Contracts

Issue Date:	Revised May 31, 2006	This Policy Replaces: October 1, 1995 policy
Policy No:	OGC 99-06	Distribution: Faculty/Academic Administrators
Subject:	Financial Conflict of Interest with Respect to Sponsored Projects	
Reference:	NSU Policy NO: FA-12-Conflicts of Interest	

A. Purpose

These guidelines define general University policy and procedures regarding financial conflicts of interest in relation to sponsored projects involving research; teaching/training, and community service. Their purpose is to protect the credibility and integrity of the University's faculty and staff in order that public trust and confidence in the University's sponsored activities are ensured.

In accordance with Federal regulations, the University has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator. Therefore, the University requires that investigators disclose any significant financial interest that would reasonably appear to be affected by sponsored research.

B. Definitions

Conflict of Interest—A potential conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the University such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An actual conflict of interest depends on the situation and on the character or actions of the individual. For the purposes of this policy, a conflict of interest exists when the University, through procedures described herein, reasonably determines that a significant financial interest could affect directly and significantly the design, conduct, or reporting of sponsored projects.

Investigator—Investigator means the principal investigator/project director, co-principal investigators, and any other person who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor. In this context, the term "Investigator" includes the investigator's spouse and dependent children.

Significant Financial Interest—Significant financial interest means anything of monetary value, including, but not limited to:

- X salary or other payments for services (e.g., consulting fees or honoraria);
- X equity interests (e.g., stocks, stock options or other ownership interests);
- X intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

- X salary, royalties, or other remuneration from the University;
- X income from seminars, lectures, or teaching assignments sponsored by public or nonprofit entities;
- X income from service on advisory committees or review panels for public or nonprofit entities; or
- X an equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests:
 - . the equity interest does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and
 - . it does not represent more than a five (5) percent ownership interest for any one enterprise or entity; or
- X salary, royalties or other payments that, when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve (12) months, are not expected to exceed \$10,000.

C. Significant Financial Interests Disclosure

1. Each Investigator is required to disclose the following significant financial interests:
 - X Any significant financial interest of the Investigator that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
 - X Any significant financial interest of the Investigator in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

Regardless of the above minimum requirements, a faculty or staff member, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.
2. Each Investigator who has a significant financial interest requiring disclosure shall complete a Significant Financial Conflict of Interest Disclosure Form (OGC/99/Pre/04). The completed disclosure form, and the [Proposal Approval Record](#) (OGC/99/Pre/02) shall be submitted with the completed proposal to the Office of Grants and Contracts using normal University procedures.
3. As required by Federal regulation, all significant financial interests must be disclosed prior to the time a proposal is submitted. All financial disclosures must be updated by Investigators during the period of the award as new reportable significant financial interests are obtained. The attached Disclosure Update Form (OGC/99/Pre/04a), which is attached, will be used for this purpose.
4. Collaborators/subrecipients/subcontractors from other academic or not-for-profit institutions must either comply with this policy or provide certification from their institutions that they are in compliance with Federal policies regarding significant financial interest disclosure and that their portion of the project is in compliance with

their institutional policies. Subcontractors from commercial firms need not make a certification, except when the prime award is from the Public Health Service (PHS). The PHS requires a certification from any subcontractor, including commercial firms, stating that it is in compliance with Federal policies regarding Investigator significant financial interest disclosure and that its portion of the project is in compliance with company policies.

D. Review Process

First-Level Review--The dean/director will review the Significant Financial Conflict of Interest Disclosure Form submitted by the PI at the time of proposal review and approval. The dean/director will use a series of questions developed by the Association of American Medical Colleges (AAMC) and published in its *Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research* in the initial review of **positive** disclosures. Some of these questions include:

- X Has all relevant information concerning the faculty member's activities been acquired (i.e., has there been full disclosure)?
- X Do the faculty member's relevant financial interests exceed the predetermined thresholds of acceptability, where specified?
- X Do the faculty member's reported external commitments exceed permissible levels?
- X Is there any indication that research results have not been faithfully and accurately reported?
- X Is there any indication that the faculty member in his or her professional role has improperly favored any outside entity or appears to have an incentive to do so?
- X Has the faculty member inappropriately represented the institution to outside entities?
- X Does the faculty member appear to be subject to incentives that might lead to inappropriate bias?
- X Is there any indication that obligations to the University are not being met?
- X Could the faculty member's circumstances represent any possible violation of federal, state, or local laws and requirements?
- X Do the current engagements of the faculty member represent any conflicts between outside interests (e.g., working on projects simultaneously for competing business entities)?

The dean/director will sign the Significant Financial Conflict of Interest Disclosure Form indicating the finding. In those instances where financial conflict has not been resolved at the initial review stage, the disclosure is referred to the second level of review.

Second-Level Review-This review is conducted by the Vice President for Research and Technology Transfer and Governmental Affairs or the HPD - Chancellor, as appropriate. Example questions outlined by the AAMC can be used at the second-level review to assist in deciding which financial conflicts can be managed in a way that can ensure the protection of the integrity of the science and the institution and which cannot. These questions include:

- X Will the negotiation of relevant research affiliations or other contracts be handled by truly disinterested representatives of the institution?
- X Will the research workplan receive independent peer review prior to its initiation?

- X Are there mechanisms in place to prevent the introduction of bias into research projects (i.e., Is the protocol double-blinded? Are research subjects randomly selected?)?
- X Will the project be supervised by someone with authority and no conflicting interests?
- X Are there means to verify research results (e.g., independent corroboration in another lab, FDA review)?
- X Will data and materials be shared openly with independent researchers? If not, who determines accessibility to such resources?
- X Will the product of collaborative effort with an outside party be published in the peer-reviewed scientific literature?
- X Will the sponsorship and relevant interests receive acknowledgment in public presentations of the research results?

The Vice President for Research and Technology Transfer or the HPD - Chancellor, as appropriate, evaluates the disclosure and makes recommendations for how the financial conflict will be managed. Criteria such as the extent and nature of the involvement, the openness of the activity, the freedom of communication about the activity, the control of intellectual property arising from the activity, and the use of University resources, including the involvement of students, will be used in deciding what is allowable and what can be conditionally allowed in accordance with University policy and experience.

In cases in which the nature of the outside activity or relationship is such that it will not be possible to ensure the integrity of the science or the institution, the outside relationship or activity should be eliminated before research can proceed. In other cases, elimination of the outside relationship or activity may not be necessary or prudent. In these instances, careful monitoring and reporting will be crucial to ensuring that the objectivity of the science and the integrity of the institution are protected. As appropriate, certain types of requirements may be imposed, including:

- X modification of the research plan;
- X disqualification from participating in the portion of the externally funded research that would be affected by the significant financial interest; or
- X divestiture of significant financial interests.

E. Notification to Sponsoring Agency

1. In accordance with Federal regulations, the University, prior to the expenditure of any funds will report to the PHS awarding office the existence of a conflict of interest, but not the nature of the interest or other details, and assure that the interest has been managed, reduced, or eliminated. The University will report to the National Science Foundation (NSF) only those conflicts which cannot be satisfactorily managed, reduced, or eliminated.
2. The University shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

F. Opportunity for Appeal

There are no opportunities to appeal a decision rendered by the Vice President for Research and Technology Transfer or the HPD - Chancellor, as appropriate, on financial conflicts of interests.

G. *Procedure for Noncompliance with the Policy*

Failure to comply with the University's policy on financial conflicts of interest will be addressed by the Vice President for Research and Technology Transfer or the HPD - Chancellor, as appropriate, and the appropriate dean.

H. *Record Retention*

Records of investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest, shall be retained by the Vice President for Research and Technology Transfer, or the HPD Office of the Chancellor, as appropriate, until three (3) years after the termination or completion of the award to which they relate, or the resolution of any government action involving those records, whichever is later.

This policy was developed based on Pennsylvania State University's and the University of Hartford's Financial Conflict of Interest policies, and the guidelines set forth by the National Science Foundation which are consistent with the final Department of Health and Human Services rule on this subject.

**NOVA SOUTHEASTERN UNIVERSITY
FINANCIAL CONFLICT OF INTEREST DISCLOSURE FORM**

Reference: NSU Policy No: FA-12-Conflicts of Interest
OGC Policy No: 99-05-Financial Conflict of Interest with Respect to Sponsored Projects

1. Interest in private firms from which equipment, instruments, materials, or items will be purchased under attached proposal.
- a) Salaries or other payment for services (e.g., consulting fees or honoraria) Yes No
 - b) Equity interests (e.g., stock, stock options, or other ownership interests) Yes No
 - c) Intellectual property rights (e.g., patents, copyrights, and royalties from such rights) Yes No
 - d) Other Yes No

If you responded "Yes" to any of the above, indicate degree of commitment _____

2. Government consultancies: _____

3. I have engaged in a related extramural program with either a governmental agency or private firm within the past year. Yes No

If so, describe the involvement: _____

4. Other pertinent information: _____

Principal Investigator _____ Date _____

I have reviewed this disclosure and
 find no conflict of interest.
 find conflict of interest.
 I have referred this disclosure to the
VP-Research and Technology Transfer
for further review.

Dean Date

I have determined that
 no conflict of interest exists.
 a conflict of interest exists.

VP-Research and Technology Transfer
OR Chancellor—HPD Date

**NOVA SOUTHEASTERN UNIVERSITY
FINANCIAL CONFLICT OF INTEREST DISCLOSURE UPDATE FORM**

Reference: NSU Policy No: FA-12-Conflicts of Interest

OGC Policy No: 99-05-Financial Conflict of Interest with Respect to Sponsored Projects

Name of Principal Investigator: _____

Title of Research Project: _____

Current or Prospective Funder: _____

1. Interest in private firms from which equipment, instruments, materials, or items will be purchased under attached proposal.

- a) Salaries or other payment for services (e.g., consulting fees or honoraria) Yes No
- b) Equity interests (e.g., stock, stock options, or other ownership interests) Yes No
- c) Intellectual property rights (e.g., patents, copyrights, and royalties from such rights) Yes No
- d) Other Yes No

If you responded "Yes" to any of the above, indicate degree of commitment _____

2. Government consultantships:

3. I have engaged in a related extramural program with either a governmental agency or private firm within the past year.

Yes No

If so, describe the involvement _____

4. Other pertinent information:

Principal Investigator _____ Date _____

I have reviewed this disclosure and
 find no conflict of interest.
 find conflict of interest.
 I have referred this disclosure to the
VP-Research, Planning and Governmental
Affairs for further review.

I have determined that
 no conflict of interest exists.
 a conflict of interest exists.

Dean Date

VP-Research, Planning and Governmental Affairs
OR Chancellor—HPD Date