



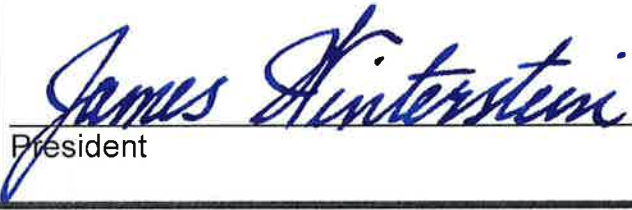
National University of Health Sciences General Policies

Title: **Financial Conflict of Interest
In Research**

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Date Adopted: 01/01/12

Date(s) Revised: 09/10/12



President



Date

POLICY STATEMENT

National University of Health Sciences (NUHS) encourages its faculty and employees to seek out and participate in sponsored research, to consult widely, and engage in other activities which may benefit not only the individuals, but also NUHS, the complementary and alternative medical profession, and the public.

When an individual has an external economic interest that affects the conduct of his or her NUHS activities, a conflict of interest exists. Financial conflicts of interest, for example, may threaten the objectivity and integrity of research. Objectivity of researchers is essential in scientific research and is important to maintain public trust. Research links to industry bring the possibility that scientific advancements will lead to financial gain. While this is not always unacceptable, concerns are raised when financial considerations may compromise or have the appearance of compromising an investigator's professional judgment and independence in the design, conduct, or reporting of research.

In pursuit of its own mission, and to meet the requirements of the United States Public Health Service (PHS) final rule on "Objectivity in Research" [42 CFR Part 50 and 45 CFR Part 94] effective October 1, 1995 and revised September 26, 2011, NUHS has formulated the following policy to identify and address potential, actual and apparent conflicts of interest and commitment. This policy is intended to help faculty, staff, and students recognize real and potential conflicts of interest, and to establish procedures whereby such conflicts may be avoided or properly managed.

PROCEDURES

In assuming its responsibility, NUHS intends to encourage the conduct of research which will benefit the human condition and, at the same time, maintain public trust by managing, reducing, or eliminating any conflicts of interest, and protect the investigators doing the research and NUHS. NUHS faculty, staff, and students conducting research under this policy are responsible for compliance with all federal regulations and any additional regulations required by NUHS or state and local laws or regulations which provide additional protections for human and animal subjects.

A. Administration

Executive functions to be performed by NUHS include the development and enforcement of this policy; making this policy publicly available via the NUHS Website; informing each Investigator of the NUHS policy; and requiring personnel to complete training with respect to policy prior to engaging in research related to any PHS-funded grant and at least every four years thereafter, or immediately if (1) NUHS revises its FCOI policy in any manner that affects the requirements of Investigators; (2) an Investigator is new to NUHS; (3) NUHS finds an Investigator is not in compliance with the policy or its management plan. If PHS-funded research is carried out through a subrecipient, NUHS will ensure that any subrecipient Investigator complies with this policy by incorporating, as part of the written agreement with the subrecipient institution, the FCOI policy that will apply to the subrecipient investigators. NUHS will provide any reports of conflicting interests of all subrecipients investigators to the PHS Awarding Components prior to expenditures of funds and within 60 days of any subsequently identified FCOI. NUHS officials responsible for carrying out or delegating these functions are the Dean of Research, Director of Financial Services, and the Vice President for Academic Services.

B. Applicability

This policy is applicable to all PHS-funded research which is conducted under the auspices of NUHS. If subgrantees, contractors, or collaborators are involved in the research, investigators working for such entities must assure NUHS that they are able to comply with this policy or a comparable policy at the sub recipient's institution. This policy is applicable to all faculty and staff of NUHS.

DEFINITIONS OF TERMS AND PHRASES

- *Investigator:* the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, including sub grantees, contractors, or collaborators. For purposes of this policy, investigator includes the investigator's spouse and dependent children.
- *PHS:* Public Health Service of the US Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- *Research:* a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research and encompasses basic and applied research and product development. As used in this policy, the term includes any such

activity for which research funding is available from a PHS Awarding Component.

- *Significant Financial Interest*: anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria; equity interests, including stocks, stock options or other ownership interests; and intellectual property rights, including patents, copyrights, and royalties from such rights.

The term does not include:

- Salary, royalties, or other remuneration from NUHS;
 - Any ownership interests in NUHS, if NUHS is an applicant under the Small Business Innovation Research Program of the Public Health Service;
 - Income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
 - Income from service on advisory committees or review panels for public or nonprofit entities;
 - An equity interest that when aggregated for the Investigator meets both of the following tests: does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity;
 - Salary, royalties, or other payments that when aggregated for the Investigator over any twelve month period does not exceed, or is not expected to exceed, \$5,000;
 - Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles
- *Disclosure of significant financial interests*: an Investigator's disclosure of significant financial interests to NUHS,
 - *Financial conflict of interest (FCOI)*: a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
 - *FCOI report*: an NUHS report of a financial conflict of interest to a PHS Awarding Component.
 - *Manage*: taking action to address a FCOI, which includes reducing or eliminating the FCOI, to ensure that the design, conduct and reporting of research will be free from bias or the appearance of bias.

DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

1. Prior to submitting applications to external agencies for Federal funding, each Investigator who is planning to participate in the research must submit to the NUHS Dean of Research a listing of all Significant Financial Interests, including the Interests of his or her spouse and dependent children, related to the Investigator's institutional responsibilities.
2. Investigators must inform the Dean of Research within 30 days of discovering or acquiring new Significant Financial Interests that may arise during the award period.
3. Investigators' Significant Financial Interests will be reviewed at least on an annual basis.
4. In their review of human subjects and animal subjects research respectively, the IRB and IACUC may request a list of Significant Financial Interests from Investigators or ask questions of investigators relating to financial conflicts of interest in order to determine that the research is objective and any conflicting interests would not pose risks to human or animal subjects.
5. The office of the Dean of Research will maintain records of all financial disclosures and actions taken by NUHS with respect to each conflicting interest for a period of at least three years from the date of submission of the final expenditures report, or other dates where applicable.

MANAGEMENT OF FINANCIAL CONFLICTING INTERESTS IN RESEARCH

After reviewing all financial disclosures, the Dean of Research will make a determination as to whether or not a conflict of interest exists. A conflict exists when a Significant Financial Interest could significantly affect the design, conduct, or reporting of the research. If the Dean of Research determines there is a conflict of interest, (s)he will determine what actions should be taken to manage, reduce, or eliminate the conflict of interest. Examples of conditions or restrictions that might be imposed to manage the conflict of interest include, but are not limited to:

1. Requiring public disclosure of significant financial interests (e.g. when presenting or publishing the research);
2. For research projects involving human subjects research, requiring disclosure of financial conflicts of interest directly to participants;
3. Requiring monitoring of the research by independent reviewers capable of taking measures to protect design, conduct, and reporting of the research against bias resulting from the FCOI;
4. Requesting a modification of the research plan;
5. Disqualifying an Investigator from participation in all or a part of the research;

6. Requesting the divestiture of significant financial interests (e.g. sale of equity interest);
7. Requesting severance of relationships responsible for actual or potential conflicts.

The Investigator with the FCOI, in conjunction with the project Principal Investigator (if a different individual) will develop a management plan incorporating the actions recommended by the Dean of Research. The plan will be submitted to the Dean of Research, the Director of Finance, and the chair of the IRB (or IACUC if the project involves research on humans or animals). The Dean of Research will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project. Prior to the NUHS's expenditure of any funds under a PHS-funded research project, NUHS will post on its Web site, or provide written response to any requestor within five business days of a request, information contained on the FCOI report including the Investigator's name, title, and role with respect to the research project; the 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. This information will be updated at least annually, or within 60 days of subsequently identified financial conflict of interest related to a PHS-funded research project.

In addition, NUHS will make information available to the Department of Health and Human Services (HHS) regarding the identification of conflicts of interest, how those interests were managed, and all records pertinent to compliance with this policy, upon request.

REPORTING FINANCIAL CONFLICTS OF INTEREST IN RESEARCH

Before any expenditure of funds under a Federal award, NUHS Director of Finance will submit a FCOI report as required by the regulation. If during the course of a project, an Investigator notifies the Dean of Research of a newly acquired or discovered significant financial interest, within 60 days, (s)he will review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and if so: implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward; NUHS Director of Finance will submit an updated FCOI report. All FCOI related records shall be maintained for at least 3 years from the date the final expenditure report is submitted.

A. Retrospective Review

Whenever a FCOI is not identified or managed in a timely manner, including the failure of an investigator to disclose a significant financial interest that is determined by NUHS to constitute a financial conflict of interest; failure by NUHS to review or manage such a financial conflict of interest; or failure by the Investigator to comply with this policy, NUHS Dean of Research shall, within

120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any portion of the project conducted during the time period of noncompliance was biased in the design, conduct, or reporting of such research. The retrospective review will be documented and include, but not necessarily be limited to, all of the following key elements:

- Project number
- Project title
- Project director/Principal Investigator (or contact PD/PI if multiple are used)
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has a FCOI
- Reason (s) for the retrospective review
- Detailed methodology used for the retrospective review
- Findings of the review
- Conclusions of the review

Based on the results of the retrospective review, if appropriate, the Director of Finance will update the previously submitted FCOI report, specifying the actions to be taken to manage the FCOI going forward. If bias is found, the Director of Finance, in conjunction with the Dean of Research, will immediately notify the PHS Awarding Component and submit a mitigation report which includes the above key elements, a description of the impact of the bias on the research project and NUHS plan of action(s) to eliminate or mitigate the effect of the bias.

SANCTIONS

If an investigator, faculty, or staff member refuses to comply with the Dean of Research recommendations regarding the elimination or management of a conflict of interest, disciplinary action shall be at the discretion of NUHS Vice President of Academic Services and consistent with NUHS policy and the Faculty Handbook procedure on grievances. Examples of such action include: removal from a project, letter of reprimand to be placed in the individual's personnel file, special monitoring of future work, probation, suspension, salary reduction, rank reduction, and termination of employment.

Sanctions shall be imposed no later than thirty (30) calendar days and no earlier than fifteen (15) calendar days after the report documenting noncompliance with this policy is forwarded to the President from the Vice President for Academic Services. Within ten (10) days after the report is forwarded, the NUHS employee shall be given an opportunity to present, in person or in writing, to the President, any facts or considerations he or she believes should be taken into account in the determination of an appropriate sanction.