

INTRODUCTION

As an institution of higher education, High Point University holds that its credibility and integrity are foundational to its existence. Sponsors, including the Federal Government, foundations, industry, and others, rely on High Point University's assurances that its research enterprise is free of influence and coercion.

This policy governing financial conflict of interest applies to all Investigators of High Point University engaging in research or other sponsored activity. The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy. This policy is in addition to other High Point University Conflict of Interest requirements.

DEFINITIONS

Clinical Trial means any research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices, or medical or other clinical procedures.

Conflict of Interest Committee (COI Committee) means the Institution's committee or individual that advises the Institutional Official on conflict of interest matters.

Family means any member of the Investigator's immediate family, but specifically refers to any dependent children and spouse.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on

behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income related to intellectual property rights and interests not reimbursed through the Institution.

Financial Conflict of Interest means a Significant Financial Interest (or, where the Institutional Official requires disclosure of other Financial Interests, a Financial Interest) that High Point University reasonably determines could directly and significantly affect the design, conduct or reporting of Institutional research.

Institutional Official means the individual within High Point University that is responsible for the solicitation and review of disclosures of significant financial interests, including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is the Director of Research Administration and Sponsored Programs.

Institutional responsibilities means the Investigator's responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Subrecipient means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that receives flow-through funding from High Point University.

CONFLICT OF INTEREST:

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs faculty about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and High Point University to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

Subrecipients that receive flow-through funding from High Point University shall meet the standards of this policy or certify that the Subrecipient possesses and maintains a conflict of interest policy that meets the requirements of all applicable Federal standards.

1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests to High Point University on an annual and on an ad hoc basis, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review, and retention of disclosure forms.

Regardless of the disclosure requirements, the Investigator, in his or her own best interest, is encouraged 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.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional Official or designee by March 1 for the previous calendar year.

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, within 30 days of their initial appointment or employment.

Prior to entering into sponsored projects or applications for sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial

Interests with the outside entity. High Point University will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

c) **Travel**

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest within thirty days of travel. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

2) **REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL**

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to eliminate, reduce, or manage the conflict, as appropriate.

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include, but are not limited to:

1. public disclosure of significant financial interests;
2. monitoring of research by independent reviewers;
3. modification of the research plan;
4. for research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
5. disqualification from participation in the portion of the research that would be affected by significant financial interests;
6. divestiture of significant financial interests; or
7. severance of relationships that create conflicts.

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of sponsor-supported research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written management plan before any related research goes forward. The affected Investigator or the COI Committee is responsible for developing and submitting a proposed management plan, in consultation with the Institutional Official.

To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to monitor the conduct of the activity

(including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

3) CLINICAL TRIALS

a) Review of Significant Financial Interests Related to Clinical Trials

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

b) Prohibition

An Investigator is prohibited from engaging in a clinical trial where a Significant Financial Conflict of Interest exists.

4) REPORTING TO PHS

Should any reported conflict or non-compliance require reporting to PHS, the Institutional Official will report in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

5) INVESTIGATOR NON-COMPLIANCE

a) Corrective Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other corrective action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

An Institutional Official's decision to apply corrective measures to an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the Investigator, Dean, Provost, and, where applicable, the Institutional Review Board, and will notify the Investigator of the right to appeal the decision.

b) Retrospective Review

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee of three faculty members appointed by the Institutional Official will complete a retrospective review of the Investigator's activities

and the research project within 120 days to determine whether the research conducted during the period of non-compliance was biased in the design, conduct, or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any previously submitted report to the sponsor, PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the sponsor or PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias. If required by PHS, High Point University will ensure disclosure of the Financial Conflict of Interest in each public presentation of the results and/or request an addendum to previously published presentations.

6) TRAINING

Each Investigator must complete training on this Policy prior to engaging in research and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

7) RECORD RETENTION

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the sponsor or longer as specified in 45 CFR 74.53(b) and 92.42(b), where applicable.

8) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, High Point University may make such information available to an agency funding research of the faculty member, to a requestor of information concerning financial conflict of interest related to sponsor, PHS funding agency or to the primary entity who made the funding available to the Institution, if requested or required. If High Point University is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

9) PUBLIC ACCESSIBILITY TO A PHS SIGNIFICANT FINANCIAL INTEREST DISCLOSURE

Prior to the expenditure of any PHS-related funds, High Point University will respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the Investigator;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS policy.

10) REGULATORY AUTHORITY

This policy implements the requirements of 42 CFR 50 and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.