

FAYETTEVILLE STATE UNIVERSITY

FINANCIAL CONFLICTS OF INTEREST (DHHS/PHS/NIH GRANTS AND CONTRACTS)

Authority:	Issued by the Chancellor. Changes or exceptions to administrative policies issued by the Chancellor may only be made by the Chancellor.
Category:	Research
Applies to:	●Administrators ●Faculty ●Staff ●Students
History:	First Issued – August 17, 2012
Related Policies:	● <i>Conflicts of Interest and Commitment and External Professional Activities for Pay</i> ● <i>Promoting Objectivity in Research</i> [42 C.F.R. Part 50, Subpart F]
Contact for Info:	Provost and Vice Chancellor for Academic Affairs (910) 672-1460 Office of Sponsored Research and Programs (910) 672-1570

I. INTRODUCTION

Financial Conflict of Interest (FCOI) regulations have been issued by the Public Health Service (PHS) of the U. S. Department of Health and Human Services which includes the National Institutes of Health (NIH). The intent of these regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by the PHS under grants, cooperative agreements or contracts will be free from bias resulting from the financial conflicts of interest.

Fayetteville State University (University) has issued this *Policy* for the purpose of ensuring compliance with these regulations. All Investigators (as defined in Section II below) applying for funds from PHS agencies are obliged to comply with the requirements of this *Policy*. This *Policy* is being issued as a supplement to the University's *Conflict of Interest and Commitment* policy

II. DEFINITIONS

The following definitions shall apply to this *Policy*:

A. Financial Conflict of Interest (FCOI)

A Financial Conflict of Interest is defined as a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

B. Financial Interest

Financial Interest is defined as anything of monetary value, whether or not the value is readily ascertainable.

C. Investigator

An Investigator is defined as the principal investigator stated in the application and other personnel, who would be responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding, which may include, for example, consultants and unpaid collaborators. In determining who is considered an investigator, the University shall consider the role, rather than the title, of those involved in the research and the degree of independence with which those individuals work. The lead principal investigator on a proposed PHS application for funding is responsible for obtaining a PHS Disclosure Form for all participating Investigators.

D. PHS

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 involved may be delegated, including the National Institutes of Health (NIH).

E. PHS Awarding Component

PHS Awarding Component is defined as the organizational unit of the PHS that funds the research that is subject to Policy.

F. Research

Research is defined as a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. 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), the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

G. Significant Financial Interest

A Significant Financial Interest is defined as a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's University's responsibility:

1. ***Remuneration from a Publicly Traded-Entity*** - With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (*e.g.*, consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership

interest, as determined through reference to public prices or other reasonable measures of fair market value.

2. ***Remuneration from a Privately Held Entity*** - With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (*e.g.*, stock, stock option, or other ownership interest).
3. ***Intellectual Property*** - Intellectual property rights and interests (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests.

Significant Financial Interest also includes ***Travel Reimbursements*** - Investigators must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to their University responsibilities in the twelve (12) months preceding the disclosure; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education (as defined at 20 U.S.C. 1001(a)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

The term Significant Financial Interest does not include the following:

- salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- 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;
- income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education (as defined at 20 U.S.C. 1001(a)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education (as defined at 20 U.S.C. 1001(a)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

H. University Responsibility

University Responsibility shall mean an Investigator's professional responsibilities on behalf of the University, including activities such as research, teaching, service or other professional responsibilities, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

III. DISCLOSURE OF FINANCIAL INTERESTS

Each Investigator who is planning to participate in PHS-funded research shall disclose to the University's Research Compliance Officer the Investigator's Significant Financial Interests (and those of the Investigator's spouse and dependent children). Such information shall be disclosed on the University's *PHS Disclosure Form*. The disclosures shall be timely made as follows:

A. Prior to Submission/Initiation of Research

Prior to an Investigator's submission of a grant application or the University's execution of a cooperative agreement or sponsored research contract, whether funded or not, each Investigator shall be required to submit the *PHS Disclosure Form* describing any Financial Interest held by the Investigator, the Investigator's spouse, or any dependent child of the Investigator that the Investigator determines to be reasonably related to the Investigator's University Responsibilities. The *PHS Disclosure Form* shall be submitted to the University's Research Compliance Officer.

B. Annual Update to Disclosure

Each Investigator who submits a *PHS Disclosure Form* to the University is required to update that disclosure annually during the period of the award or, for non-sponsored research, annually during the conduct of the project. Annual updates must be submitted by **April 30th** of each calendar year.

It is the responsibility of the principal investigator or project director of a research project to ensure that each Investigator, working on or who will work on a project, submits a timely annual update to a previously-submitted *PHS Disclosure Form*.

The annual update shall be submitted to the Research Compliance Officer, who will then review any updated Financial Interest disclosed.

C. Updating or Submitting a New Disclosure in an Ongoing Project

Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a Significant Financial Interest or an existing Investigator discloses a new Significant Financial Interest to the University, the Research Compliance Officer shall ensure that the following is done within sixty (60) days:

- review the disclosure of the Significant Financial Interest,
- determine whether it is related to PHS-funded research, and
- determine whether a FCOI exists, and, if so, notify the Associate Vice Chancellor for Research of the need to implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage the FCOI.

Depending on the nature of the Significant Financial Interest, the University may determine that additional interim measures are necessary with regard to the Investigator's

participation in the PHS funded research project between the date of disclosure and the completion of the University's review.

IV. REVIEW OF PHS DISCLOSURE FORMS

PHS Disclosure Forms submitted by Investigators shall initially be reviewed by the University's Research Compliance Officer. If a determination is made that a FCOI exists, further review by appropriate University officials will be necessary.

A. Review by Research Compliance Officer

The Research Compliance Officer shall review all *PHS Disclosure Forms* and determine whether an Investigator's Significant Financial Interest is related to PHS-funded research and, if so related, whether the Significant Financial Interest is a FCOI. An Investigator's Significant Financial Interest is related to PHS-funded research when the Research Compliance Officer reasonably determines that the Significant Financial Interest could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. A FCOI exists when the Research Compliance Officer reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

B. Review by the Associate Vice Chancellor for Research

If a determination is made by the Research Compliance Officer that a disclosed financial interest constitutes a Significant Financial Interest and that a FCOI may exist, the Research Compliance Officer shall notify the Associate Vice Chancellor for Research. The Associate Vice Chancellor for Research, in consultation with the Dean of the school or college where the Investigator has an appointment, shall review the submitted materials and determine if an actual or potential FCOI exists.

If after consulting with the Dean, the Associate Vice Chancellor for Research determines that no FCOI exists, the Associate Vice Chancellor for Research shall notify the appropriate parties to proceed with acceptance of the proposal and/or award, as applicable.

If after consulting with the Dean, the Associate Vice Chancellor for Research reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research, the Associated Vice Chancellor shall follow the procedures outlined in Section V below.

V. IDENTIFICATION OF A FINANCIAL CONFLICT OF INTEREST

If after consulting with the Dean, the Associate Vice Chancellor for Research reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research, the Associated Vice Chancellor for Research shall proceed as outlined below:

A. Significant Financial Interests Less than or Equal to \$10,000.00

For cases involving the disclosure of a Significant Financial Interest having a value less than \$10,000.00, the Associate Vice Chancellor for Research shall be responsible for determining whether further action is required to implement conditions designed to manage the conflict and if so, determining the necessary components of a management plan. A management plan shall be developed in consultation with the Investigator, the appropriate Department Chair or Director and the Investigator's Dean. The Associate Vice Chancellor for Research may also consult with others as needed.

B. Significant Financial Interests Greater than \$10,000.00

For cases involving the disclosure of a Significant Financial Interest having a value greater than \$10,000.00, the Associate Vice Chancellor for Research and the Department appropriate Department Chair or Director, the Dean and the Chair of the Ethics Committee shall be responsible for determining whether further action is required to implement conditions designed to manage the conflict and if so, determining the necessary components of a management plan. A management plan shall be developed in consultation with the Investigator, the appropriate Department Chair or Director, the Investigator's Dean and the Chair of the Ethics Committee. The Associate Vice Chancellor for Research may also consult with others as needed.

VI. MANAGEMENT OF FINANCIAL CONFLICTS OF INTERESTS

When a determination has been made that a FCOI exists, the individual or individuals mentioned above will develop and implement a plan to manage the FCOI. Managing the conflict should include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

Conditions or restrictions that may be imposed to manage a FCOI include, but are not limited to the following:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, or the appearance of bias, resulting from the financial conflict of interest;
- 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 financial interest (e.g., sale of an equity interest); and
- Severance of relationships that create actual or potential financial conflicts.

When the University implements a management plan pursuant to this *Policy*, the Research Compliance Officer shall be responsible for monitoring the Investigator's compliance with the management plan on an ongoing basis until the completion of the PHS-funded research is completed.

VII. SUBRECIPIENTS COMPLIANCE AND REPORTING

Any University PHS-funded research carried out through a subrecipient (e.g., subcontractors or consortium members), shall include as part of a written agreement with the subrecipient terms that establish whether the University's or the subrecipient's policy on conflict of interest in research will apply to the subrecipient's Investigators.

If the subrecipient's policy will apply, the subrecipient shall certify as part of the agreement that its policy complies with the PHS regulations on Objectivity in Research. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient's Investigators are subject to this *Policy* for the disclosure of Significant Financial Interests that are directly related to the subrecipient's work for the University.

If the subrecipient can provide such certification, the agreement shall specify time period(s) for the subrecipient to report all identified FCOIs to the University to enable the University to provide timely reports to the PHS Awarding Component.

Alternatively, if the University's *Policy* will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures of Significant Financial Interests to the University. Such time periods (, *i.e.*, prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI) shall be sufficient to enable the University to comply with timely review, management, and reporting obligations to the PHS Awarding Component.

VIII. REPORTING REQUIREMENTS

A. Reporting Financial Conflicts of Interests

Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, the University, through the Associate Vice Chancellor for Research, shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's Significant Financial Interest found by the University to be a FCOI. This report shall be submitted by the Associate Vice Chancellor for Research on behalf of the University. If the FCOI is eliminated prior to the expenditure of PHS-awarded funds, the University will not be required to submit an FCOI report to the PHS Awarding Component.

B. Reporting After Filing an Initial Report

If subsequent to the University's initial FCOI report, the University identifies any Significant Financial Interest as being a FCOI during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the University shall submit a FCOI report regarding the FCOI and ensure that a management plan has been implemented, at least on an interim basis. Such must be done within sixty (60) days of the identification of the FCOI.
FCOI report involves a significant

C. Annual Reports

For any financial conflict of interest previously reported by the University with regard to an ongoing PHS-funded research project, the University shall provide to the PHS

Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. The University shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

IX. NONCOMPLIANCE

A. Failure to File or Truthfully Disclose

Failure to file a PHS Disclosure Form or truthfully disclose a Significant Financial Interest as required by this *Policy* constitutes a violation of this Policy and may be violation of state and/or federal law.

Such failure shall subject the Investigator to appropriate sanctions consistent with applicable disciplinary policies. In addition, the University may suspend an ongoing research project, halt the expenditure of funds, or suspend technology transfer activity to prevent continued violation of this Policy. The University shall also consider the withdrawal of any affected applications for funding if the project cannot otherwise be completed without the services of the Investigator.

If the Investigator's failure to file or truthfully disclose plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Associate Vice Chancellor for Research shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

B. Failure to Comply with a Management Plan

Failure to comply with the conditions or restrictions imposed in the resolution, management, or elimination of an FCOI constitutes a violation of this Policy and may be violation of state and/or federal law.

Such failure shall subject the Investigator to appropriate sanctions consistent with applicable disciplinary policies. In addition, the University may suspend an ongoing research project, halt the expenditure of funds, or suspend technology transfer activity to prevent continued violation of this Policy. The University shall also consider the withdrawal of any affected applications for funding if the project cannot otherwise be completed without the services of the Investigator.

If the Investigator's failure to comply with the management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Associate Vice Chancellor for Research shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

C. Retrospective Review for Untimely Disclosures

In the event the University identifies a Significant Financial Interest that was not disclosed in a timely manner such as the following:

- failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest,
- failure by the Institution to review or manage such a financial conflict of interest, or
- failure by the Investigator to comply with a financial conflict of interest management plan,

and where it has been determined that the undisclosed Significant Financial Interest constitutes a FCOI related to a PHS-funded research project, the Associate Vice Chancellor for Research shall, within 120 days of the University's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS funded research project. Such a review shall occur 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.

If the Associate Vice Chancellor for Research determines in the conduct of the retrospective review of PHS-funded research that the research or any part of it was biased, the Associate Vice Chancellor for Research shall recommend a mitigation plan to the Provost and Vice Chancellor for Academic Affairs to address any such issues.

The Associate Vice Chancellor for Research shall also update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI in the future. If bias is found, the Associate Vice Chancellor for Research will promptly notify and submit a mitigation report to the PHS Awarding Component.

X. RECORDS

The University, through its Office of Sponsored Research and Programs shall maintain records relating to all Investigator disclosures of Financial Interests and the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the University's determination of a FCOI) and all actions under the University's policy or retrospective review, if applicable, for at least three (3) years from the date the final expenditures report is submitted to the PHS Awarding Component or, where applicable, from other dates specified by federal laws or regulations.

XI. TRAINING

Prior to engaging in a PHS-funded research project, all Investigators shall complete training on the Investigator's obligations under this *Policy*. This training must be repeated at least every four years and must be completed immediately if this *Policy* is revised so as to affect the Investigator's obligations, if an Investigator is new to the University, or if the University finds an Investigator to have violated this *Policy* or any applicable management plan.

**FAYETTEVILLE STATE UNIVERSITY
PUBLIC HEALTH SERVICE (PHS) DISCLOSURE FORM**

Investigator	
School/College/Center	
Principal Investigator of Record	
Project Title	
PHS Sponsor	

Do you (or your spouse or dependent children) have a Significant Financial Interest consisting of one or more of the following that reasonably appears to be related to your University's responsibilities. (Please see the University's policy on *Financial Conflicts of Interest* for definitions.)

Yes NO (If Yes, please check all that apply)

- Remuneration from a publicly traded entity exceeding \$5,000.00 in the twelve months preceding this disclosure. Remuneration includes *salary* and *any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest* includes *any stock, stock option, or other ownership interest..*
- Remuneration from a privately held entity exceeding \$5,000.00 or any equity interest (*e.g., stock, stock option, or other ownership interest*)
- Intellectual Property Rights (*e.g., patents, copyrights or royalties from such rights*)
- Travel Reimbursements (Does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education (as defined at 20 U.S.C. 1001(a)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

A written explanation of each Significant Financial Interest must accompany this form. Submit this form and the documentation to the Research Compliance Officer in a sealed envelope marked Confidential. This documentation must be submitted

DISCLOSURE CERTIFICATION

In submitting this form, I certify that the above information is true to the best of my knowledge and that I have read and understand the University's policies governing conflicts of interest. Further I agree to the following:

- To provide additional information or supporting documentation, if requested;
- To update this disclosure during the period of the award should any new reportable Significant Financial Interest be obtained; and
- To comply with any conditions or restrictions imposed by the University to manage, reduce or eliminate actual or potential conflicts of interest or forfeit the award

Signature _____ Date _____