

Regulation on Implementing the UNC Conflict of Interest and Commitment Policy

I. Purpose. The purpose of these guidelines is to provide a framework for Constituent Institutions in the development, implementation, publicizing, training, monitoring, and enforcement of implementing Institutional policies and procedures for the UNC Policy on Conflict of Interest and Commitment (see UNC Policy Manual 300.2.2). These guidelines are organized to provide definitions and examples of conflicts of interest and commitment within the context of the policy; however, Constituent Institutions shall adopt their own policies, regulations, and rules that best fit their Constituent Institution's regulatory framework not inconsistent with federal and state law and University policies. The System Office and Constituent Institutions will be compliant regarding conflict of interest and commitment standards as required by the terms of its agreement with external sponsors, which may change from time to time. As federal agencies may have differing requirements, standards and reporting on these research projects will be responsive to the standards and guidelines set by those agencies.

II. Categories of Potential Financial Conflicts of Interest. Activities that may involve a Conflict of Interest may be categorized under four general headings: first, those that are allowable and are disclosed; second, those that are allowable with administrative approval and are disclosed; third, those that generally are not allowable and require an approved conflict of interest management plan; and fourth, those that are not allowable under any circumstances. The following examples are merely illustrative and do not purport to include all possible situations within the four categories:

A. Activities that are allowable and are disclosed.

The examples cited below involve activities external to University Employment, and thus may present the appearance of a financial conflict of interest but have little or no potential for affecting the objectivity of the Covered Employee's performance of University Employment Responsibilities; at most, some such situations could prompt questions about conflicts of commitment.

1. A Covered Employee receiving royalties from the publication of books or for the licensure of patented inventions subject to the UNC Patent and Copyright Policies.
2. A Covered Employee receiving compensation in the form of honoraria or expense reimbursement, in connection with service to professional associations, service on review panels, presentation of scholarly works, and participation in accreditation reviews.

B. Activities requiring disclosure for further administrative review and analysis.

The examples cited below suggest a possibility of conflicting interests that can impair objectivity, but disclosure and resulting analysis of relationships may render the activity permissible and may result in the establishment of an approved Conflict of Interest Management Plan.

1. A Covered Employee requiring students to purchase the textbook or related instructional materials authored by the employee or members of their immediate family, which produces compensation for the employee or family member.
2. A Covered Employee receiving compensation or gratuities from any individual or entity doing business with the University. Nothing in this subsection authorizes accepting compensation or gratuities where prohibited by federal or state law.
3. A Covered Employee serving on the board of directors or scientific advisory board of an enterprise that provides financial support for University research where the employee or a member of their immediate family may receive such financial support.
4. Covered Employee participating in a Foreign Government Talent Recruitment Program as defined in UNC Policy Manual, Section 300.2.2.
5. A Covered Employee or a member of their immediate family (see UNC Policy Manual, Section 300.2.2, which includes the person's spouse and dependent children) having an equity or ownership interest in a publicly or non-publicly traded entity or enterprise.
6. External Professional Activities governed by and approved pursuant to UNC Policy Manual, Section 300.2.2.1[R].

C. Activities or relationships that are generally not allowable or permitted unless an approved Conflict of Interest Management Plan is in place.

The examples cited below involve situations that are not generally permissible, because they involve potential financial conflicts of interest, or they present obvious opportunities or inducements to favor personal interests over Institutional interests. Before proceeding with such an endeavor, the Covered Employee would have to demonstrate that in fact their objectivity would not be affected, and University interests otherwise would not be damaged, and an approved Conflict of Interest Management Plan is in place.

1. A Covered Employee participating in University research involving a technology owned by or contractually obligated to (by license or an option to license, or otherwise) an enterprise or entity in which the individual or a member of their immediate family has a consulting relationship, has an equity or ownership interest, or holds an executive position.
2. A Covered Employee participating in University research that is funded by a grant or contract from an enterprise or entity in which the individual or a member of their immediate family has an equity or ownership interest.
3. A Covered Employee assigning students, post-doctoral fellows, or other trainees to University research projects sponsored by an enterprise or entity in which the individual or a member of their immediate family has an equity or ownership interest.

D. Activities that are not allowable under any circumstances.

1. A Covered Employee making referrals of University business to an external enterprise in which the individual or a member of their immediate family has a financial interest.
2. A Covered Employee associating their own name with the University in such a way as to profit financially by trading on the reputation or goodwill of the university.
3. A Covered Employee making unauthorized use of privileged information acquired in connection with one's University responsibilities.
4. A Covered Employee signing agreements that assign Institution patent and other intellectual property rights to third parties without prior Institutional approval.
5. A Covered Employee benefiting from a public contract in violation of G.S. 14-234, accepting gifts or favors from vendors or contractors in violation of G.S. 133-32, or engaging in activities prohibited under G.S. Chapter 138A.
6. Any activity otherwise prohibited by law or University policy.

III. Federal and State Regulations. The following resources are established to provide guidance to UNC Constituent Institutions in the establishment of implementing policies for the avoidance of conflicts of interest and conflicts of commitment in the conduct on university responsibilities including teaching, research, and service. The Institution may have more stringent financial disclosure requirements. Please refer to the constituent Institution's conflict of interest policy and confer with the Institution's designated official(s) to determine the Institution's disclosure requirements.

A. Public Health Service/US Department of Health and Human Services

The Public Health Service (PHS) and the U.S. Department of Health and Human Services issued revised regulations on the *"Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors"* (commonly known as the Financial Conflict of Interest (FCOI) regulations) on August 25, 2011. These regulations establish new standards and clarify previously issued standards to be followed by Institutions that apply for or receive research funding from PHS Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts. The 2011 revised regulations were written to increase accountability, add transparency, enhance regulatory compliance and effective Institutional management of Investigator's financial conflicts of interest, and strengthen PHS's compliance oversight. The primary goal is to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements, and research contracts will be free from bias resulting from Investigator financial conflicts of interest.

Institutions must maintain an up-to-date written Conflict of Interest policy, must ensure the policy is enforced, and must make the policy available via a publicly available website. The Institution must inform Investigators of their responsibilities regarding disclosure of significant financial interests and the applicable federal regulations.

The full regulatory citation for the PHS policy is located at the following URL:
<http://grants.nih.gov/grants/policy/coi/>

1. Required Compliance/Implementation Date

An Institution applying for or receiving PHS funding from a grant or cooperative agreement must be in compliance with all revised regulatory requirements no later than 365 days after publication of the regulation in the Federal Register, i.e., August 24, 2012, and immediately upon making the Institution's Financial Conflict of Interest policy publicly accessible as described in 42 CFR part 50.604(a). When the Institution posts its Financial Conflict of Interest policy (or, if the Institution does not have a current presence on a publicly accessible website, makes the policy publicly accessible by written request), it signifies that the Institution applying for or receiving PHS funding from a grant or cooperative agreement that is covered by the 2011 revised regulation is in full compliance with all the regulatory requirements. The Institution must be in compliance with the 2011 revised regulation no later than August 24, 2012.

2. Applicability of Revised FCOI Regulations (Institutions)

The regulation is applicable to each Institution that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement. The revised regulation will apply to each grant or cooperative agreement with an issue date of the Notice of Award that is subsequent to the compliance dates of the final rule (including noncompeting continuations) no later than August 24, 2012 and immediately upon making its Financial Conflict of Interest policy publicly accessible. Through their policies, however, Institutions may choose to apply the revised regulations to all active PHS awards. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) Small Business Technology Transfer Research (STTR) applications.

3. Applicability of Revised FCOI Regulations (Investigators)

The regulation is applicable to each Investigator, through implementation of the regulation by the Institution, who is planning to participate in, or is participating in PHS research funded by means of a grant or cooperative agreement. The term Investigator applies to the individual identified as 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 and may apply to faculty, post-doctoral fellows, and graduate students. For purposes of financial disclosure only, the regulation covers the Investigator's spouse and dependent children. The regulation also applies to those few cases where an individual, rather than an Institution, is applying for or receives PHS research funding. However, in those cases, the PHS will make case-by-case determinations on the steps an Institution or an Investigator must take, consistent with the regulation, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from a Financial Conflict of Interest of the individual.

4. Applicability of Revised FCOI Regulation (Subrecipients)

The revised regulation is applicable to each Institution that applies for or receives PHS funding for research through grants or cooperative agreements and, through the implementation of the regulation by each Institution, to each Investigator planning to participate in, or participating in, such research. A subrecipient relationship is established

when federal funds flow down from or through an awardee Institution to another individual or entity and the subrecipient will be conducting a substantive portion of the PHS-funded research project and is accountable to the awardee Institution for programmatic outcomes and compliance matters. Accordingly, as a recipient of federal funds from an awardee Institution, the Financial Conflict of Interest regulation applies to subrecipients (e.g., subcontractors or consortium members). See 42 CFR 50.604 (c). The awardee Institution must determine if the Conflict-of-Interest policy of the awardee Institution or the Subrecipient will apply to the Subrecipient's Investigator(s) and incorporate language into the written agreement that designates the applicable Conflict of Interest policy.

5. Organizational Structure/Designated Official

An Institution may administer its policy through whichever office or structure it chooses as long as the policy is applicable to all Investigators and the policy meets all requirements of the regulation. Each Institution must designate official(s) to review all financial disclosures by Investigators and determine whether any Significant Financial Interest is related to a PHS-funded research and a Financial Conflict of Interests exists by making a reasonable determination 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.

6. Required Training

Institutions are expected to develop and implement their Financial Conflict of Interest policies during the 365-day implementation period provided in the 2011 revised regulation. Once the Institution implements and posts their Financial Conflict of Interest policy as required under the final rule, Investigators are expected to then complete required training prior to engaging in PHS-supported research or by the issue date of the Notice of Award issued subsequent to the Institution's implementation date. NIH has issued a Conflict of Interest tutorial that can be incorporated into campus training programs, which can be accessed from the URL cited at the beginning of Section I of the Guidelines. Each Investigator (as defined by the regulation), including Subrecipient Investigator(s), must complete training prior to engaging in PHS-funded research and at least every four years, and immediately under specifically designated circumstances:

- a. Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements;
- b. An Investigator is new to an Institution; or,
- c. An Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest policy or management plan.

7. Disclosure

a. *Institutional responsibilities:*

1. Under the revised FCOI regulation, Significant Financial Interests that are subject to disclosure by an Investigator to an Institution are those

that reasonably appear to be related to the Investigator's "Institutional responsibilities," as defined by the Institution. As a result, when read in conjunction with the revised Investigator disclosure requirements under 42 CFR 50.604, the revised Significant Financial Interest definition results in the disclosure by Investigators to Institutions of a wider array of interests on a more frequent basis. In addition to their own, Investigators are required to disclose the Significant Financial Interests of their spouse and dependent children.

b. *Monetary threshold:*

1. The Significant Financial Interest *de minimis* threshold is \$5,000 and, in some circumstances, monetary thresholds for disclosure may be \$0.

2. The definition also differentiates between remuneration to the Investigator (and the Investigator's spouse and dependent children) from a publicly traded entity and remuneration from a non-publicly traded entity. With regard to a publicly traded entity, a monetary threshold of \$5,000 applies to the aggregated amount of any remuneration received from the entity in the twelve months preceding disclosure and the value of any equity interest as of the date of disclosure. With regard to a 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).

c. *Timing:*

1. The revised Significant Financial Interest definition applies to any remuneration received from an entity in the twelve months preceding the disclosure. Any Investigator who is planning to participate in PHS-funded research must disclose the Investigator's Significant Financial Interests no later than the time of application for PHS-funded research. In addition, each such Investigator must submit an updated disclosure or Significant Financial Interests within thirty days of discovering or acquiring (such as through purchase, marriage, or inheritance) a new Significant Financial Interest.

d. *Reimbursed or Sponsored Travel:*

1. 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 the Investigator's Institutional responsibilities. However, the disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- a. a federal, state, or local government agency,
- b. an Institution of higher education as defined at 20 U.S.C. 1001(a),
- c. an academic teaching hospital,
- d. a medical center, or
- e. a research institute that is affiliated with an Institution of higher education.

e. *Exclusions:*

1. The revised regulation modifies the types of interests that are specifically excluded from the Significant Financial Interest definition.

The exclusions are:

- a. salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
- b. intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- c. any ownership interests in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- d. 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;
- e. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined in 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;
- f. income from service on advisory committees or review panels for a federal, state, or local government agency, or 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.

f. *Paid Authorships:*

1. Paid authorships are considered payment for services under the revised regulations and must be disclosed.

8. Consequences of Investigator Non-Compliance

- a. When an Investigator fails to comply with the Institution's Financial Conflict of Interest policy or the management plan, the Institution shall within 120 days:

1. complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine any bias in the design, conduct, or reporting of research;

2. document the retrospective review consistent with the regulation; and

3. document the Institution's determination as to whether any PHS-funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with the Institution's Financial Conflict of Interest policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research.

4. If bias is found, the Institution shall notify the PHS promptly and submit a mitigation report to the PHS that shall address the following:

- a. impact of the bias on the research project, and

- b. the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.

5. Thereafter, the Institution shall submit FCOI reports annually, in accordance with the regulation. Depending on the nature of the Financial Conflict of Interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the Financial Conflict of Interest is identified and the completion of the Institution's independent retrospective review, in accordance with 42 CFR 50.605(a)(3) and 42 CFR 50.605(b)(3).

9. Clinical Research to Evaluate the Safety or Effectiveness of Drug, Medical Device, or Treatment

The revised regulations contain special provisions for Clinical Research. If the HHS determines that an PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not managed or reported by the Institution as required by the regulation, the Institution must require the Investigator(s) involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to

previously published presentations. Institution's Financial Conflict of Interest policy may have additional requirements.

10. Institutional Reporting of Identified Financial Conflicts of Interest to PHS

Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS awarding component any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with the revised regulations. Further, the Institution will provide annual FCOI reports for the duration of the project period. Any FCOI report required under the revised regulations shall include, at a minimum, the following information:

- a. PHS-Funded Research Project Number
- b. Name of the Principal Investigator
- c. Name of the Investigator with the financial conflict of interest
- d. Name of the entity with which the Investigator has a financial conflict of interest
- e. Nature of the financial interest
- f. Value of the financial interest, or a statement if the interest is one whose value cannot be readily determined through to public prices or other reasonable measures of fair market value
- g. Description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with the research
- h. Description of key elements of the Institution's management plan, including:
 1. Role and principal duties of the conflicted Investigator in the research project
 2. Conditions of the management plan
 3. How the management plan is designed to safeguard objectivity in the research project
 4. Confirmation of the Investigator's agreement to the management plan
 5. How the management plan will be monitored
 6. Other information as needed

11. Public Accessibility of Identified Financial Conflicts of Interest

Prior to the expenditure of PHS funds on or after August 24, 2012, the Institution must ensure public accessibility (via publicly available website or response to written request within five (5) business days of the request) of information concerning significant financial interests disclosed to the Institution that are:

- a. Previously disclosed and currently held by Investigators or Senior/Key Personnel;
- b. The significant financial interest is related to PHS-funded research; and
- c. The Institution has determined the Significant Financial Interest is a Financial Conflict of Interest. The information the Institution must make publicly available must be updated at least annually, must be maintained for a period of three years from the last update, and must include the following data elements at a minimum:
 1. Investigator Name
 2. Investigator Title
 3. Investigator role with respect to the research project
 4. Name of the entity in which the Significant Financial Interest is held
 5. Nature of the Significant Financial Interest
 6. Approximate dollar value of the Significant Financial Interest, or a statement if the interest is one whose value cannot be readily determined through to public prices or other reasonable measures of fair market value.

B. Definitions

See the notice announcing the availability of new Frequently Asked Questions (FAQs) related to the 2011 revised regulations for a list of definitions at <http://grants.nih.gov/grants/policy/coi/>. Following are some key definitions:

1. *Senior/Key Personnel* means the Project Director/Principal Investigator (PD/PI) and any other person *identified* as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation.
2. *Investigator* means 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 (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of Investigator is limited to titles

or designations (e.g., to principal Investigators, key personnel, faculty) the risk increases that an unidentified FCOI may comprise the research.

3. *Institutional responsibilities* are defined by the 2011 revised regulation as an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on Financial Conflict of Interest, which may include, for example, activities such as research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards. The Institution can include other professional responsibilities within the definition, as appropriate.

4. A *Financial Conflict of Interest* exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a PHS-funded research project and could directly and significantly affect the design, conduct or reporting of the PHS-funded research.

5. *Significant Financial Interest* is defined as follows:

a. 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 Institutional responsibilities:

1. 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. 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); or

3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

b. Investigators also 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). See Section II.A.7.d above.

c. The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including:

1. intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
2. any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
3. 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;
4. 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
5. 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.

C. National Science Foundation

The full regulatory citation for the National Science Foundation is located at the following URL: http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510

1. NSF requires each grantee Institution employing more than fifty persons to maintain an appropriate written and enforced policy on conflict of interest. Guidance for such policies has been issued by University associations and scientific societies.
2. An Institutional conflict of interest policy should require that each Investigator disclose to a responsible representative of the Institution all significant financial interests of the Investigator (including those of the Investigator's spouse and dependent children) (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.
3. The term "Investigator" means the principal Investigator, co-principal Investigators, and any other person at the Institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.
4. The term "significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees

or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

- a. salary, royalties, or other remuneration from the applicant Institution;
- b. any ownership interests in the Institution, if the Institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
- c. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- d. income from service on advisory committees or review panels for public or nonprofit entities;
- e. an equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
- f. salary, royalties, or other payments that, when aggregated for the Investigator and the Investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve-month period.

5. An Institutional policy must ensure that Investigators have provided all required financial disclosures at the time the proposal is submitted to NSF. It must also require that those financial disclosures are updated during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained.

6. An Institutional policy must designate one or more persons to review financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by the Institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the reviewer(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

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

- a. public disclosure of significant financial interests;
- b. monitoring of research by independent reviewers;
- c. modification of the research plan;
- d. disqualification from participation in the portion of the NSF-funded research that would be affected by significant financial interests;

- e. divestiture of significant financial interests; or
- f. severance of relationships that create conflicts.

8. If the reviewer(s) determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s) may allow the research to go forward without imposing such conditions or restrictions.

- a. The Institutional policy must include adequate enforcement mechanisms and provide for sanctions where appropriate.
- b. The Institutional policy must include arrangements for keeping NSF's Office of the General Counsel appropriately informed if the Institution finds that it is unable to satisfactorily manage a conflict of interest.
- c. Institutions must maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

D. North Carolina General Statute 138A "State Government Ethics Act"

The purpose of the "State Government Ethics Act" is to ensure that elected and appointed State agency officials exercise their authority honestly and fairly, free from impropriety, threats, favoritism, and undue influence. To this end, it is the intent of the General Assembly in this Chapter to ensure that standards of ethical conduct and standards regarding conflicts of interest are clearly established for elected and appointed State agency officials, that the State continually educates these officials on matters of ethical conduct and conflicts of interest, that potential and actual conflicts of interests are identified and resolved, and that violations of standards of ethical conduct and conflicts of interest are investigated and properly addressed. (2006-201, s. 1.)

The full general statute is located at the following URL:
http://www.ncga.state.nc.us/enactedlegislation/statutes/html/bychapter/chapter_138a.html

E. North Carolina General Statutes 14-234 "Public Officers or Employees Benefiting from Public Contracts"

The purpose of the Public Officers or Employees Benefiting from Public Contracts statute is to ensure the making and administering of public contracts is free of bias, inappropriate influence, conflict of interest, and does not result in personal benefit to the public officer or employee.

The full general statute is located at the following URL:
http://www.ncga.state.nc.us/EnactedLegislation/Statutes/HTML/BySection/Chapter_14/GS_14-234.html

IV. Other Matters

A. Effective Date. The requirements of this regulation will be effective on the date of adoption of this regulation by the president.

B. Relation to State Laws. The foregoing regulation as adopted by the president is meant to supplement, and does not purport to supplant or modify, those statutory enactments, regulations, and policies which may govern the activities of public officials.