

Wake Forest University

Reynolda Campus

Conflicts of Interest Policy



as of February 1, 2018

Introduction

Wake Forest University is committed to meeting the highest ethical and legal standards. This policy is designed to reinforce a standard of conduct that engenders public trust in the University, preserves its reputation and financial well-being and protects it from exposure to unnecessary legal risk.

This policy provides:

- A definition of Conflicts of Interest.
- A means of disclosing actual and potential Conflicts of Interest.
- A process for review of such conflicts.
- A means of developing plans to manage such conflicts when needed.
- A source of advice regarding management of such conflicts.
- An appeal process when differences arise over conflict management plans.
- Sanctions for non-compliance with policy, management plans or annual disclosure completion.

Compliance with the policy is required of all Members of the Wake Forest community, defined in **Appendix A**. For policies regarding conflicts of commitment, please consult the appropriate Faculty Handbook or Staff Handbook.

Definitions

Definitions of capitalized terms used within this policy can be found in **Appendix A**.

Statement of Policy

1. Members will strive to identify and avoid Conflicts of Interest. While this policy focuses on the relationships of the Member and the Member's Family, it is important to note that any relationship between the Member and an individual or entity that is similar to a Family relationship in loyalty or importance, may need to be disclosed.
2. All Conflicts of Interest must be reported to the University:
 - Annually, when notified by the Conflict of Interest Office (COI Office), Members will submit an electronic disclosure describing any actual or potential Conflicts of Interest as defined in **Appendix A**. The electronic disclosure will be routed for review by the appropriate Reviewer noted in **Appendix B**.

- In addition to the annual disclosure, Members must immediately disclose to their Reviewer and the COI Office new potential conflicts of interest within 30 days of the Member's awareness of such actual or potential conflicts. If the new conflict of interest involves any sponsor of the Member's research or a research project that evaluates intellectual property with which the Member has a financial interest, the Office of Research and Sponsored Programs must be notified immediately.
3. A Member must work with his/her Reviewer and the COI Office to manage or resolve identified conflicts.
 4. Members involved in research funded by a Public Health Service (PHS) Agency must comply and must assist the University in complying with the requirements of **Appendix C**.

Good judgment is essential; no list of rules or guidelines can provide direction for all the circumstances that may arise. Examples of actual and potential Conflicts of Interest are included in **Appendix D**.

Review

The Reviewer (see **Appendix B**) will work with the COI Office to determine whether Conflicts of Interest exist and if so, what conditions or restrictions, if any, should be imposed by the University to manage, reduce, or eliminate such Conflicts of Interest. If guidance is needed, the COI Office should be consulted. All determinations will be made and communicated to the Reviewer promptly. If management is necessary, the management plan may be developed with the assistance of the COI Office and by using the Management Plan Template found at: <http://compliance.wfu.edu/conflict-of-interest/>

A review by the COI Office to determine if a management plan falls within standards set by the Committee on Conflicts of Interest (the Committee) will proceed in a timely and confidential manner. A flow chart describing the review and appeals process is in **Appendix E**.

At least annually researchers with a Conflict of Interest will describe how the Member and other financially-interested parties have demonstrated compliance with each management plan by completing an Interim Report using the template found at:

<http://compliance.wfu.edu/conflict-of-interest/>

The report will be approved by the Reviewer and forwarded to the COI Office to review for compliance with the management plan.

Appeal

A Member or Reviewer may appeal the determination and disposition of a proposed management plan made by the Committee as described in **Appendix E**. A notice of appeal must be made in writing to the Committee within 15 calendar days of the Member's or Reviewer's receipt of the Committee's determination and disposition.

Reporting and Record Keeping

Records of disclosures, determinations, conflict management plans, interim reports and all supporting documentation (e.g., minutes of meetings) will be maintained in the secure electronic system maintained by the COI Office for a minimum of three years. Such records regarding all Members engaged in sponsored research shall be maintained and available to the Office of Research and Sponsored Programs for three years after the close of the relevant grant.

Failure to Comply

The University expects its Members to comply fully and promptly with this policy. Examples of breaches of the disclosure, review, and appeal process include but are not limited to:

- failures to comply with such process, whether by virtue of a Member's refusal to disclose or respond or by his/her disclosing or responding with incomplete or knowingly inaccurate information
- failures to comply with a prescribed conflict management plan

Alleged breaches will be reviewed by the COI Office and the COI Office will make recommendations for resolution of the breach to the Member in writing. The Member will have an opportunity to respond to allegations in writing to the COI Office. The COI Office will append such written response to its report and make recommendations for sanctions if it determines a breach occurred. Sanctions may include disciplinary action ranging from a letter of reprimand to termination of employment. The report and recommendations will be forwarded to the Reviewer; the Reviewer will impose appropriate sanctions and notify the COI Office of the sanctions imposed. Instances of deliberate breach of policy – including failure to file a required disclosure form or failure to comply with prescribed conflict management plans – will be handled in accordance with applicable disciplinary policies and procedures of the University. Additionally, instances of a deliberate breach of policy related to a federally sponsored research program will be reported to the appropriate federal funding agency.

Responsibilities of the Conflict of Interest Office

The Conflict of Interest Office provides administrative oversight to this process and is charged with the following:

- Providing guidance to Members and Reviewers who have questions
- Ensuring the efficiency, consistency and effectiveness of the disclosure and review process
- Communicating the results of the disclosure process
- Assessing overall compliance with the policy
- Providing administrative support and informing the Committee about national best practices

Responsibilities of the Committee on Conflicts of Interest

The Committee, administratively supported by the Conflict of Interest Office, is charged with the following:

- Developing standards for management of real and potential conflicts of interest
- Reviewing management plans that fall outside the standards set by the Committee.
- Approving management plans forwarded for review by the COI Office and, when necessary, recommending revisions to conflict management plans

Composition of the Committee

The Committee is appointed by and reports to the President or his designee, and is comprised of the following members:

Voting members:

- Five faculty representatives
- Three representatives from the staff
- One representative from the Office of Research and Sponsored Programs

Non-voting members:

- One representative from the Compliance Office
- One representative from the Legal Department
- Two representatives from the Conflict of Interest Office

The voting members of the Committee are appointed for a term of three years.

Appendix A - Definitions

Committee on Conflicts of Interest means the University body responsible for developing conflict management guidelines to be implemented by the COI Office and for reviewing Member management plans that fall outside the guidelines developed by the Committee. The Committee is administratively supported by the Conflict of Interest Office.

Conflict of Interest Office means a section of the University Compliance Office responsible for collecting annual disclosures from Members, working with Reviewers to determine conflicts of interest, assisting Reviewers and Members to develop management plans, monitoring compliance with management plans and administratively supporting the Committee on Conflicts of Interest.

Conflict of Interest means a situation in which a Member's Financial Interest or other personal considerations or that of the Member's Family may compromise, or have the appearance of compromising the Member's professional judgment in the conducting or reporting of research, hiring of staff, procurement of materials or other activities influencing the Member's responsibilities to the University; it includes any situation in which the Member or Member's Family possesses a Significant Financial Interest in an entity that involves the Member's University responsibility.

Family means the spouse, domestic partner, and/or dependent children of a Member.

Financial Interest means anything of value, whether or not the value is readily ascertainable; including, but not limited to salary or other payments (e.g., consulting fees or honoraria); forbearance or forgiveness of debt; gifts that are meant to, or which appear to, improperly influence a Member's performance of his or her job; equity interests (e.g., stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights, trademarks, trade secrets and royalties from such rights); fiduciary or management relationships, whether paid or unpaid; and any other similar interest a Member may have in an entity outside the University. It does not include income from seminars, lectures, or engagements sponsored by, and 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. However, the Faculty Handbook or Staff Handbook may restrict or require prior approval of such activities.

Member means an officer, Investigator, faculty engaged in sponsored research and exempt staff.

Reviewer means the person responsible for reviewing a Member's disclosure who works with the Conflict of Interest Office to determine if a Conflict of Interest exists.

Significant Financial Interest means a financial interest for the Member and his or her Family consisting of one or more of the following: a) 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 the equity interest in the entity as of the date of disclosure when aggregated for the Member and his or her Family 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 stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value; b) 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 Member and his or her Family holds any equity interest (e.g. stock, stock option, or other ownership interest); or, c) intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

Third Party or Organization means any legal entity such as partnerships, firms, trusts, joint ventures, and corporations.

University means the Reynolda Campus of Wake Forest University.

Definitions specific to PHS-funded research:

Financial Conflict of Interest means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. This may include ownership of intellectual property being evaluated in research at the University and equity in start-ups.

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, or proposed for such funding, which may include, for example, collaborators or consultants.

Appendix B -- Reviewers

<u>Member</u>	<u>Reviewer</u>
Faculty	Department Chair or Dean
Academic Department Chair	Dean
Dean	Provost
Staff/Post Docs	Supervisor
Staff Department Head	Vice President, Provost, Athletic Director or Designee
Provost, Vice President, Athletic Director	President
President	Chair of the Board of Trustees

Appendix C

Compliance with 42 CFR Part 50, Subpart F and 45 CFR, Part 94 in PHS-funded research

Prior to the expenditure of funds and within 60 days of any subsequently identified Financial Conflict of Interest on PHS-funded research the University will, in order to comply with the above regulations:

- (a) Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with the PHS guidelines, and make such policy available via a publicly accessible Web site.
- (b) Inform each Investigator of the University's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of Significant Financial Interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:
 - (1) University revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 - (2) An Investigator is new to the University; or
 - (3) University finds that an Investigator is not in compliance with the University's financial conflict of interest policy or management plan.
- (c) Incorporate in all subrecipient agreements terms that establish whether the University's financial conflicts of interest policy or that of the subrecipient will apply to the subrecipient's Investigators.
- (d) Designate a University official(s) to solicit and review disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.
- (e)
 - (1) Require that each Investigator who is planning to participate in the PHS-funded research disclose to the University's designated official(s) the Investigator's Significant Financial Interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS funded research.
 - (2) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of Significant Financial Interests at least annually, in accordance with the specific time period prescribed by the University, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the University pursuant to

- paragraph (e)(1) of this section, or in a subsequent disclosure of Significant Financial Interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
- (3) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of Significant Financial Interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.
- (f) Provide guidelines consistent with the applicable PHS subpart for the designated institutional official(s) to 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 financial conflict of interest. An Investigator's Significant Financial Interest is related to PHS-funded research when the University, through its designated official(s), 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. The University may involve the Investigator in the designated official(s)'s determination of whether a Significant Financial Interest is related to the PHS-funded research. A Financial Conflict of Interest exists when the University, through its designated official(s), reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
- (g) Take such actions as necessary to manage Financial Conflicts of Interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section. Management of an identified Financial Conflict of Interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to § 50.605(a) and §94.5(a).
- (h) Provide initial and ongoing FCOI reports to the PHS as required pursuant to § 50.605(b) and §94.5(b).
- (i) 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 financial conflict of interest) and all actions under the University's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.
- (j) Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

(k)

- (1) Ensure public accessibility, via written response to any requestor within five business days of a request, to information concerning any SFI disclosed to the University that meets the following three criteria:
 - i. The SFI was disclosed and is still held by Investigator
 - ii. The University determines that the SFI is related to the PHS-funded research
 - iii. The University determines that the SFI is a FCOI

- (2) Include in the information available via written response to such requestor within five business days, at a minimum, the following:
 - i. Investigator's name,
 - ii. Investigator's title and role with respect to the research project,
 - iii. Name of the entity in which the SFI is held,
 - iv. Nature of the SFI, and
 - v. Approximate dollar value of the SFI, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Appendix D – Examples

Note: The following examples are intended to provide guidelines for the possible presence or absence of Conflicts of Interest. This is **not** intended as an exhaustive list.

Activities Unlikely to Constitute Conflicts of Interest

The following are examples of types of activities that normally will not constitute Conflicts of Interest. Disclosure to the University of such activity is not required unless the Member believes a potential conflict exists.

1. Income or personal gain to the Member or the Member's Family from activities unrelated in any way to the Member's relationship with the University.
2. Service on boards, review panels, accreditation bodies, learned societies, and visiting committees 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 which enhances the value of the Member to the University, provided such service does not adversely affect the Member's responsibilities to the University.
3. Acceptance of publication royalties or honoraria for commissioned papers, occasional lectures, concerts, exhibits, conferences, or short-term seminars or workshops.
4. Receipt of royalties for copyrights and patents obtained in accordance with University policy. <http://www.wfu.edu/organizations/CIT/docs/CopyrightPolicy.htm>.
5. A Member's interest in a business as a holder of a mutual, pension, or other institutional investment fund in which the Member has no direct control of specific investments.
6. A Member's requiring or recommending the Member's or Member's Family's textbook or other teaching aids, materials, software, equipment or the like, to be used in connection with a University instructional program.
7. Use of the telephone for personal local calls.
8. Use of the library for purposes unrelated to one's University responsibilities.
9. Travel that is reimbursed or sponsored by 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.

Appendix D - Examples (continued)

Activities With Potential to Constitute Conflicts of Interest

The following are examples of types of activities that have the potential to constitute Conflicts of Interest depending upon the particular circumstances. Open communication and discussion including electronic disclosure of such activity and/or discussion with the Conflict of Interest Office should take place in case of doubt between the Member and his/her Reviewer to determine whether a potential Conflict of Interest exists. Many of these examples may require a formal written management plan, and if federally funded may require reporting to the sponsor.

1. Relationships (e.g., consulting, equity interest, etc.) that might enable a Member to influence the University's dealing with an outside entity in ways leading to personal gain for the Member or the Member's Family. For example, a Member may have a Financial Interest in an entity with which the University does or seeks to do business and also hold a University position with the ability to influence relevant business decisions pertaining to that entity.
2. The Member's service as an officer, director or in any management capacity in an external for-profit or non-profit business, including start-ups, that deals or seeks to deal with the University.
3. Activities (e.g., research projects, summer camps, consulting arrangements, etc.) for which Members are personally compensated and that involve, or might reasonably be perceived to involve, the University, its name or registered marks, its Members, facilities (e.g., labs), equipment (e.g., computers) or other resources.
4. The Member's devotion of such time or creative energy to paid or unpaid outside activities (e.g., consulting, outside employment, club activities) as to compromise the Member's ability to adequately fulfill University responsibilities.
5. Associating one's name or one's work with an external activity in a way that implies endorsement or sponsorship by the University.
6. Exerting pressure on others associated with the University to purchase a product or to pursue a particular course of action when the Member or Member's Family has a proprietary or personal interest at stake or will either receive or retain something of value.
7. The Member's participation in University research involving a technology owned by or contractually obligated (by license, option, or otherwise) to a business in which the Member or Member's Family has a financial or fiduciary relationship that meets the definition of "Significant Financial Interest."

8. The Member's participation in University research sponsored by an entity that the Member or Member's Family owns, holds equity in, or holds a fiduciary relationship (leadership position) in, that meets the definition of "Significant Financial Interest."
9. The Member's participation in University research involving a technology for which the Member receives royalties.
10. The referral of an individual who comes to a Member in the Member's capacity as an employee of the University to an entity or firm for services if the Member or Member's Family has a Significant Financial Interest in such firm or entity.
11. A Member's provision of services to an external entity, in which the Member or the Member's Family has a Financial Interest, that competes directly with the University.
12. 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 institutional responsibilities.

Appendix D - Examples (continued)

Activities that Constitute Unacceptable Conflicts of Interest

The following are examples of activities constituting Conflicts of Interest. Full electronic disclosure of such activity and discussion with the Conflict of Interest Office should take place between the Member and his or her Reviewer. If a conflict does in fact exist, all measures must be used to resolve or manage the conflict.

1. Use of University time, property, or services for the personal benefit of a Member, the Member's Family or Third Party or Organization in which the Member or the Member's Family has an interest, that entails additional cost to the University.
2. Influence on or participation in the negotiation of an agreement between the University and an entity or organization in which the Member or the Member's Family holds a key position or has a Financial Interest.
3. Influence on or participation in the negotiation of an agreement between the University and an individual or entity with whom the Member has a relationship characterized by loyalty or importance similar to that which exists between the Member and the Member's Family.
4. Use of confidential or proprietary University information resulting from research or accessed from other University sources for the Member's personal gain, or assisting an external entity in which the Member has an interest by giving it access to such information.
5. A Member's acceptance of personal gifts of cash in any amount, or gifts of property, services or benefits meant to, or that appear to, improperly influence a Member's performance of the Member's job. In addition to items of favor or hospitality, a gift may include, but is not limited to, gratuities or tools of one's profession, such as laboratory equipment.

Appendix E Disclosure, Review, Management and Appeals Flowchart

