



WAKE FOREST UNIVERSITY

Policy on Conflicts of Interest or Commitment

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Responsible Official: Chief Audit & Compliance Officer
Related Policies: Copyright Policy
Human Resources Consensual Relationship Policy
Human Resources Nepotism Policy
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Last Review Date: April 20, 2023

Purpose of the Policy

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.

Wake Forest University encourages and supports faculty and staff participation in various external scholarly, professional, business and community activities. The University recognizes the value of these endeavors in that they often benefit the University as well as the Individual. This policy is intended to provide guidance in the identification of potential Conflicts of Interest and Conflicts of Commitment and a process for their disclosure, consistent evaluation, and management.

Application

This policy applies to full-time faculty and exempt staff (Individuals) employed by Wake Forest University. Faculty and staff employed by the Wake Forest University School of Medicine and Wake Forest University Health Sciences follow the Atrium Health Wake Forest Baptist COI policy and process.

Policy Statement

Individuals are expected to devote their primary professional time and effort to their duties and responsibilities at Wake Forest University and should identify and avoid situations and activities that may constitute a Conflict of Interest or Conflict of Commitment in the execution of their University duties. Activities, situations, and relationships that might create the perception of, or potential for, such Conflicts must be identified and managed appropriately.

Individuals should evaluate and arrange their external interests to avoid compromising their ability to carry out their obligations to the University. Most Conflicts can be avoided, and if not avoided, resolved, through the Individual's exercise of prudent personal judgment. However, in every instance of a potential Conflict, the University reserves the right to make a determination of the acceptability of, or the management of, the activity in light of the University's best interests.

This policy provides:

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

The term "Conflicts" is used in this policy to refer to Conflicts of Interest or Conflicts of Commitment (as each are separately defined in this policy). In instances where the guidance differs, reference will be made to the specific type of conflict. Capitalized terms in this policy are defined in the Definitions section below.

Responsibilities

Disclosure

1. All potential Conflicts must be disclosed to the University.
 - a. Newly-hired Individuals should disclose potential Conflicts to their Reviewer within 30 days of their hiring and any resulting management plans should be forwarded to the Compliance Office for review.
 - b. Annually, the Compliance Office will provide an electronic survey to Individuals through which they will disclose Conflicts. An Individual's disclosure will describe any actual or potential Conflicts, and will be routed to the Individual's Reviewer for evaluation.
 - c. In addition to the annual disclosure, Individuals must disclose to their Reviewer and the Compliance Office new potential Conflicts within 30 days of the Individual's awareness of such actual or potential Conflicts and in any event before engaging in the disclosed activity.

- d. If the new Conflict involves any sponsor of the Individual's research, or a research project that evaluates intellectual property in which the Individual has a Financial Interest, the Office of Research and Sponsored Programs must also be notified immediately.
- 2. An Individual must work with their Reviewer and the Compliance Office to manage or resolve identified Conflicts.
- 3. 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 are included in Appendix A.
- 4. Individuals involved in research funded by Federal entities including Public Health Service (PHS) agencies, National Science Foundation (NSF), or other Federal or State entities must comply, and must assist the University in complying, with the requirements outlined in federal regulations and agency policies on Conflict of Interest in research. See Appendix B.

Review

Disclosures of potential or actual Conflicts are reviewed by the appropriate Reviewer and the Compliance Office. A diagram of the process is included in Appendix E.

- 1. The Reviewer will consider whether a Conflict exists and if so, what conditions or restrictions, if any, should be required by the University to manage, reduce, or eliminate the Conflict. If management of the Conflict is necessary, a management plan should be developed using the Management Plan Templates found in Appendix C or at <http://compliance.wfu.edu/conflict-of-interest/>.

<u>Individual</u>	<u>Reviewer</u>
Faculty	Department Chair or Dean
Academic Department Chair	Dean
Academic/Administrative Provosts/Deans	Provost
Staff/Postdocs	Manager/Supervisor
Staff Department Head	Vice President, Provost, Athletic Director or Designee
Provost, Vice President, Athletic Director	President
President	Chair of the Board of Trustees

2. The Compliance Office will review the draft management plan to determine if the plan adequately addresses the Conflict.
3. If the Individual, the Reviewer, and the Compliance Office are in agreement concerning the Management Plan, then the Individual and the Reviewer will sign the Management Plan, each retaining a copy, and another copy will be sent to the Compliance Office for its files.
4. If the Individual, the Reviewer, and the Compliance Office are not in agreement concerning the Management Plan, then it will be sent to the Committee on Conflicts of Interest and Commitment for review and determination.
5. An Individual or Reviewer may appeal the determination and disposition of a proposed management plan made by the Committee on Conflicts of Interest and Commitment as described in Appendix E. Notice of appeal must be given in writing to the Committee within 15 calendar days of the Individual's or Reviewer's receipt of the Committee's determination and disposition. See the Appendix E diagram for the disposition of the appeal.
6. With respect to Conflicts involving researchers, at least annually, until such time that the Conflict no longer exists, researchers with a Conflict will describe how they and other financially-interested parties have demonstrated compliance with each management plan by completing and submitting to their Reviewer an interim report using the Research Interim Report Template found in Appendix D or at <http://compliance.wfu.edu/conflict-of-interest/>. The interim report approved by the Reviewer will be attached to the current disclosure for the Compliance Office to review for adherence to the management plan.

Reporting and Record Keeping

Records of disclosures, determinations, Conflict management plans and interim reports will be maintained in the secure electronic system maintained by the Compliance Office for a minimum of three years.

Such records regarding Individuals 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 Individuals 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 an Individual's refusal to disclose or respond or by 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 Compliance Office which will make written recommendations for resolution of the breach to the Individual. The Individual will have an opportunity to respond in writing to the Compliance Office which will append such written response to its report. The Compliance Office,

in collaboration with the University's General Counsel and/or the appropriate Reviewer, will 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 Compliance 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.

Compliance Office

The Compliance Office provides administrative oversight of the execution of this policy and is charged with the following:

- Providing guidance to Individuals and Reviewers
- 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 advice to the Committee

Committee on Conflicts of Interest and Commitment

The Committee is charged with the following:

- Approving standards for management of actual and potential Conflicts
- Reviewing management plans that fall outside the standards set by the Committee
- Approving management plans forwarded for review by the Compliance 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 their 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:

- Two representatives from the Compliance Office
- One representative from the Legal Department

The voting members of the Committee are appointed for a term of three years which may be extended at the end of the term.

Definitions

Close Friend or Colleague means a person with whom an Individual has an extraordinarily close relationship that is similar to a Family relationship in loyalty or importance.

Committee on Conflicts of Interest and Commitment means the University body responsible for approving Conflict of Interest and Commitment management guidelines to be implemented by the Compliance Office and for reviewing Individual management plans that fall outside the guidelines developed by the Committee. The Committee is administratively supported by the Compliance Office.

Compliance Office means a section of the University Audit and Compliance Services department responsible for collecting annual disclosures, working with Reviewers to determine Conflicts of interest, assisting Reviewers in developing management plans, monitoring compliance with management plans and administratively supporting the Committee on Conflicts of Interest and Commitment.

Conflicts refer to Conflicts of Interest and to Conflicts of Commitment.

Conflict of Commitment means a situation where an Individual's involvement in external activities, whether paid or unpaid, that may in fact or appearance 1) adversely affect the Individual's time and/or ability to fulfill their duties to the University; or 2) materially overlap with their duties to the University. Conflicts of Commitment often result when Individuals regularly devote time to external activities rather than their University responsibilities. A Conflict of Commitment may exist even in the absence of a Conflict of Interest.

Conflict of Interest means a situation in which an Individual's Financial Interest or other personal interests, or that of the Individual's Family or Close Friend or Colleague, may compromise, or have the appearance of compromising, the Individual's professional judgment in the conduct of administration, management, instruction, research, or other activities on behalf of the University. It includes any situation in which the Individual or Individual's Family or Close Friend or Colleague possesses a Financial Interest in an entity that involves the Individual's University responsibility.

Family means the spouse, domestic partner, and/or dependent children of an Individual.

Financial Interest means anything of value, whether or not the value is readily ascertainable; including, but not limited to:

- a) salary or other payments (e.g., consulting fees, gifts or honoraria),
- b) forbearance or forgiveness of debt,
- c) gifts of cash, property, or anything else of value,

- d) equity interests (e.g., stock options or other ownership interests),
- e) intellectual property rights (e.g., patents, copyrights, trademarks, trade secrets and royalties from such rights), or ownership of intellectual property being evaluated in research at the University,
- f) fiduciary or management relationships, whether paid or unpaid, or
- g) any other similar interest an Individual may have in an entity outside the University.

It does not include income from permitted academic activities such as seminars, lectures, or engagements sponsored by 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 service on advisory committees or review panels for a federal, state, or local government agency. However, the time required to conduct these activities should be considered under the Conflict of Commitment definition.

Individual means full-time faculty or exempt staff member employed by Wake Forest University.

Reviewer means the person responsible for reviewing an Individual's disclosure and management plan. See defined roles in the Responsibilities section above.

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

University means Wake Forest University.

Definitions specific to PHS-funded research:

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

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.

Significant Financial Interest means (1) 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:

- (i) 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;

(ii) 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

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

(2) 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), related to their institutional responsibilities; 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 Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

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

Appendix A – Examples

Activities Unlikely to Constitute Conflicts

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

1. Income or personal gain to the Individual or the Individual's Family from activities unrelated in any way to the Individual's relationship with the University.
2. Service on, and honoraria or travel reimbursements related to 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 Individual to the University, provided such service does not adversely affect the Individual's responsibilities to the University. (US only, similar foreign activities should be disclosed.)
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. See WFU Copyright Policy.
5. An Individual's interest in a business as a holder of a mutual, pension, or other institutional investment fund in which the Individual has no direct control of specific investments.
6. An Individual's requiring or recommending their, or their Family's, textbook or other teaching aids, materials, software, equipment or the like, to be used in connection with a University instructional program.

Appendix A – Examples (continued)

Activities With Potential to Constitute Conflicts of Interest or Commitment

The following are examples of types of activities that have the potential to constitute Conflicts of Interest (COI) or Conflicts of Commitment (COC) and should be disclosed. Many of these examples may require a formal written management plan, and if federally funded, may require reporting to the sponsor.

1. Relationships that might enable an Individual to influence the University's dealing with an outside entity in ways leading to personal gain for the Individual, Individual's Family, or Close Friend or Colleague. (COI)
2. Workplace relationships in which an Individual reports to a Family member or vice versa, either in the University organizational structure or on a research grant. (COI) See HR Nepotism Policy and HR Consensual Relationship Policy
3. Teaching or research and scholarship for another institution. It is important to note that this activity, if conducted in accordance with the Faculty Handbook, is encouraged as it often enriches the faculty member's body of knowledge and, as a result, also benefits the University. (COI and COC)
4. The Individual's service as an officer, director or in any management capacity in an external for-profit or non-profit business, including start-ups, including those that deal or seek to deal with the University. (COI and COC)
5. Activities (e.g., research projects, summer camps, consulting arrangements, etc.) for which Individuals are personally compensated and that involve, or might reasonably be perceived to involve, the University, its name or registered marks, its personnel, facilities (e.g., labs), equipment (e.g., computers) or other resources. (COI and COC)
6. The Individual's devotion of such time or creative energy to paid or unpaid external activities such as consulting, secondary employment, or self-employment. (COC)
7. Associating one's name or one's work with an external activity in a way that implies endorsement or sponsorship by the University. (COI)
8. Exerting pressure on others associated with the University to purchase a product or to pursue a particular course of action when the Individual, Individual's Family, or Close Friend or Colleague has a proprietary or personal interest or will receive something of value. (COI)
9. The Individual's participation in University research involving a technology owned by or contractually obligated (by license, option, or otherwise) to a business in which the Individual or Individual's Family has a Financial Interest or fiduciary relationship that meets the definition of "Significant Financial Interest." (COI)
10. The Individual's participation in University research sponsored by an entity that the Individual or Individual's Family owns, holds equity in, or holds a fiduciary relationship (leadership position) in, that meets the definition of "Significant Financial Interest." (COI)

11. The Individual's participation in University research involving a technology for which the Individual receives royalties. (COI)
12. An Individual's provision of services to an external entity, in which the Individual or the Individual's Family or Close Friend or Colleague has a Financial Interest, that competes directly with the University. (COI and COC)
13. The occurrence of any third-party reimbursed or sponsored travel (i.e., that which is paid on behalf of the Individual and not reimbursed to the Individual so that the exact monetary value may not be readily available), related to their institutional responsibilities. (COI)

Appendix A – Examples (continued)
Activities that Constitute Unacceptable Conflicts

The following are examples of activities constituting Conflicts. Full electronic disclosure of such activity and discussion with the Compliance Office should take place between the Individual and their Reviewer. If a Conflict does in fact exist, steps must be taken to resolve or manage the Conflict.

1. Working full-time for another institution or having a concurrent academic appointment outside the University during any semester in which the Individual is working for the University. (COI and COC)
2. Part-time employment, consulting, or Board participation with a competing University or non-profit organization. (COI and COC)
3. Use of University time, property, or services for the personal benefit of the Individual, the Individual's Family, Close Friend or Colleague, or Third Party or Organization in which the Individual, the Individual's Family, or Close Friend or Colleague has an interest, that entails additional cost to the University. (COI)
4. Influence on or participation in the negotiation of an agreement between the University and an entity or organization in which the Individual, the Individual's Family, or Close Friend or Colleague holds a key position or has a Financial Interest. (COI)
5. Influence on, or participation in, the negotiation of an agreement between the University and a Close Friend or Colleague of the Individual. (COI)
6. Use of confidential or proprietary University information resulting from research or accessed from other University sources for the Individual's personal gain, or assisting an external entity in which the Individual has an interest by giving it access to such information. (COI)
7. An Individual'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 an Individual's performance of the Individual'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. (COI)

Appendix B
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 comply with the above regulations as they are revised from time to time. The most pertinent excerpts from these regulations are reproduced below as of the adoption of this policy on June 23, 2023:

- (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) If PHS-funded research is carried out through a subrecipient (e.g., subcontractors or consortium members),
 - (1) Incorporate as part of a written agreement with the subrecipient 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 §94.5(a).
- (h) Provide initial and ongoing FCOI reports to the PHS as required pursuant to §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 of final payment or, where applicable, for the time periods specified in 48 CFR part 4, subpart 4.7.
- (j) Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- (k) Certify, in each contract proposal to which this part applies, that the University:
 - (1) Has in effect at the University an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;
 - (2) Shall promote and enforce Investigator compliance with this part's requirements including those pertaining to disclosure of significant financial interests;
 - (3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this part;
 - (4) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such

disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and

(5) Shall fully comply with the requirements of this part.

Appendix C
Research and Administrative Management Plan Templates

Research Conflict of Interest Management Plan

FINANCIALLY-INTERESTED PARTY (ies): *Conflicted Individual*

PRINCIPAL INVESTIGATOR: *Investigator*

SPONSOR: *Name*

LICENSING ENTITY: *Company name*

Project Title	Technology/IP

[Conflicted Individual(s)] will cooperate with officials of Wake Forest University (WFU) in managing potential conflicts of interest for grants and contracts awarded to WFU in which *[Conflicted Individual(s)]* has a significant financial interest.

LAY DESCRIPTION OF PROJECT:

BRIEF DESCRIPTION OF CONFLICT:

Relationship: Describe the relationship (income, equity, intellectual property licensing, royalties, or leadership position) with the entity/sponsor that creates the appearance of a conflict of interest.

Relatedness: Describe how the interest in sponsor/entity is related to the research or how the research could directly benefit the individual with the interest.

Ability to Affect the Research: Describe how the individual is able to directly affect the research (role of PI, designed study, oversees students on the project, could impact enrollment of human subjects, etc.)

1. Human Subjects Protections (delete section a. or b. that is not applicable)

a) The conflict of interest will be managed for participants to ensure their safety and welfare. *Conflicted individual's* financial relationship will be disclosed during the informed consent process and he/she will not recruit or consent study subjects. *Financially-disinterested party, such as a study coordinator or other faculty member, who has no related financial interest will consent study subjects. The clinical study staff*

will adhere strictly to inclusion/exclusion criteria and randomization as stated in the protocol to avoid enrollment bias. The conflict of interest and its management will be disclosed formally to the IRB.

b) No human subjects research will be conducted in this project.

2. Personnel

All personnel directly involved in the conduct of the project will be made aware of the associated conflict of interest and the manner in which it will be managed.

3. Nepotism and Cronyism

All employees and contractors involved in this project were selected in accordance with University policy and based on qualifications, rather than prior personal relationship.

4. Students and Other Trainees (delete section a. or b. that is not applicable)

a) At this time, trainee name(s), role(s) (e.g., students, post-docs, etc.) and department(s) are expected to participate in this project. Their roles in the project will remain consistent with their overall training.

Trainees will be informed that trainee advocate name (e.g. graduate student program director, dissertation committee chair, post-doctoral program director or other senior, financially-disinterested faculty member) will function as the trainees' advocate. Each trainee is instructed to notify the advocate if he or she feels that involvement with conflicted investigator in any way adversely affects his/her academic progress. The advocate will be available to the trainees should concerns arise regarding the appropriateness of research assignments. Prior to engaging in the project, all trainees must complete an attestation of understanding that will be provided by the Compliance Office.

b) At this time, no trainees are expected to participate in this research. If conditions change, this plan must be amended and approved by the conflict of interest committee before any trainees may participate.

5. Intellectual Property

Inventorship and ownership of any new intellectual property arising from this project will be determined in accordance with University policy.

6. Publications

Scholarly publications of this project will be submitted in accordance with the research agreement with WFU.

- In the absence of journal specific requirements, the following disclosure language will be used for any publications, presentations, or media events from this research related to author's (or family

member's) financial interests: [use suggested language from instructions] Ex., Professor X has a significant financial interest in ABC Corp., Inc. that provided the funding for this research, etc.

Any trainees involved in this research project will be ensured the freedom of writing and publication about the research results without limitations or delays.

7. Data Oversight

Specify who will oversee outcomes assessments and/or data analysis for the conflicted individual, if applicable. Delete sections that are not applicable.

a) Financially-disinterested faculty member will provide data oversight by reviewing the outcomes assessments of subjects or test results prior to data release or publication and will provide a memo indicating such activity in each interim report.

b) Financially-disinterested faculty member will provide oversight of data analysis or perform the data analysis to ensure accepted statistical principles and to avoid the appearance of bias, and will provide a memo indicating such activity in each interim report.

8. Additional Project Oversight

If the conflicted investigator is the department chair, a senior financially-disinterested faculty member must be assigned this duty and procedure shall be specified.

Other circumstances may call for an additional level of oversight beyond the data oversight. Financially-disinterested faculty member designated will indicate his review and the results in the interim report.

9. Use of Institutional Resources

This project is being conducted in WFU space. The space currently proposed for the conduct of the project is Bldg., Rm, assigned to faculty member.

No institutional facilities, equipment or staff will be utilized for the direct benefit of the financially-interested party or the Entity unless such work is covered by a Research Agreement. Should institutional facilities, equipment, or staff be utilized, WFU must approve the activity before it occurs, must be compensated fully, and such projects must be well documented and charged to the sponsor.

10. Interim Reporting and Monitoring

Conflict management plans are approved for a period of no more than 12 months at a time. In order to continue this plan, Conflicted investigator will prepare a report updating all information relevant to the management plan, which will be reviewed and approved by department chair or designee, his/her Department Chair or designee, who has no financial interest. The report will minimally include:

- all required oversight memos

- a copy of related publications from the past year
- a copy of related presentation disclosure slides from the past year.

The interim report will be signed by the Principal Investigator and Department Chair or designee and forwarded to the University’s Compliance Services office for administrative review and presentation to the Conflict of Interest Committee on at least an annual basis.

The information contained in this management plan, including any attachments, is confidential and maintained by the WFU Conflict of Interest Committee. This document, and the specific information included therein, is not available for review, disclosure, copying, or distribution to parties outside WFU. In general, an overview of the management plan and its safeguards may be reported to a sponsor as required or if requested.

Management plan participants

Role	Name	Signature	Date
Conflicted Investigator			
Data Oversight			
Trainee Advocate			
Project oversight			

Department Approval*

_____ Date: _____
 (Department Chair or designee, name)

Compliance Services acceptance

_____ Date: _____
 (Chief Audit & Compliance Officer)

Non-Research Conflict of Interest or Commitment Management Plan

Individual Name :

Title:

Contact information:

Reviewer Name:

Title:

Contact information:

Description of the nature of the actual or perceived conflict:

[Please include sufficient information to understand whether this is a conflict of interest (financial) or commitment (time) disclosure, the origin of the conflict, names of parties or companies involved, bias or perceived bias the relationship(s) may create, and the nature and amount of financial components, royalties, ownership, intellectual property, etc.]

Strategies for management of the actual or perceived conflict:

[This should describe how the activity will be conducted to control bias and/or ensure that the Individual's University duties are not affected.]

How will the management strategies be monitored for compliance?

[It is generally the Reviewer's responsibility to monitor the disclosed activity.]

Individual Signature

Date

Reviewer Signature

Date

Committee on Conflicts Chair Signature
(For significant conflicts)

Date

Appendix D
Research Interim Report Template

CONFLICT MANAGEMENT PLAN INTERIM REPORT _____
(CMP number)

REPORT INTERVAL: _____ (Annual, Semi-Annual, etc.)

REPORT SUBMISSION DATE: _____

FINANCIALLY INTERESTED PARTY: _____

SPONSOR: _____

ENTITY: _____

Project Title	Technology/IP

*If Sponsor is funded under a Public Health Service (PHS) grant or cooperative agreement, such as NIH, the following questions must be answered:

A. Title of Grant _____

B. What date was the Annual Report submitted to Sponsor _____

C. Is the project in a No Cost Extension? Yes No

D. If yes, what is the termination date of the No Cost Extension? _____

LAY DESCRIPTION OF PROJECT:

BRIEF DESCRIPTION OF CONFLICT:

Relationship: Describe the relationship (income, equity, intellectual property licensing, royalties, or leadership position) with the entity/sponsor that creates the appearance of a conflict of interest.

Relatedness: Describe how the interest in sponsor/entity is related to the research or how the research could directly benefit the individual with the interest.

Ability to Affect the Research: Describe how the individual is able to directly affect the research (role of PI, designed study, oversees students on the project, could impact enrollment of human subjects, etc.)

All questions below pertain to compliance with the management plan during the interval since implementation of the plan or since the last interim conflict management plan report. Please describe the departmental processes followed to comply with the conflict management plan in order to monitor and manage the conflict of interest. Enter NA if section is not applicable.

1. Changes
 - a. What changes, if any, have occurred in the project? e.g., key personnel, resources, space, sponsorship, etc.
 - b. Provide a narrative description of any changes and/or activities that have occurred regarding the relationship between the entity and the conflicted individual, e.g., licensing, intellectual property, equity distribution, participation on boards, consulting, speaking or other activities.
2. Human subjects protection: e.g., limitations on PI performing informed consent, disclosure during consent, limitations on subject recruiting.
 - a. Attach current watermarked informed consent.
3. Trainees (Student, residents, and fellows) and trainee advocacy:
 - a. Name the trainees (include trainees whose participation has changed)
 - b. Describe the role of each trainee in the project
 - c. What steps have been taken to provide advocacy for each trainee involved in the project- e.g. name the trainee advocate(s)
 - d. Attach a trainee attestation for each new trainee added since the last report.
4. Data oversight:
 - a. What steps have been taken to provide review of data analysis or prevention of bias during data collection as specified in the management plan? Attach a memo or report from individual appointed to provide data analysis oversight
5. Project Oversight:
 - a. What steps have been taken to provide oversight of the project as specified in the management plan?
 - b. Attach a memo or report from individual(s) appointed to provide oversight
6. Please attach the following:
 - A copy of related publications from the past year.
 - A copy of related presentation slides from the past year (only need the title slide and the financial interest disclosure slide).

Principal Investigator

(Principal Investigator signature)

Date

Department Approval

(Department Chair or designee identified per the plan)

Date

Compliance Services acceptance

Chief Audit & Compliance Officer

Date

Appendix E Disclosure, Review, Management and Appeals Flowchart

