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## REG - 50.03.11 - FINANCIAL CONFLICT OF INTEREST REGULATION

Authority: Chancellor

Responsible Office: Division of Research and Sponsored Programs

Number: REG - 50.03.11 - FINANCIAL CONFLICT OF INTEREST REGULATION

History: Effective Date: August 24, 2012 Reformatted/Updated: May 10, 2016

Related Policies/Sources: [42 CFR Part 50](#), [45 CFR Part 94](#), [UNC Manual 300.2.2](#),

Contact Info: Research Compliance & Technology Transfer, 919-530-6398

### 1. Purpose

Regulations identified in this document are implemented to underscore to the research community, the necessity of timely disclosure of financial interests, reporting and management of identified conflicts. Compliance sustains the University's research integrity; maintains continuity of support from funding agencies; prevents the threat of debarment from the research community at-large; and protects the viability of the University-Sponsoring Agency-Research relationship.

### 2. Scope

This document applies to all applies to all persons responsible for designing, conducting or reporting PHS-funded research under the auspices of North Carolina Central University.

### 3. Definitions

3.1 PHS-Funded Research means Research funded by or proposed to be funded by PHS, including without limitation NIH awards. The term includes any Research for which funding is available from a PHS awarding component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship, award, infrastructure award, institutional training grant, program project, or research resources award. PHS-Funded Research as it appears in this document shall not include Phase 1 Small Business Innovative Research ("SBIR") or Small Business Technology Transfer ("STTR") applications or awards. Additionally, PHS-Funded Research also includes Research sponsored by entities that are not PHS agencies,, but have adopted as policy 42 CFR Part 50 and 45 CFR Part 94.

- 3.2 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.
- 3.3 Designated Official means an institutional official designated to solicit and review disclosures of Significant Financial Interests from investigators. The Designated Official shall be the Director, Office of Research Compliance and Technology Transfer and/or such other individual as designated by the Dean of Research and Sponsored Programs.
- 3.4 Institutional Responsibilities means an investigator's professional responsibilities on behalf of NCCU, comprising both primary and secondary duties as outlined in UNC Policy Manuel 300.2. These duties include but are not limited to research, research consultation, teaching, professional practice, administration and service such as membership on committees, boards and panels.
- 3.5 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 PHS-Funded Research. This may include, for example, postdoctoral scholars, technicians, collaborators or consultants if they have such responsibilities.
- 3.6 Manage means taking action to address a FCOI, which can include reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- 3.7 Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including biomedical, behavioral and social-sciences research. The term encompasses basic, applied, translational and clinical research (e.g., a published article, book or book chapter), product development (e.g., a diagnostic test or drug), or clinical trial.
- 3.8 Senior/key personnel means the project director or principal investigator and any other person identified as senior/key personnel in the grant application, contract proposal, contract, progress report, or any other report submitted to sponsor for PHS-Funded Research.
- 3.9 Significant Financial Interest" ("SFI") means a financial interest consisting of one or more of the following interests of an Investigator, or the Investigator's spouse or dependent children, that reasonably appears to be related to the Investigator's Institutional Responsibilities:
- 3.9.1 Publicly traded entity, a SFI exists if the value of any remuneration from the entity in the 12 months preceding the disclosure of the SFI and/or the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5000. Remuneration includes any payment for services not otherwise identified as University-paid salary (e.g., consulting fees, honoraria, paid authorship fees). 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.
- 3.9.2 Nonpublicly traded entity, a SFI exists if the value of any remuneration, as described above, received from the entity in the 12 months preceding the disclosure of the SFI, when aggregated, exceeds \$5000 or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interests).
- 3.9.3 Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of royalties or other income related to such rights and interests that exceed \$5000 not compensated through the University.
- 3.9.4 Reimbursed or sponsored travel (sponsored travel being 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) as related to an Investigator's Institutional Responsibilities.

### 3.9.5 Exceptions- SFI does not include:

3.9.5.1. Salary, royalties, or other remuneration paid by NCCU to the Investigator, if the Investigator is currently employed or otherwise currently holding an appointment at such institution;

3.9.5.2. Intellectual property rights assigned to NCCU and agreements to share in royalties related to such rights (e.g., an Investigator's royalties received under the NCCU Intellectual Property Policy.)

3.9.5.3. 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; and

3.9.5.4. Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, or travel expenses that are 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, a research institute affiliated with an institution of higher education.

## 4. Procedures

4.1 The University will certify in the research application to the Institution's effective, implemented policy and full compliance with federal regulations, 42 CFR Part 50 and 45 CFR Part 94, as specifically enumerated in 42 CFR §50.604(k)(1-5) and 45 CFR §94.4(k) (1-5).

4.2 Prior to expenditure of any funds for a PHS-Funded Research project, the Designated Official will perform the following actions:

4.2.1 Solicit and review Investigator Significant Financial Interest ("SFI") disclosures and any other information deemed relevant (e.g. research proposal summary, IRB application, etc.). In connection with this review, the Designated Official may require the Investigator to provide additional information.

4.2.2 Determine (1) whether an Investigator's SFI is related to PHS-Funded Research, and if it is, (2) whether the SFI is a Financial Conflict of Interest ("FCOI"). An Investigator's SFI is related to PHS-Funded Research when the Institution, through its Designated Official, reasonably determines that the SFI could be affected by the PHS-Funded Research or is in an entity whose financial interests could be affected by the PHS-Funded Research.

4.2.3 Take such actions as necessary to Manage the FCOI, including development and implementation of a management plan.

4.2.4 An FCOI exists when the Institution, through its Designated Official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-Funded Research.

4.2.5 Determination of FCOIs is done case-by-case. The Designated Official will prepare a report for the Dean of Research and Sponsored Programs detailing a recommended management plan, including any proposed conditions or restrictions to Manage the FCOI.

4.2.6 The Dean of Research and Sponsored Programs may accept, return the report to the Designated Official for clarification or supplementation, modify or reject the determination and recommendation in its entirety. The Dean of Research and Sponsored Programs will make a final determination in writing and specify the conditions or restrictions, if any, that should be imposed to Manage the FCOI.

4.2.7 The Office of Research Compliance and Technology Transfer will provide copies of the final decision to the Investigator, the Dean of the Investigator's School or College, Institute and/or Center Director, Chair of the Investigator's department, Institutional Review Board (if human subjects research is involved), Institutional Animal Care and Use Committee (if animal subjects are involved) and the Office of Sponsored Research and Programs.

## **5. Management Plans for FCOIs**

5.1 Each management plan shall specify the actions including conditions and or restrictions that have been, and shall be taken to Manage the FCOI. Examples of conditions or restrictions that might be imposed to Manage an FCOI include, but are not limited to:

5.1.1. Public disclosure of the FCOI (e.g., when presenting or publishing the research);

5.1.2. Projects involving human subjects research, disclosure of the FCOI directly to the study participants as approved by the Institutional Review Board;

5.1.3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the PHS-Funded Research against bias resulting from the FCOI;

5.1.4. Modification of the research plan;

5.1.5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the PHS-Funded Research;

5.1.6. Reduction or elimination of a financial interest (e.g., sale of an equity interest); and

5.1.7. Severance of relationships that create the FCOI.

5.2 In any case in which the Department of Health and Human Services determines that a PHS-Funded Research 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 an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

5.3. The Office of Research Compliance and Technology Transfer will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS- Funded Research.

## **6. Ongoing PHS- Funded Research: Reporting of New SFIs**

During the course of ongoing PHS-Funded Research, a newly participating Investigator to the PHS-Funded Research discloses an SFI or an existing Investigator discloses a new SFI, the Designated Official will perform the following, within sixty (60) days:

6.1. Review the Significant Financial Interest;

6.2. Determine whether it is related to PHS-Funded Research;

6.3. Determine whether a FCOI exists, and, if so;

6.4. Implement a management plan that shall specify the actions that have been, and will be taken to Manage identified FCOI.

## **7. Ongoing PHS-Funded Research: Review of Existing SFIs and Retrospective Review of**

## **FCOIs**

7.1. Review of Existing SFIs. Whenever NCCU identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed during ongoing PHS-Funded Research (e.g. was not timely reviewed or reported by a subrecipient), the Designated Official will, within sixty (60) days, undertake the same review, determinations and management plan implementation set forth above.

7.2. Retrospective Review. Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI that is determined by the Institution to constitute an FCOI, failure by the Institution to review or manage such an FCOI, or failure by the Investigator to comply with an FCOI management plan, the Designated Official will, within 120 days of the Institution's determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-Funded Research to determine whether any PHS-Funded Research, or portion thereof, conducted during the time period of the non-compliance, was biased in design, conduct, or reporting of such Research.

7.3. The Office of Research Compliance and Technology Transfer will document the retrospective review in accordance with federal requirements set in 42 CFR, Part 50, Subpart F, §50.605(a)(3)(ii)(B)(1-9), for PHS-funded research grants or cooperative agreements, or 45 CFR Part 94, §94.5(a)(3)(ii)(B)(1-9), for PHS-funded research contracts, and if appropriate, will update the previously submitted FCOI report, describing the new management plan.

## **8. Reporting FCOIs to the PHS-Awarding Component**

8.1. Prior to the University's expenditure of any funds under PHS-Funded Research, the Designated Official shall provide to PHS, as required, an FCOI report regarding any Investigator's FCOI (unless eliminated) and ensure that a management plan has been implemented. The FCOI report to PHS will contain all information required under federal regulations at 42 CFR, Part 50, Subpart F, § 50.605(b)(3) and 45 CFR, Part 94, § 94.5(b)(3), as applicable.

8.2. For newly acquired FCOIs during ongoing PHS-Funded Research, as described in Section H, Policy and Procedures: University Responsibilities, the Designated Official shall provide to the PHS awarding component, within sixty (60) days, an FCOI Report ensuring that the University has implemented a management plan.

8.3. For FCOIs not previously disclosed, reviewed or managed during ongoing PHS-Funded Research, described in Section I, Policy and Procedures: University Responsibilities, the Designated Official shall, if the retrospective review results in a finding of bias in the design, conduct or reporting of the PHS-Funded Research, promptly submit its mitigation report to the PHS awarding component. In accordance with 42 CFR, Part 50, Subpart F, § 50.605(a)(3)(iii) and 45 CFR, Part 94, § 94.5a(3)(iii), the mitigation report shall include the key elements documented in the retrospective review and a description of the impact of the bias on the PHS-Funded Research and the Institution's plan of action or actions taken to eliminate or mitigate the effects of the bias.

8.4. After the submission of any initial FCOI Report with regard to ongoing PHS-Funded Research, the Designated Official shall provide the PHS awarding component with annual FCOI Reports that address the status of the FCOI and any changes to the management plan for the duration of the PHS-Funded Research (including extensions with or without funds) in the time and manner specified by the PHS awarding component.

8.5. The Office of Research Compliance and Technology Transfer on behalf of NCCU shall, upon request of the PHS awarding component, make information available to PHS 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 an FCOI.

## **9. Notification and Mitigation Report**

If the Designated Official finds bias in the design, conduct, or reporting of PHS-Funded Research, the Office of Research Compliance and Technology Transfer will notify the PHS awarding component promptly and submit a mitigation report, as required by and including all key elements specified in 42 CFR, Part 50, Subpart F, § 50.605(a)(3)(iii) and 45 CFR, Part 94, § 94.5(a)(3)(iii).

## **10. Non-Compliance**

The University may impose sanctions for non-compliance including suspension, denial of eligibility to engage in Research, or other appropriate penalties. Such sanctions may require giving notice to the public, professional bodies and/or journals.

If an Investigator fails to comply with NCCU policy and procedures or a management plan in a way that could have biased the design, conduct, or reporting of PHS-Funded Research, the Institution shall promptly notify the PHS awarding component of the corrective action taken or to be taken (e.g., a mitigation report for the PHS-Funded Research, as further described below in Section G), and implement corrective action.

## **11. Training**

Every Investigator will complete training on Investigator policy responsibilities at the following times:

- 11.1. Prior to engaging in PHS-Funded Research and at least once every four (4) years thereafter;
- 11.2. When NCCU Policy and Procedures are revised in any manner that affects the requirements of Investigators;
- 11.3. When an Investigator is new to NCCU, even if the PHS-Funded Research has already begun;
- 11.4. When an Investigator is not in compliance with University policy and procedures or a management plan, as determined by the Designated Official.

## **12. Subrecipients**

If NCCU is the awardee or prime and conducts PHS-Funded Research through a subrecipient (e.g. subcontractors or consortium members), the Designated Official will take reasonable steps to ensure that subrecipient Investigators comply as follows:

12.1. NCCU's written agreement with the subrecipient will establish whether the University's policy and procedures or the subrecipient's FCOI policy will apply to the subrecipient's Investigators. The written agreement will state either:

12.1.1. The subrecipient certifies that its FCOI policy complies with the applicable federal regulations, and that the subrecipient's Investigators will comply with the subrecipient's policy or,

12.1.2. If the subrecipient cannot provide such certification, that subrecipient Investigators are subject to NCCU policy and procedures.

12.2. If the subrecipient's policy applies, the written agreement will specify the time period(s) for the subrecipient to report all identified FCOIs initially and annually thereafter to NCCU. The time period(s) will be sufficient to enable NCCU to provide FCOI reports to PHS prior to the expenditure of funds and within 60 days of finding any additional FCOI.

12.3 If NCCU's policy, as awardee, applies, the subrecipient Investigators will disclose all SFIs that are directly related to the subrecipient's work for NCCU. The written agreement with the subrecipient will specify the time period in which to comply, sufficiently allowing NCCU enough time to comply timely with its review, management and reporting obligations, e.g., to provide FCOI reports to PHS prior to the expenditure of funds, within 60 days of finding any additional FCOI and annually thereafter.

#### **14. Maintenance of Records**

The Office of Research Compliance and Technology Transfer will maintain records relating to all Investigator SFI disclosures, including the review of and response to such disclosures (whether or not resulting in an FCOI finding), for at least three (3) years from the date the final expenditures report is submitted to PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b), relating to records retention.

#### **15. Public Accessibility**

15.1. This document and related forms shall be made publicly available on North Carolina Central University's website.

15.2. Upon written request to North Carolina Central University's Office of Research Compliance and Technology Transfer, information will be provided including as specified in 42. CFR, Part 50, Subpart F, §50.605(a)(5)(ii) and 45 CFR, Part 94, § 94.5(a)(5)(ii), concerning a specific SFI disclosed to NCCU and meeting the following criteria:

15.2.1 The SFI was disclosed and is still held by the Senior/Key Personnel;

15.2.2 The Institution has determined that the SFI is related to the PHS-Funded Research; and

15.2.3 The Institution has determined that the SFI is an FCOI.

15.3. Information concerning the SFIs of Senior/Key Personnel shall remain available for responses to written requests for at least three (3) years from the date that the information was most recently updated.

15.4. When the PHS-Funded Research is conducted by a subrecipient Investigator, and under their written agreement the subrecipient is required to comply with the subrecipient's FCOI policy, the subrecipient will have the responsibility of making such information publicly accessible.

15.5. Responses will be returned within five (5) business days from when the Director, NCCU Office of Research Compliance and Technology Transfer receives the written request.

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