



NORTH CAROLINA AGRICULTURAL AND TECHNICAL STATE UNIVERSITY

SEC. V —CONFLICTS 2.0

FINANCIAL CONFLICT OF INTEREST AND COMMITMENT FOR PUBLIC HEALTH SERVICE FUNDED RESEARCH AND COOPERATIVE AGREEMENTS

ADMINISTRATIVE POLICY

I. BACKGROUND

Federal Requirements

An institution applying for or receiving National Institutes for Health (NIH) funding from a grant or cooperative agreement must be in compliance with Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR Part 94). The federal register states that “the subparts promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.”

North Carolina A&T State University Policy for Financial Conflict of Interest

It is the policy of North Carolina Agricultural and Technical State University (A&T) to comply with 42 CFR Part 50, Subpart F and 45 CFR Part 94, concerning financial conflict of interest. This policy serves as an addendum to the University’s existing Conflict Of Interest policy. Effective August 24, 2012, covered employees applying for, receiving, or being supported on

PHS funds must be compliant on rules governing disclosure, training, and conflict of interest management plans in addition to the requirements listed in the current COI policy which remains in effect.

II. DEFINITIONS

The University adopts the following definitions:

- A. *Conflict of Commitment* relates to an individual's distribution of time and effort between obligations to University employment and participation in other activities outside of University employment. The latter may include such generally encouraged extensions of professional expertise as professional consulting (i.e. External Professional Activities for Pay). Such activities promote professional development and enrich the individual's contributions to the institution, to the profession, and to society. However, a conflict of commitment occurs when the pursuit of such outside activities involves an inordinate investment of time or is conducted at a time that interferes with the employee's fulfillment of University Employment Responsibilities.
- B. *Conflict of Interest (COI)* relates to situations in which financial or other personal considerations, circumstances, or relationships may compromise, may involve the potential for compromising, or may have the appearance of compromising a Covered Employee's objectivity in fulfilling their University duties or responsibilities, including research, service and teaching activities and administrative duties. The bias that such conflicts may impart can affect many University responsibilities, including decisions about personnel, the purchase of equipment and other supplies, the selection of instructional materials for classroom use, the collection, analysis and interpretation of data, the sharing of research results, the choice of research protocols, the use of statistical methods, and the mentoring and judgment of student work. A Covered Employee may have a conflict of interest when he or she, or any member of that person's immediate family has a personal financial interest in an activity that may affect decision making with respect to his or her Employment Responsibilities. For the purposes of this Policy, a Covered Person's immediate family includes that person's spouse and dependent children. While a Conflict of Interest may result from nonfinancial interests or considerations, the overwhelming majority of Conflicts of Interest result from a Financial Interest of a Covered Employee who is in a position to make a supervisory, academic, or administrative decision which may be compromised because of potential financial gain from a Financial Interest.
- C. *Constituent Institution* means the 17 campuses of the University of North Carolina and includes affiliated entities of the University of North Carolina, General Administration, and units associated with General Administration.
- D. *Covered Employee* means any faculty or non-faculty employee exempt from the State Personnel Act (EPA) employed by A&T and any affiliated entities who is designated as a Principal Investigator (PI) or "Key Personnel" involved in the design, conduct, or reporting for a PHS funded project or an SBIR/STTR Phase II project. Post doctoral

employees, students, and trainees listed and/or receiving payment from PHS funded research are included in this policy as Covered Employees.

E. External Professional Activities for Pay (EPAP) is defined as any activity that: 1) is not included within one's University Employment Responsibilities; 2) is performed for any entity, public or private, other than the University employer; 3) is undertaken for compensation; and 4) is based upon the professional knowledge, experience and abilities of the employee. Activities for pay not involving such professional knowledge, experience and abilities are not subject to the advance disclosure and approval requirements of this policy, although they are subject to the basic requirement that outside activities of any type must not result in the neglect of primary University duties, creation of Conflicts of Interest, involve inappropriate uses of the University name or resources, or include claims of University responsibility for the activity.

F. Financial Conflict of Interest: An SFI that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

G. Financial Interest:

1. Payment for services to the Covered Employee not otherwise defined as institutional salary (e.g. consulting fees, honoraria, paid authorship);
2. Equity or other ownership interest in a publicly or non-publicly traded entity (e.g. stock, stock options, or other ownership interest); or
3. Intellectual property rights and interests upon receipt of income related to such rights and interest, held by the Covered Employee or members of his/her immediate family.

Income from investment vehicles, such as mutual funds or retirement accounts, in which the Covered Employee or member of his/her immediate family do not directly control the investment decisions and intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights are excluded from the definition of Financial Interest. Covered Employees are required to disclose Financial Interests in a timely and accurate manner consistent with this Policy.

H. Inappropriate Use or Exploitation of University Resources means using any services, facilities, equipment, supplies or personnel which members of the general public may not freely use for other than the conduct of Institutional Responsibilities. A person engaged in external professional activities for pay may not use University Resources in the course and conduct of externally compensated activities, except as allowed by applicable University policies. Under no circumstances may any employee use the services of another employee during University employment time to advance the externally compensated employee's professional activities for pay.

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

J. *NOI* means Notice of Intent.

K. *ORCE* means the Office of Research Compliance and Ethics.

L. *OSP* means the Office of Sponsored Programs.

M. *Senior/Key Personnel* means the Project Director (PD)/Principal Investigator (PI) and any other person identified as senior/key personnel by A&T in the grant application, progress report, or any other report submitted to the PHS by A&T under the regulation. **Note: Different definition than the NIH Grants Policy Statement**

N. *Significant Financial Interest (SFI)*:

(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 excluded sources provided in regulation.

O. *University Employment Responsibilities* include "Primary Duties" and "Secondary Duties."

1. Primary Duties consist of assigned teaching, scholarship, research, institutional service requirements, administrative duties and other assigned employment duties.
2. Secondary Duties may include professional affiliations and activities traditionally undertaken by Covered Employees outside of the immediate University employment context. Secondary Duties may or may not entail the receipt of honoraria, remuneration or the reimbursement of expenses, including membership in and service to professional associations and learned societies; membership on professional review or advisory panels; presentation of lectures, papers, concerts or exhibits; participation in seminars and conferences; reviewing or editing scholarly publications and books without receipt of compensation; and service to accreditation bodies. These activities, which demonstrate active participation in a profession are encouraged, provided they do not conflict or interfere with the timely and effective performance of the individual's Primary University Duties or University policies.

III. FINANCIAL CONFLICT OF INTEREST AND SIGNIFICANT FINANCIAL INTEREST

A. Disclosure Requirements

Covered Employees

All covered employees must provide disclosure beginning with a period of 12 months prior to August 24, 2012:

- Prior to and no later than at the time of a PHS application submission through the Office of Sponsored Programs (OSP)
- Upon submission of an application for development of a PHS funded SBIR/STTR Phase II contract
- Prior to engaging in ongoing PHS funded research as a new project team member
- Annually (usually during annual reporting to the PHS agency)
- Within 30 days of acquiring a new SFI

If a reported SFI is determined by the Vice Chancellor of Research and Economic Development to be a FCOI that is PHS related and may affect the design, conduct, or research results, the principal investigator and project team are required to:

- Implement a FCOI management plan as written
- Comply with the management plan until the end of the project
- Release all FCOI related documentation upon request

Office of Sponsored Programs (OSP)

- Obtain completed disclosure forms from investigators prior to PHS application submissions to sponsor
- Obtain completed disclosure forms from investigators newly added to a project
- Obtain annual disclosures from existing investigators (annual progress reports, multi-year progress reports, or at time of extension)
- Obtain certification from subrecipients that they have an enforced PHS FCOI Policy
- Maintain disclosure forms in the appropriate RAMSES file (for the PHS funded project)

Office of Outreach and Technology Transfer

- Obtain disclosures prior to final approval of SBIR/STTR Phase II applications/contracts

Office of Research Compliance and Ethics (ORCE)

- Review all PHS related FCOI disclosure forms
- Determine if a disclosure meets requirements for review by:
 - Vice Chancellor for Research and Economic Development: Reviews all FCOI disclosures that meet regulatory criteria for an SFI
 - ORCE: Expedited review (existing FCOI, less than \$5,000, funded)
 - Full COI Committee for Review and Monitoring review (new FCOI, greater than \$5,000, funded or non-funded)
- Implement process for FCOI disclosure and development of management plans for protocols reviewed by Research Compliance committees:
 - Institutional Animal Care and Use Committee (IACUC)
 - Institutional Biosafety Committee (IBC)
 - Institutional Review Board (IRB)
 - Radiation Safety Committee
- Participate in start-up meetings as requested regarding this policy
- Coordinate procedures for the COI Committee for Review and Monitoring, which is an ad hoc committee appointed by the Vice Chancellor for Research and Economic Development as needed

Vice Chancellor for Research and Economic Development

- Review all investigator SFI disclosures
- Determine if SFI is related to PHS funded research
- Determine whether an SFI is a FCOI (SFI that could directly or significantly affect the design, conduct, or reporting of the PHS/NIH funded research)
- Serve as final decision-maker for COI management plans, with an appeal to the Provost
- Determine whether any bias exists in the design, conduct, or reporting of NIH funded research

- Conduct retrospective reviews for non-compliance within 120 days of determination of non-compliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner
- Document retrospective reviews consistent with the regulations
- Determine whether any additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Vice Chancellor for Research and Economic Development's review.
- Develop mitigation plans

COI Committee for Review and Monitoring

- Recommend actions for managing FCOI to the Vice Chancellor for Research and Economic Development, who is the decision maker
- Monitor compliance with management plans
- Report non-compliance with management plans to the Vice Chancellor for Research and Economic Development and the Research Misconduct Committee
- Recommend corrective actions for non-compliance with this policy and management plans

Chairpersons and Deans

- Assist the Vice Chancellor for Research and Economic Development in developing COI management plans
- Implement the COI management plan as required by the Vice Chancellor for Research and Economic Development
- Report non-compliance with management plans to the Director of the ORCE

B. Training Requirements

Human Resources (HR)

- Notify all EPA employees of the PHS FCOI policy during new employee orientation

Research Services

- Provide training requirements on the Notice of Intent (NOI) to submit proposal forms and/or on responses to NOI forms submitted

Covered Employee

- Complete training prior to engaging in PHS supported research
- Renew training every 4 years and:
 - Upon notice that the policy has been revised in a manner that affects investigators

- Upon determination of non-compliance with this policy
- Upon determination of non-compliance with an FCOI management plan
- Upload completion reports for training in the project-specific file in RAMSES

Director, Office of Research Compliance and Ethics (ORCE)

- Provide training for all covered employees supported by PHS funded research
- Maintain on-line training system and all training records

Office of Sponsored Programs (OSP)

- Notify investigators of training requirement upon receipt of PHS awards and during start-up meetings
- Verify training records in the online training system upon notice of award

Contracts and Grants

- Verify COI training prior to releasing a PHS account number to investigators
- Provide documentation of expenditures upon request from Vice Chancellor for Research and Economic Development or COI Committee

C. Reporting Requirements

Director of Research Compliance and Ethics

- Report initial, annual, and revised FCOI to the NIH (via eRA Commons) and to the OSP
 - Prior to expenditure of funds
 - Within 60 days of identification for an investigator that is new to a project
 - Within 60 days for new, or newly identified, FCOIs for existing investigators
 - At least annually to provide the status of the FCOI and any changes to the management plan, if applicable until the completion of the project
- Provide the Vice Chancellor for Research and Economic Development's Mitigation Report to NIH and OSP in accordance to regulation
- Report promptly to NIH any corrective action for non-compliance with this policy or the management plan

D. Enforcement Mechanisms, Remedies, and Non-Compliance

Enforcement mechanisms for non-compliance with this policy may be determined on a case-by-case basis and will include, but are not limited to:

- Withholding of the PHS related funds for the project involved
- Additional COI, Responsible Conduct in Research, or other training
- Suspension of the research

- Revocation of designation as principal investigator or key personnel
- FCOI management plan audit requirements (interview, records, other documentation)
- FCOI management plan revision
- Revision of the funding award agreement/contract related to the FCOI

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 designated, conducted, or reported by an investigator with an FCOI was not managed or reported by the University as required by the regulation, the University shall require the investigator to:

- Disclose the FCOI in each public presentation of the results of the research, and
- To request an addendum to previously published presentations

E. Subrecipient Requirements

Generally, the University will require that all subrecipients rely on its own institutional policy for complying with PHS FCOI regulations.

Office of Sponsored Programs (OSP)

- Require subrecipients to certify in the subrecipient Notice of Intent (NOI) that an up-to-date written and enforced administrative process to identify and manage FCOIs related to all PHS research projects is in effect for their institution
- Require the above in the award letter

If accepted under the University's PHS FCOI policy:

- Provide disclosure statements for all investigators, key personnel
- Provide disclosure for all persons meeting criteria for Covered Employees as defined in this policy

Office of Outreach and Technology Transfer

- Obtain certification of subrecipients' PHS FCOI compliant policy
- Include in the written agreement a requirement that the subrecipient will report identified FCOIs for its investigators and key personnel in a time frame that allows the University to report the same to NIH as required by the regulation

If the subrecipient cannot certify that a PHS FCOI policy is in place:

- Provide a copy of a new PHS FCOI policy to the Vice Chancellor for Research and Economic Development and Director of the ORCE for approval prior to accepting subrecipients' agreement (i.e. subrecipient institution's signatures)

- Include in the written agreement a requirement to submit subrecipient disclosures that enable the University to identify, manage, and report identified FCOIs to the NIH as required by the regulations

F. Public Accessibility Requirements

Office of Research Compliance and Ethics (ORCE)

Manage public accessibility of the University's PHS FCOI policy:

- On the DORED website
- On the Office of Legal Affairs' web page for approved policies

If requested, provide information concerning identified FCOIs held by Senior/Key Personnel:

- Include at least the minimum elements required by the regulation
- Be made publicly accessible prior to expenditure of funds
- Be updated annually and
- Within 60 days of a newly identified FCOI
- Remain available for 3 years from the date the information was most recently updated

Manage requests for information related to identified FCOIs held by Senior/Key Personnel:

- Respond within 5 calendar days of the date that a written request arrives at the General Counsel's office.

IV. CONFLICTS OF COMMITMENT

A. External Professional Activities for Pay (EPAP) by Faculty and Non-Faculty EPA Employees

While external activities for pay are recognized for producing important contributions towards society and economic development, EPAPs should be monitored and only be undertaken if they do not:

- 1) Create a Conflict of Commitment by interfering with the obligation of the individual to carry out all University Employment Responsibilities in a timely and effective manner;
- 2) Create a Conflict of Interest because of the individual's status as a Covered Employee of the University;
- 3) Involve any inappropriate use or exploitation of University resources;
- 4) Make any use of the name or marks of the University of North Carolina or any of its Constituent Institutions for any purpose other than professional identification; or
- 5) Claim, explicitly or implicitly, any University or institutional responsibility for the conduct or outcome of the External Professional Activities for Pay.

Faculty and Non-Faculty EPA employees are required to make disclosures via Notice of Intent (NOI) for EPAPs that are:

- Supported by a private entity and supports activities directly related to a covered employee's University Employment Responsibilities; or
- Where the covered employee or member of their immediate family holds an equity or ownership interest, or an holds office

Such NOIs are required to be submitted to the department chair:

- Initially, during the disclosure process for PHS funded and SBIR/STTR Phase II applications
- Not later than 10 days prior to the date the activity is to begin

Covered Employees

- Report external activity for pay on the NOI for EPAP
- Provide signed NOI for EPAP to the department chair when seeking approval for PHS funded grant proposals
- File a separate NOI for each activity meeting criteria for an EPAP
- File a new NOI for EPAP activity that will continue beyond the end of the relevant academic or fiscal year

Department Chairs

- Receive, consult with employee, and approve or disapprove of NOI for EPAPs
- Renew approval of EPAP
 - Upon annual reporting to the PHS funding agency or
 - Within 12 months of initial disclosure:
 - The calendar year for 12-month employees and those providing contract service that includes summer session
 - The academic year for 9-month employees with no summer session contract
- Notify employee and the dean if the NOI reveals an EPAP that is not consistent with policy within 10 calendar days of the NOI being filed
- Advise the employee to refrain from initiating the proposed activity
- Advise the employee of the appeals process (i.e. dean, then Provost)
- Provide departmental summaries of NOIs filed and actions taken during the preceding fiscal year to the dean

EPAPs for a proposed activity for an entity that provides funding that directly support the Faculty/EPA employees' University Employment Responsibilities or activities or a proposed

activity for a private entity in which the Faculty/EPA employee or member of their immediate family holds an equity or ownership interest, or an holds office:

- The dean shall review promptly and approve or disapprove within 10 days of receipt; and
- Advise the employee of the option to appeal to the Provost and to refrain from initiating the proposed activity.

Provost

- Serve as final decision-maker for EPAP appeals
- Provide an appeal decision (in writing) to the covered employee within 10 calendar days of the date on which the appeal was received
- Upon notice, submit annual report of NOIs to UNC-GA

V. Regulations for Senior Academic and Administrative Officers (SAAO) on External Professional Activities for Pay and Honoraria

Senior Academic and Administrative officers who engage in activities for pay that are not a part of their University employment shall:

- Use annual leave when such activities take place during the conventional work week (i.e. between 8:00 am and 5:00 pm, Monday through Friday).
- File appropriate disclosures of financial interests and NOIs for EPAPs in accordance with policies to the employee's supervisor
- Provide satisfactory assurances that such activity will not interfere with University employment obligations.

EPAP performed for another institution or agency of the State of North Carolina also must comply with State policies governing dual employment and compensation.

Honorarium

Honorarium may be paid under the following circumstances:

- Only for activities performed outside of normal working hours, as defined by the institution, or
- While the employee is on paid or annual leave, and
- All expenses are the responsibility of the employee or a third party that is not a State entity.

Sponsored Travel

- Sponsored travel, including when paid by a third party, for activities related to university employment responsibilities, for which no leave is taken, must be reported on the Travel Authorization Form.
- No travel authorization is required for travel taken for a purpose which is outside the definition of University Employment Responsibilities

SAAOs may also be subject to special regulations regarding honoraria which require leave to be taken when External Professional Activities for Pay will take place during the regular work week. Please refer to the *UNC Policy Manual*, 300.2.2.2

Employees who are exempt from the Fair Labor Standards Act and who are out of work due to an External Professional Activity for Pay, or who wish to retain an honorarium, may use periodic uncompensated leave rather than annual leave.

Exclusions

- These regulations may not apply to faculty and non-faculty EPA employees serving on academic year (9-month) contracts, if the External Professional Activity for Pay is wholly performed and completed outside of the contract service period and the activity does not conflict with the policies of A&T or Board of Governors and is not conducted concurrently with a contract service period for teaching, research, or other services to the institution during a summer session.
- In those instances when State-reimbursed travel, work time, or resources are used or when the activity can be construed as related to their University Employment Responsibilities, on behalf of the State, the employee shall not receive any financial consideration, including an honorarium.

VI. Enforcement Mechanisms, Remedies, and Non-Compliance

University employees not complying with this Policy will be subject to disciplinary action, up to and including discharge.

VII. Maintenance of Records

All records related to this policy shall be maintained for a period of 3 years from the final expenditure report of a PHS funded project or 3 years from the final decision for NOIs related EPAPs and disclosure of reimbursement of sponsored travel. All disclosures, reports, reviews, management plans, and related PHS FCOI documentation shall be held as confidential personnel-information. Only the required elements will be reported upon request.

FCOI Disclosures

The following records will be stored in RAMSES within the project specific file:

- Initial disclosure forms
- SFI/FCOI Review records
- Management Plans
- Mitigation Reports
- All other FCOI related reports required by NIH

Training

UNC-Chapel Hill serves as the training software provider for PHS/FCOI. Training records will be stored in the online training system. Representatives from the following offices will have access for verification purposes:

- DORED
- Contracts and Grants
- Committee Chair of the COI Committee for Review and Monitoring

EPAP Disclosures and NOIs

Disclosures for EPAP and sponsored or reimbursed travel for Faculty and Non-EPA Employees will be maintained by department chairs (or directors)

Disclosures for SAAO Professional Activities for Pay Disclosures will be maintained by the Division of Human Resources.

VIII. RELATED POLICIES

UNC Policy Manual 300.2.2, Policy on Conflict of Interest and Commitment

UNC Policy Manual 300.2.2[G]

UNC Policy Manual, 300.2.2.2 [R]

N.C. General Statute Sections 14-234, 14-236 and 133-32

NC A&T: HR (Annual Certification/2004 and Secondary Employment/2008)

<http://www.ncat.edu/provost/docs/Conflict%20of%20Interest%20Statement.pdf>

NC A&T: Purchasing

<http://www.ncat.edu/divisions/business-and-finance/purchasing/policies/conflict.html>

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