

# THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

## STANDARD OPERATING PROCEDURES FOR INDIVIDUAL CONFLICTS OF INTEREST AND COMMITMENT

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- I. Introduction
- II. Committee Structure
- III. Conflict of Commitment
- IV. Conflict of Interest
- V. Management of COI
- VI. Investigation and Resolution of Policy Violations

### I. Introduction

These Standard Operating Procedures (“SOPs”) are based on the University’s *Policy on Individual Conflicts of Interest and Commitment* (“the Policy”) and are intended to provide effective and transparent processes for the disclosure, review, management, and reporting of potential conflicts of interest within the University community. The SOPs do not apply to situations arising under the *Policy on Institutional Conflicts of Interest* or to situations governed by the Ethics in Government Act.

Terms used in these SOPs shall have the meaning as under the Policy unless otherwise noted. The SOPs are maintained and executed, except as noted, by the Conflict of Interest (COI) Officer and the COI staff who are part of the Research Compliance Program. In the absence of the COI Officer, the Director of the Research Compliance Program can fulfill such functions assigned to the COI Officer. These SOPs are subject to change.

### II. Committee Structure

The University currently has five standing individual conflict of interest committees: School of Medicine, School of Dentistry, School of Pharmacy, School of Public Health and the College of Arts & Sciences.

### III. Conflict of Commitment

External Professional Activities for Pay (EPAP) requests should be submitted online by the requesting employee 10 days prior to the activity through the [air.unc.edu](http://air.unc.edu) website. Any EPAP request will be routed to the designated EPAP approver(s) for review. EPAP approvers can approve or deny the requests. The decision, with any available comments, is automatically routed back to the requesting employee.

For further information, please see the policy for *External Professional Activities of Faculty and Other Professional Staff*.

#### **IV. Conflict of Interest**

Conflict of Interest disclosures shall be reviewed under the definition specified in the UNC Board of Governor's Policy on Conflict of Interest and Commitment. The definition of a conflict of interest being situations where a Covered Individual's personal or financial interest:

- may compromise,
- may involve the potential for compromising, or
- may have the appearance of compromising

his or her objectivity in meeting University duties or Institutional Responsibilities, including research activities.

##### **A. University Responsibilities Annual Administrative Role Disclosure**

The COI Officer shall create a schedule of required submission dates for University employees specifically required by the Policy to submit a conflict of interest annual form. Such form will be designed by the COI Officer and shall be filed electronically. Any employee who fails to file a required form on or before the date specified by the COI Officer other than for good cause (as determined by the COI Officer) shall be deemed to be in violation of the Policy and subject to disciplinary review by his or her supervisor.

The COI Officer will review all conflict of interest annual forms and determine whether or not the information disclosed in each represents a potential COI. Upon making the determination that there is a potential COI, the COI Officer will forward the applicable disclosure form with a preliminary analysis and recommendation for resolution to the Vice Chancellor or other officer with analogous administrative authority ("the reviewing officer") supervising the affected employee.

The reviewing officer shall issue a decision regarding the disclosure within fourteen days of receipt of the conflict of interest annual form, provided that that deadline may be extended by the COI Officer for good cause. Where the reviewing officer agrees with the COI Officer's analysis, the employee will be required to recuse himself or herself from any University activities affected by his or her COI. In situations where recusal of the employee cannot be effected consistent with his or her Institutional Responsibilities, the employee will be required to resolve the COI by divestment of the personal financial interest causing the COI.

Where the reviewing officer disagrees with the COI Officer's conclusion that a COI exists, he or she shall set out the basis for that decision in a memorandum to the Chancellor, with a copy to the COI Officer and the employee. The Chancellor may accept or reject the reviewing officer's decision and order such further measures to resolve or manage the COI as the Chancellor deems appropriate.

##### **B Research and Sponsored Projects Conflicts of Interest**

The following sections provide details on the procedures for complying with Section V.H of the Policy.

## **1. COI Training**

As specific in the Policy, all Covered Individuals are required to complete Conflict of Interest training prior to involvement in a Project. The training requirement applies whether the Project is funded or unfunded. Administrative offices which support the research enterprise are encouraged to take this training as well.

The training modules are on-line at [coi-training.unc.edu](http://coi-training.unc.edu). Except as detailed in the Policy, completion of training is valid for four years. Training status for an individual will be reflected in any appropriate Electronic Administration Research system. The sponsoring department or unit is responsible for ensuring that training has been completed prior to assigning a Covered Individual to a sponsored award account number.

Any principal investigator requesting use of alternative training should submit an email to [coi@unc.edu](mailto:coi@unc.edu) and attach a proposed plan for the alternative training.

## **2. Disclosures**

The University requires that all Investigators involved in a Project submitted through the Office of Sponsored Research (“OSR”) or the Office of Human Research Ethics (“OHRE”) submit conflict of interest disclosure forms detailing their personal and financial interests. Investigators will also need to complete an annual conflict of interest disclosure form.

The requirement to complete a specific conflict of interest disclosure form is communicated through an email notification to the Investigator. The email provides a link to access the form.

Other conflict of interest disclosures are self-initiated by an Investigator. All conflict of interest disclosure forms can also be accessed through the central website at [air.unc.edu](http://air.unc.edu).

### **A. Paid Authorship Disclosure**

Investigators with PHS funding must disclose any compensation received from paid authorship which includes textbooks, book chapters, etc. This information will need to be disclosed in the conflict of interest annual disclosure form. The University will determine if any further information is needed from the Investigator to assess the disclosure.

### **B. Reimbursed or Sponsored Travel Disclosure Form**

Investigators with PHS funding must self-disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities. To assist PHS funded Investigators in submission of this information, Investigators will receive a monthly reminder email to submit travel disclosures if appropriate. Such disclosure will include the sponsor or organizer, the purpose of trip, the destination, and the duration. Disclosure of reimbursed or sponsored travel is done through a specific travel disclosure form, separate from the annual and project-specific disclosures.

PHS funded Investigators are NOT required to disclose travel that is reimbursed or sponsored:

- directly through the University
- by a US federal, state, or local government agency, or
- by a US institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Reimbursed or sponsored travel from all other sources, including private entities, foreign governments, foreign universities, non-profits or NGO's must be disclosed.

The travel disclosure form should be submitted prior to the travel but must be submitted no later than 30 days after the occurrence of the travel. PHS funded Investigators will receive a monthly reminder email to submit travel disclosures if appropriate. The University will determine if any travel disclosure requires further information, including but not limited to the disclosure of the monetary value.

### **3. Review**

Upon completion of either the annual or project specific conflict of interest disclosure by an Investigator, the COI system checks for affirmative answers that might be an indication of a potential COI. If a potential COI is not indicated, the disclosure is finalized in the COI system. Electronic research systems (such as RAMSeS and IRBIS) are updated automatically indicating the review status of the particular disclosure as complete and may include a "no conflict" designation.

If a potential COI is identified by the system, the disclosure is flagged and reviewed by COI Staff, who will make a threshold determination of whether a potential COI exists, upon consultation with the COI Officer if necessary. The Investigator may be contacted to gather additional or supplemental information necessary to evaluate the disclosure.

If the COI Staff determines that no potential COI exists, the COI Officer or Staff will inform the Investigator of the determination. RAMSeS and IRBIS will be updated automatically to reflect the determination.

If the COI Staff determines that a potential COI exists, an alert is sent to the COI Review Committee Chair(s) with jurisdiction over the Investigator indicating that a review is necessary. The COI Review Committee Chair(s), with input from the COI Staff or COI Officer, will review the disclosure and make a determination regarding whether the case can be handled through expedited review or whether the case should be assigned to an agenda for full committee review. If the Committee Chair determines that expedited review is appropriate, he or she will make recommendations to the COI Officer on management of the conflict. In schools, centers or departments that have no standing conflict of interest committee, information on potential conflicts of interest will be shared with the appropriate Dean or Unit Head, who will perform the review in conjunction with the COI Officer.

Taking into account any conclusion reached by a COI Review Committee Chair (or Dean or Unit Head, as applicable) or a COI Review Committee, the COI Officer will determine whether a COI exists and, if so, whether it can be managed or must be resolved in order for

the Project to proceed. The COI Officer may proceed to make a determination regarding the existence of a COI if no advice is provided by the applicable COI Review Committee Chair (or Dean or Unit Head) or the COI Review Committee within fourteen (14) days of transmission by the COI Staff of the need for a COI evaluation; this deadline may be extended by the COI Officer for good cause and where doing so will not jeopardize the proposed research relationship.

The COI Officer shall indicate in the COI system one of the following determinations and the COI staff will convey the decision to the Investigator:

- (i) No COI exists;
- (ii) A COI exists that is subject to administrative considerations by the University,
- (iii) A FCOI exists that is subject to management by the University,
- (iv) A COI or FCOI exists that cannot be managed.

Where a COI is deemed to be subject to administrative considerations, the COI staff will promptly contact the Investigator with the proposed details and will secure the Investigator's agreement to such administrative considerations.

Where a FCOI is deemed to be subject to management, the COI Officer will promptly contact the Covered Individual to discuss the Management Agreement and will arrange necessary meetings with the Investigator to resolve any questions he or she may have prior to gaining the Investigator's agreement to abide by the created a Management Agreement.

The IRB retains final jurisdiction over Human Subjects Research and may decline to approve an application on grounds of COI notwithstanding a decision by the COI Officer that there is no COI or that a COI is present but capable of being managed.

## **V. Management of Conflicts of Interests**

### **A. Management Principles**

The COI Officer is responsible for designing appropriate management mechanisms for conflict of interest activities which have been determined to be capable of being managed. The COI staff will work with the applicable COI Committees and/or Committee Chair(s), Deans or Unit Heads on determining the management plan and tools. The COI Officer may seek advice from individuals outside as well as within the University in proposing such mechanisms.

Possible measures to be taken in managing a COI include, but are not limited to, any of the following:

- Public disclosure of financial interests
- Reformulation of the work plan

- Close monitoring of the project; independent review committee
- Substituting supervisors and/or any other personnel
- Divestiture of financial interests
- Termination or reduction of involvement in the relevant projects
- Termination of inappropriate student involvement in projects
- Severance of relationships that pose actual, potential or the appearance of conflicts
- Separation of the Covered Individual from involvement in human subjects research in the critical areas of recruitment, inclusion/exclusion evaluation, enrollment, and adverse event evaluation and reporting.

## **B. Reporting of FCOI for PHS Funded Investigators**

As required by PHS regulations, the University shall report the following information regarding FCOIs related to PHS funded research to the funding agency through the eRA Commons:

- Project Number
- PD/PI or Contact PD/PI if multiple PD/PI model is used
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has a the FCOI
- Nature of the financial interest (e.g. equity, consulting fee, travel reimbursement, honorarium)
- Value of the financial interest, or a statement that the interest is one whose valued cannot be readily determined through reference to public prices or other reasonable measure of fair market value
- A description of how the financial interest relates to the PHS-funded research and the basis for the University's determination that the financial interest conflicts with such research
- A description of key elements of the University's Management Plan including:
  - Role and principal duties of the conflicted Investigator in the research project
  - Conditions of the Management Plan
  - How the Management Plan is designed to safeguard objectivity in the research project
  - Confirmation of the Investigator's agreement to the Management Plan
  - How the Management Plan will be monitored to ensure Investigator compliance
  - Other information as needed or requested by the funding agency

## **C. Public Accessibility**

In accordance with the federal regulations, the University will make information available to the public regarding **FCOIs** for those **Senior/Key Personnel** in conjunction with a specifically **PHS** funded research project. Requests must be submitted in writing to the Office of University Counsel, 110 Bynum Hall, CB 9105, 222 East Cameron Avenue Chapel Hill, NC 27599-9105, Attention: Public Records Request, or via email to [publicrecords@unc.edu](mailto:publicrecords@unc.edu). Request will be answered within five business days from the date of receipt at the Office of University Counsel. The request must identify the specific PHS project number for which the information is being requested and must include a named recipient. If the request is in writing, a return address with a physical street address must

be included, P.O. Boxes are not acceptable.

The University will note in its written response that the information is current as of the date of the correspondence, and is subject to updates at least annually and within 60 days of the University's identification of a new FCOI, which must be requested under separate cover by the requestor.

In accordance with PHS regulations, the following information will be provided:

1. Project Number
2. Name of the Investigator with a conflicted interest;
3. Investigator's title and role with respect to the PHS research project;
4. Nature of the financial interest (e.g. equity, consulting fee, travel reimbursement, honorarium); and Value of the financial interest (in ranges), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

## **VI. Investigation and Resolution of Policy Violations**

Any time the COI Officer becomes aware of a potential violation of the Policy or of any other situation that could indicate that University research, education and training may have been affected inappropriately by a Conflict of Interest, the COI Officer shall conduct a preliminary investigation to determine whether the concerns appear to be warranted.

On receipt of such a report, the COI Officer shall notify the General Counsel and the Director of Research Compliance. In consultation with those persons, the Conflict of Interest Officer may:

- (1) Investigate the matter and make a written memorandum of his or her conclusions;
- (2) Request that the person or committee assigned to monitor the activity conduct an investigation and file a written report of the results of that investigation; or
- (3) Appoint another faculty member or a committee of faculty members to conduct an investigation and file a written report of the results of that investigation.

Any such investigation should, at a minimum, include a personal interview with the person bringing forth the allegations or concerns and a personal interview with the Covered Individual, who should be informed with specificity of the allegations or concerns that have arisen. While the Covered Individual has a right to know the identity of a person making such allegations, he or she should be informed that University policy prohibits retaliation against a person making such allegations in good faith.

Upon determination that a violation of this Policy has occurred or of the existence of a situation that could indicate that University research, education, training, business administration or other performance may have been affected inappropriately by a conflict of interest, the COI Officer should take any steps necessary to correct the situation, including and up to disapproval of the conflict of interest being managed. In addition, where

appropriate the COI Officer must consider recommending to the relevant officials the imposition of disciplinary or other action under other appropriate University policies, including the Policies and Procedures on Ethics in Research and disciplinary policies for faculty, staff or students. Such possible actions or sanctions could include a letter of reprimand, increased monitoring of the conflict or other appropriate actions. The COI Officer, in consultation with the Vice Chancellor for Research, shall have the authority to direct that the research activities of the Covered Individual affected by the COI be suspended pending conclusion of an investigation or, on conclusion of an investigation, that they be suspended pending amelioration of the Policy violation.

Upon a determination that no violation of the Policy has occurred, or otherwise at the conclusion of any investigation conducted under this Policy, all materials generated in the course of such investigation should be placed with the Covered Individual's personnel file or, if a student, with the Office of the Vice Chancellor for Student Affairs, marked as "confidential" and stored in a secure manner, in order to ensure the confidentiality of these records.

For PHS funded studies, the University and Investigators are subject to the following additional procedures when a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a financial interest that is determined by the University to constitute a FCOI; failure by the University to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI Management Plan.

- (1) The University must implement, on at least an interim basis, a Management Plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward;
- (2) Within 120 days of the University's determination of noncompliance, the University must complete a retrospective review of the Investigator's activities and the PHS funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
- (3) The University must document the retrospective review and include, at minimum, the following information:
  - (a) Project number
  - (b) Project title
  - (c) PD/PI or contact PD/PI if a multiple PD/PI model is used
  - (d) Name of the Investigator with the FCOI
  - (e) Name of the entity with which the Investigator has a FCOI
  - (f) Reason(s) for the retrospective review
  - (g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
  - (h) Findings of the review
  - (i) Conclusions of the review

Based on the results of the retrospective review, if appropriate, the University shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If the retrospective review team members find bias, the University is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

Thereafter, the University will submit to the PHS Awarding Component FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the FCOI, the University may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded research project between the date that the Investigator's noncompliance is determined and the completion of the University's retrospective review.