

UNC Policy Manual 300.2.2 - Summary of Revisions

The U.S. Public Health Service (PHS) issued a final rule August 23, 2011 changing the requirements for the disclosure and reporting of financial interests of faculty researchers and institutions that apply for or receive funding from the Public Health Service, including the National Institutes of Health (NIH). UNC institutions and PHS-funded researchers must be in compliance with the final rule by August 24, 2012.

The UNC System received over \$1.2B in external funding in FY 2011 with approximately 41% awarded by PHS/NIH. UNC-CH receives ~60% of its external funds from the PHS/NIH and all UNC campuses except NCSSM and UNCSA have received some PHS/NIH funding.

The changes in PHS/NIH regulations were prompted by the growing complexity of interaction among federal agencies, research institutions and the private sector in the research enterprise and highly publicized events over the last several years involving medical school/clinical faculty and their financial interests in pharmaceutical firms that either sponsor their research or whose drugs they are testing. The primary interest of PHS/NIH is to achieve greater transparency, greater assurance that research results are not biased and greater accountability from institutions and investigators.

A working group comprised of research compliance/conflict of interest officers, university attorneys and technology transfer officers reviewed the current BOG policy against the revised federal regulations and crafted the revised BOG policy. Stakeholders at the campus level including Chief Research Officers, Provosts, University Attorneys, Technology Transfer Officers and others then vetted the revised policy at the campus level. The revised policy, regulations and guidelines are the result of this multi-stage review process.

The Board of Governor's Policy on Conflict of Interest and Conflict of Commitment has been substantially revised to be compliant with the revised federal regulations and has been edited throughout for presentation and clarity of intent and understanding by institutional officials and faculty. Following are some new aspects of the revised BOG policy:

- I. Financial interests and conflicts of interest are reviewed in the context of the Covered Employee's University Employment Responsibilities;
- II. Constituent Institutions are directed to develop implementing policies and procedures that clarify permissible and impermissible conduct, include processes to manage or mitigate conflicts of interest, provide for training on the Conflict of Interest Policy and comply with prevailing federal regulations; and
- III. The revised policy cites an August 24, 2012 implementation date. This is the required date of compliance and will give Constituent Institutions time to further develop implementing policies and procedures, train Covered Employees on the Conflict of Interest policy, and develop mechanisms to meet the requirements of the PHS/NIH final rule.

Specific Revisions to *UNC Policy Manual* 300.2.2

Reordered the policy sections as follows: I-Definitions, II-Conflicts of Interest and III-Conflicts of Commitment

Edited the definition of Conflict of Interest to provide for the review of financial interests in terms of the Covered Employee's University Employment Responsibilities

Added a definition of Financial Interest

Edited the definition of University Employment Responsibilities for clarity

Added a definition of Covered Employee

Edited the definition of Inappropriate Use or Exploitation of University Resources for clarity

Expanded Section II-Conflicts of Interest to address the responsibilities of Constituent Institutions to develop implementing policies and procedures and text on "Avoiding Conflicts of Interest" moved to this section

Edited Section III Conflict of Commitment to include reference to External Professional Activities for Pay and for clarity

Conflict of Interest and Commitment

The Code of the University of North Carolina affirms that the basic mission of the faculty is "the transmission and advancement of knowledge and understanding." Faculty employment entails the core responsibilities of teaching, scholarly research and publication, and other professional service to the institution and to society. Realization of those objectives is facilitated and encouraged by certain distinctive characteristics of employment within an academic community, which differs markedly from the conventional work-day and work-week employment models in most business and industrial settings.

Faculty members pursue their specialized professional interests in other contexts, collateral to their immediate University employment. They hold memberships in and attend meetings of professional associations and learned societies; they serve on review or advisory panels; they present lectures, papers, concerts and exhibits; they participate in seminars and conferences; they review and edit scholarly publications; and they participate in accreditation reviews. Faculty and non-faculty EPA employees ("Covered Employees") have opportunities to use their specialized competencies in secondary professional employment, as paid consultants to public and private agencies, and thereby contribute to the transfer and application of knowledge.

As relationships between Covered Employees and private industry, federal and state governments, and nonprofit agencies have grown in number and scope, there has been a corresponding increase in concern about conflicts of interest and commitment. While these Covered Employees are encouraged to engage in appropriate relationships with public and private agencies outside of the University, there is a need for commonly understood principles and corresponding procedures that will identify, address and manage potential conflicts that would detract from or interfere with a Covered Employee's dedication of unbiased primary professional loyalty, time, and energy to University teaching, research, and service.

All members of the University community are expected to avoid conflicts of interest and conflicts of commitment that have the potential to directly and significantly affect the University's interests or compromise their objectivity in carrying out their University Employment Responsibilities, including research, service and teaching activities and administrative duties, or otherwise compromise performance of University responsibilities, unless such conflicts are disclosed, reviewed and appropriately managed in accordance with the provisions of this Policy.

It is the policy of the University of North Carolina that activities undertaken by its faculty, staff and students in furtherance of the mission of the University shall be conducted in an ethical and transparent manner consistent with federal and state law and university policy.

I. Definitions

A. *Conflict of Interest* 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.

B. *Financial Interest* is defined as:

- 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 entities (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 the implementing policies of the Constituent Institutions.

C. *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.

D. *External Professional Activities for Pay* 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 Section III 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. External activities for pay of employees covered by the State Personnel Act are addressed in the State Personnel Act, Section 3 Employment and Records, Secondary Employment.

E. *University Employment Responsibilities* include "Primary Duties" and "Secondary Duties." Primary Duties consist of assigned teaching, scholarship, research, institutional service requirements, administrative duties and other assigned employment duties. 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 (see additional regulations, *UNC Policy Manual*, 300.2.2.2 [R]) or the reimbursement of expenses, include 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.

F. *Covered Employee* is defined as any faculty or EPA non-faculty person employed by the University of North Carolina or a Constituent Institution, an affiliated entity, or other agency or unit of the University of North Carolina. The implementing policies of Constituent Institutions may further define Covered Employee to include additional classifications of personnel and students, which would further be considered Covered Individuals.

G. *Constituent Institution*, for the purposes of this policy, includes affiliated entities of the University of North Carolina, General Administration, and units associated with General Administration. Affiliated entities and other units of General Administration may implement Conflict of Interest policies consistent with this policy or adopt the policy of one of the constituent institutions.

H. *Department* means an academic department, a professional school without formally established departments, or any other administrative unit designated by the chancellor of an institution or by General Administration, for the purposes of implementing this policy. "Department Head" refers to the person with supervisory responsibility for the Covered Employee, whether in an academic or non-academic department.

I. *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 the constituent institution's implementing policies and other 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.

II. Conflicts of Interest

Constituent Institutions shall develop detailed implementing policies and procedures that establish parameters of general applicability that will permit their institution and their employees to recognize potential Conflicts of Interest, and to institute basic procedures for disclosing Financial Interests and managing potential or actual Conflicts of Interest. Institutional policies shall require that a Covered Employee's professional activities and financial interests must be arranged to avoid circumstances that do or may prevent or limit objectivity in the performance of University Employment Responsibilities or that otherwise do or may adversely affect any University interests. The implementing policies and procedures of the Constituent Institutions will ensure compliance with prevailing Federal regulations. Institutions may develop separate policies to address specific federal and state requirements. In the event federal agencies or other external sponsors impose additional disclosure requirements on Constituent Institutions, disclosure to the sponsor must also include disclosure to the University.

A. Avoiding conflicts of interest

Each constituent institution must adopt policies and procedures that:

- 1) effectively impart a clear understanding of permissible and impermissible conduct;
- 2) provide for disclosure of Financial Interests, review of disclosures in the context of University Employment Responsibilities and processes to manage or mitigate conflicts of interest;
- 3) provide for training of employees on its conflict of interest policy, the audience, content and frequency of which will be determined by the Constituent Institution's implementing policies and procedures; and
- 4) provide for compliance with applicable federal regulations.

Critical to the success of any program established to address Conflicts of Interest is employee understanding of the potential problems, so that individuals are equipped to avoid such conflicts on their own initiative. While in many situations the conflict of interest would be obvious to all, in other situations the potential difficulty would not be so apparent. Since concern about Conflicts of Interest appropriately embraces situations in which there is a potential for or appearance of conflict, as well as actual conflict, there may be differing views about what is or is not a problematic activity or affiliation. Thus, the faculty and administration of each Constituent Institution must establish basic definitions of activities and circumstances with a potential to create Conflicts of Interest and then must ensure that all affected employees are fully informed, on a regular and continuing basis, through training and distribution of institutional policies and procedures on individual Conflicts of Interest and Conflicts of Commitment.

Each Constituent Institution must establish procedures that elicit information in a timely manner about potential Conflicts of Interest related to the Covered Employee's University Employment Responsibilities. Designated administrative officials or faculty, as defined by the Constituent Institution's implementing policies and procedures shall analyze the disclosed financial interest in the context of the Covered Employee's University Employment Responsibilities and decide whether the activity or affiliation in question actually presents a Conflict of Interest and, if so, what safeguards or remedial actions should be taken. Covered Employees shall be required to supplement the information elicited by the Conflict of Interest questionnaire at any time during the academic year when a new Financial Interest might entail a Conflict of Interest. In each case a designated administrative officer would provide a final ruling, subject to any prescribed rights of appeal in the Constituent Institution's implementing policies and procedures.

In combination, the University's policy on Conflicts of Interest, the required disclosure process, and publicity and training should assist all Covered Employees avoid any difficulties recognizing and managing Conflicts of Interest.

Each Constituent Institution may adopt additional related internal policies, procedures, and guidelines consistent with this Policy.

The UNC Board of Governors' Policy on Conflict of Interest and Commitment, *UNC Policy Manual* 300.2.2, is effective August 24, 2012.

Each Constituent Institution shall submit to the President a copy of its institutional policies and procedures on individual Conflicts of Interest, including definitions of Conflicts of Interest, methods for publicizing the policy and training Covered Employees on institutional definitions and requirements, and procedures and questionnaires for disclosing relationships and circumstances that may raise questions about Conflicts of Interest. Any substantial modifications

of the Constituent Institution policies and procedures for individual Conflicts of Interest should also be forwarded to the President after approval by the Constituent Institution.

III. Conflicts of Commitment

Questions about conflict of commitment are more easily recognized and resolved than questions about Conflicts of Interests. Although full-time faculty and other non-faculty EPA employment is not amenable to precise, time-clock analysis and monitoring, administrators at the department and school levels regularly evaluate the work of employees within their units. The formal occasions for determining whether an individual is devoting sufficient time and effort to University employment include regular reviews of performance in connection with annual salary decisions and scheduled reviews incident to promotion, reappointment or tenure decisions. In addition, complaints from students, colleagues, or administrators about possible failures to meet assigned responsibilities may arise and require investigation. The issue, in each case, is whether the employee is meeting the requirements of the job. If presented with evidence that he or she is not meeting full-time responsibilities to the University, *The Code* prescribes that "neglect of duty" is a ground for disciplinary action, including the possibility of discharge. The following describe instances of activities that require specific monitoring to demonstrate compliance with policies.

A. External Professional Activities for Pay

The University of North Carolina and its Constituent Institutions seek to appoint and to retain, as employees, individuals of exceptional competence in their respective fields of professional endeavor. Because of their specialized knowledge and experience, these individuals have opportunities to apply their professional expertise to activities outside of their University employment, including secondary employment consisting of paid consultation or other service to various public and private entities. These practical compensated applications of their professional qualifications enhance capabilities in teaching, research, and administration. Thus, participation of employees in external professional activities for pay, typically in the form of consulting, is an important characteristic of academic employment that often leads to significant societal benefits, including economic development through technology transfer. However, External Professional Activities for Pay are to be undertaken only 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.

The *UNC Policy Manual*, 300.2.2.1 [R], contains provisions established to monitor possible Conflicts of Commitment, including mandatory pre-approval at appropriate university levels of External Professional Activities for Pay. A faculty or non-faculty EPA employee who wishes to engage in External Professional Activity for Pay must adhere to these regulations to provide satisfactory assurances that the activity will not interfere with University Employment Responsibilities. 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 the Constituent Institution 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 the Covered Employee's University Employment Responsibilities on behalf of the State, the employee shall not receive any financial consideration, including an honorarium. In these instances the employee may request that the honorarium be paid to the University. The honorarium may be retained by the employee only for activities performed outside of normal working hours, as defined by the institution, or while the employee is on earned paid or annual leave, and all expenses are the responsibility of the employee or a third party that is not a State entity. Third party support may need to be disclosed under the implementing policies and procedures for Constituent Institutions. In addition, senior academic and administrative officers 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 [R].

Instead of using earned paid or annual leave as set out above 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 be able to use periodic uncompensated leave rather than annual leave, provided the Constituent Institution implementing policies allow the use of uncompensated leave, and the appropriate Department Head approves.

External Professional Activities for Pay performed for another UNC Constituent Institution or agency of the State of North Carolina also must comply with applicable State policies governing dual employment and compensation, unless an exception to those State policies is expressly authorized by the chancellor or the President.

The Board of Governors has also established rules for monitoring and regulating the involvement of University employees in political candidacy and office-holding that could interfere with full-time commitment to University duties. Please refer to *UNC Policy Manual*, 300.5.1 et seq. for specific policy details.