

RECOGNIZE & MANAGE COI

If it is determined that the potential for a conflict exists and therefore should be managed or reduced, the COI Officer, in consultation with the COI Committee and/or administrative resource team as appropriate, will determine the appropriate course of action.

Options available for management of conflict of interest, include

1. Notice to those involved in the project of the employee's conflicting interests
2. Appointment of additional, non-conflicted employees to monitor the project in terms of guarding against bias in research findings, providing additional accountability for financial matters, and/or protecting student interests.
3. Public disclosure of the conflicting interest
4. Acknowledgement of the conflict interest in consent forms
5. Modification of the research or project design
6. Removal of the employee from specific responsibilities

In some circumstances, elimination of the conflict may be deemed necessary, including

1. Non-acceptance of the gift or grant
2. Withdrawal of the proposed project
3. Employee divestiture of the conflicted interest

The course of action decided upon should be documented in the form of a management plan. The management plan should be shared with and acknowledged by the employee's direct supervisor (e.g., department chair). When the project involves external funding and/or human subjects research, the management plan also must be signed by a representative of the Dean's Office (or equivalent) and the Vice Chancellor for Research and Economic Development. Management plans should be reviewed annually or any time that changes occur with the project that could impact the nature of the conflict. Approved management plans should be stored with the initial disclosure via the AIR system and shared with individuals responsible for oversight of research compliance (e.g., The Office of Research Integrity).

MANAGEMENT PLAN GUIDING PRINCIPLES

1. Existing University policies, State law, and Federal regulations dictate boundaries that employees must keep between their roles associated with the University and their private interests outside of the University.
2. The substance and impact of the project should be appropriate to the mission of the University. That is, the project should contribute to advances in scholarship and/or provide educational opportunities for students.
3. The conditions under which research and teaching take place should allow for the free exchange of ideas and materials, including the publication and dissemination of research results. Situations that would place restrictions on these activities should be carefully considered in light of University policies and should give reviewers pause.
4. Any proposed use of University resources should be appropriate per University policy and State regulations. University resources should be defined in a broad sense, including equipment, office space, and staff time. This also includes resources unique to the university environment, such as students (e.g., in the testing of teaching materials), software (where license agreements often restrict use for instructional or academic purposes only), and the Institutional Review Board. University resources should not be used for personal or private gain, but are resources vested under our care for the public good.
5. The potential effect of any given financial interest on a situation or project should be viewed in terms of
 - The reasonable likelihood that the results of the project could directly affect the value of related products, services or intellectual property in which an entity outside the University has an interest; and
 - The reasonable likelihood that the results of the project significantly impact the value of the outside entity or its sales.

SMALL BUSINESS/STTR GRANTS

Of special note are Small Business Innovation Research (SBIR) grants and Small Business Technology Transfer (STTR) grants. Employees may not serve as the Principal Investigator of an SBIR/STTR grant for both the outside small business and the University, as this would render it impossible for the interests of the business and the University to be kept distinct. In general, employees who have a financial interest in an outside entity may not serve as the Principle Investigator of an agreement between that entity and the University. Additionally, there must be a very clear distinction between activities that are conducted at the University using University resources and activities performed at the small business site, and all work done using University resources must be consistent with University and State policy. Generally this means that the University's involvement in the project should be focused on long-range exploratory work without immediate commercial value.

MANAGEMENT PLANS

Conflict of interest refers to situations in which employees may have the opportunity to influence the University's business decisions in ways that could lead to personal gain or give advantage to associates or firms in which employees have an interest. A management plan is required whenever there is a potential for a conflict of interest or commitment, or the perception of such a conflict.

Procedure:

- *The employee should download and complete the appropriate form in draft and send it to the Conflict of Interest Official for initial review and clarification of issues.*
- *The plan should be submitted to the head of the department, lab or center where the employee works or the sponsored project will be conducted; as well as Dean of the home department where the investigator is appointed for review and vetting.*
- *Once the details of the plan have been finalized, the employee/researcher should finalize the document, sign it, and circulate it for signature to the appropriate department head or dean.*
- *A scan of the final, completed documents should be submitted to the COI Official for final signature authorization and record keeping.*

FAMILY RELATIONSHIPS: OWNERSHIP INTERESTS & REPORTING STRUCTURES

According to the Code of Federal Regulations (CFR), Title 2.A §200.318(c)(2), which defines uniform administrative requirements, costs principles, and audit requirements for federal awards:

"No employee, officer, or agent may participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest. Such a conflict of interest would arise when the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in or a tangible personal benefit from a firm considered for a contract."

Per CFR §200.465 family members are defined as:

Family members include one party with any of the following relationships to another party:

1. Spouse, and parents thereof;
2. Children, and spouses thereof;
3. Parents, and spouses thereof;
4. Siblings, and spouses thereof;
5. Grandparents and grandchildren, and spouses thereof;
6. Domestic partner and parents thereof, including domestic partners of any individual in 2 through 5 of this definition; and
7. Any individual related by blood or affinity whose close association with the employee is the equivalent of a family relationship.

SIGNIFICANT FINANCIAL INTERESTS, EQUITY OWNERSHIP, ENTREPRENEURIAL ACTIVITIES

The 2011 NIH/PHS revised regulation defines a “Significant Financial Interest” and provides for what is required to be disclosed as follows:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s family members) that reasonably appears to be related to the Investigator’s institutional responsibilities:

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

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

(3) The term *significant financial interest* does not include: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.”

CONSULTING AND OTHER EXTERNAL PROFESSIONAL ACTIVITIES FOR PAY

The UNC Board of Governors’ policy on Conflict of Interest and Commitment provides provisions governing External Professional Activities for Pay of Faculty and EPA non-Faculty employees^[1]. All Faculty and EPA non-Faculty employees of the University are required to receive approval in advance (minimum of 10 days) of engaging in external professional activities for pay (except for contract employees performing external professional activities for pay entirely outside the months of their University contract employment).

A small group of activities are exempted from the requirement for prior approval because they can typically be considered to be secondary employment responsibilities and, given their nature, will not generate financial conflicts of interest. These exempted activities include:

1. Seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education;
2. Service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education;

Activities for pay not involving the professional knowledge, experience and abilities you are employed for at ASU are not subject to the advance disclosure and approval requirements of the Board of Governors’ 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 a Conflict of Interest, involve inappropriate uses of the University name or resources, or include claims of University responsibility for the activity.