



Subject: Conflict of Interest on Extramurally Funded Programs		Policy No: 359
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Division: All University		
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Approved By: Kathleen H. Goepfing, Ph.D. President and CEO		

PURPOSE

The teaching, research and service mission of the University must be conducted by all applicable individuals in a manner that is free from any inappropriate influence that may arise from an individual's private interests outside the University. This policy is intended to serve as a guide for individuals so that their relationships with private industry and any other external agencies are structured in full consideration of their primary responsibility for teaching, research and service to the University. In addition, this policy ensures compliance with the U.S. Department of Health and Human Services (HHS) financial conflict of interest (FCOI) regulation, which promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research conducted under the Public Health Service (PHS), including National Institutes of Health (NIH) grants or cooperative agreements, will be free from bias resulting from individuals' financial conflicts of interest. In those situations, where a possible conflict of interest exists, this policy will enable applicable individuals to recognize such conflicts and ensure that the facts are reviewed and if necessary, the individual participants comply with these policies and the FCOI regulation and are supervised or monitored to assure that the integrity of the University's mission is not compromised. This policy applies to all University faculty and staff and any other person, regardless of title or position with the University, who is responsible for the design, conduct or reporting of research funded by the NIH, or proposed for such funding, including post-doctoral fellows, graduate and undergraduate students, collaborators and consultants. The only NIH award programs that are excluded from the FCOI regulation are the Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) Phase I applications.

POLICY

It is the policy of the University to comply with the FCOI regulation with respect to any research or other activity for which there has been an application for or receipt of NIH funding from a grant or cooperative agreement, and that all applicable individuals shall avoid conflicts of commitment and conflicts of interest that may impair their ability to meet their University responsibilities. Each individual proposing or holding extramurally funded grants and/or contracts must, prior to funding and within thirty (30) days of discovering or acquiring a new financial activity or interest and at least annually thereafter during the period of an award, disclose those outside financial activities or interests that could reasonably appear to or be expected to result in a conflict of interest or to compromise the individual's ability to conduct teaching, service or research activities at the University.

1. General Guidelines

- A. Individuals must conduct their personal financial affairs in a manner that does not impede or conflict with their responsibilities to the University.
- B. As further described below, all individuals applying for, holding extramurally funded grants and/or contracts and all persons responsible for the design, conduct or reporting of research funded by the NIH, or proposed for such funding, must provide full and complete disclosures of external financial activities and Significant Financial Interests (as defined below) of such person and his/her spouse and dependent children to ensure that no conflicts of commitment or conflicts of interest to University activities arise. These disclosures will allow the University to develop a plan to manage, reduce or eliminate any conflicts so that the integrity of the University's mission and the continued availability of extramurally funded teaching, research, or service activities are not compromised.

2. Type of Conflicts

A. Conflicts of Commitment

- An individual is engaged in a conflict of commitment if consulting agreements, grants, contracts or activities or other commitments to or with outside agencies are sufficiently demanding of the individual's time that such outside commitments interfere or may interfere with the individual's administrative,

teaching, service, research and scholarly commitments to the University. The individual's commitment to the University must have priority over external interests, and the University's resources may not be used for either personal or private gain or directed for the benefit of others without appropriate approval by the University.

B. Conflicts of Interest

- A conflict of interest situation exists when the individual uses or would appear to an independent third party to have used his or her position to advance his or her own personal financial interests or the personal or financial interests of his or her immediate family or an associated entity, or when an individual or his or her spouse or dependent children have a Significant Financial Interest (as defined below) that reasonably appears to be related to the individual's University responsibilities.

3. Significant Financial Interest.

A. A Significant Financial Interest for purposes of the required disclosures means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights) of an individual and his or her spouse and dependent children, in each case that reasonably appear to be related to any of the individual's professional responsibilities to or on behalf of the University.

B. The requirement to disclose Significant Financial Interests includes a requirement to disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the individual and not reimbursed to the individual so that the exact monetary value may not be readily available), related to his or her 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 as defined at 20 U.S.C. 1001 (a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. University official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest.

C. Significant Financial Interest does not include:

1. salary, royalties or other remuneration from the University if the individual is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
2. income from investment vehicles, as long as the individual does not directly control the investment decisions made in these vehicles;
3. income from seminars, lectures, or teaching engagements 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, or a research institute that is affiliated with an Institution of higher education;
4. income from services on advisory committees or review panels for 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, or a research institute that is affiliated with an Institution of higher education;
5. a current or pending equity interest (including stock, stock options and other ownership interests) in a publicly traded entity that when aggregated with any salary, royalties or other payments for services (e.g. consulting fees, honoraria or paid authorship) from such entity for the individual and the individual's spouse and dependent children over the preceding twelve months, does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value; or

6. salary, royalties or other payments for services (e.g. consulting fees, honoraria or paid authorship) from any non-publicly traded entity that when aggregated for the individual and the individual's spouse and dependent children over the preceding twelve months, does not exceed \$5,000, provided that neither the individual nor such individual's spouse or dependent children hold any equity interest (including stock, stock options or other ownership interest) in such non-publicly traded entity.

4. Examples of Unacceptable Conflicts Include (not all-inclusive):

- A. Diverting to outside entities grant or contract support that the University might otherwise receive;
- B. Using University resources, including assigned time and facilities (in excess of that allowed for consulting), for private gain without proper compensation to or consent from the University;
- C. Using University resources for purchases or payments to any entity in which a faculty or staff member (or other applicable individual under this policy) holds a Significant Financial Interest, without approval of the University.
- D. Impeding the dissemination of research information;
- E. Using a position of influence or authority to involve other faculty staff or students of the University in non-University activities without the consent and supervision of the University.

5. Financial Disclosure.

- A. Any individual submitting an application for a grant or contract, and any individuals who are participating in or who are planning to participate in NIH funded research, must file a Conflict of Interest Policy Disclosure Form C disclosing all Significant Financial Interests:
 - 1. Prior to the submission of the application, disclosing all Significant Financial Interests over the preceding twelve-month period;
 - 2. Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) a new Significant Financial Interest; and
 - 3. At least annually thereafter during the period of the award.

All details should be disclosed. At the time of each filing of Form C, if the individual submitting the grant or contract does not have a Significant Financial Interest, he or she must certify on the Form that no potential conflict of interest exists. Any potential conflict of interest that appears on the Form must be resolved before the University can approve any initial or subsequent expenditures of any funds under the grant or contract, as applicable.

- B. The Supervisor or administrative official in the Office of Research and Sponsored Programs may require the member of faculty or staff (or other applicable individual) to complete and submit further disclosures as deemed necessary.

PROCEDURE

- A. All individuals applying for extramurally funded grants or contracts and any individuals who are participating in or who are planning to participate in NIH-funded research must submit a Conflict of Interest Policy Disclosure Form C to their Supervisor, who is responsible for providing a preliminary assessment regarding potential conflicts of interest and a recommendation for action.

- B. The Supervisor will sign off and forward the forms to the administrative official in the Office of Research & Sponsored Programs who will certify that no conflict exists, that sufficient controls are in place to manage and identify conflicts or that the activity constitutes an unacceptable conflict. If necessary, the administrative official will develop a Memorandum of Understanding after meeting with the individual involved in the possible conflict of interest. The Memorandum of Understanding will address the potential conflicts and specify the details of a management process to assure that any conflicting interests will be managed, reduced or eliminated. Any management process will be promptly implemented.
- C. With respect to a form submitted in the event of a Significant Financial Interest that is acquired or discovered during the awarded project period, the applicable foregoing procedures must be completed within sixty (60) days of receiving the form from the applicable individual.
- D. In an effort to manage possible conflicts of interest due to outside interests, the University may impose conditions or restrictions to manage, reduce, or eliminate potential or actual conflicts of interest disclosed by individuals in a Memorandum of Understanding. The administrative official in the Office of Research and Sponsored Programs, may, in his or her discretion, appoint an *ad hoc* committee of faculty and administration to review the conflict of interest and disclosures and prepare a Memorandum of Understanding to manage any conflict. The *ad hoc* committee may meet with or ask questions of the affected individual to discuss the process of preparing the Memorandum of Understanding. The conditions or restrictions imposed by the Memorandum of Understanding may include, among others:
1. Public disclosure of the private interest;
 2. Independent monitoring of all activities under the grant or contract;
 3. Modification of such activities;
 4. Divestiture of the private interest, and/or;
 5. Severance of the relationships creating the conflict.
- E. If the individual is dissatisfied with the resolution of a conflict of interest provided through a Memorandum of Understanding, the individual may appeal to the President. The decision of the President shall be final.
- F. In any case in which the HHS determines that an NIH-funded 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 individual with a conflicting interest that was not managed or reported by the University as required by the FCOI regulation, the University must require the individuals involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

6. REPORTING AND RECORD KEEPING

- A. The University will maintain records of Conflicts of Interest Policy Disclosures for three years after the later of the termination of the externally sponsored activity or the submission of the final expenditures report. In the event that an individual fail to comply with the University's Conflict of Interest Policy, the University will notify the appropriate federal agency sponsoring the activity of the corrective action taken or to be taken.

The federal agency may inquire into the University's procedures and actions regarding conflict of interest in federally funded research, including a requirement for submission of, or review on site of all records pertinent to compliance with appropriate federal law.

- B. The administrative official in the Office of Research and Sponsored Programs will act as the University's certifying official for reporting to federal agencies. All Conflict of Interest Policy Disclosures and Memoranda of Understanding shall be maintained in confidential files in the Office of Research and Sponsored Programs.

- C. Subject to its duties to report to or to share information with appropriate federal or private funding agencies, as well as pertinent faculty, staff and administrative personnel, the University will maintain the disclosures required to be made under this Policy by individuals in confidence.

7. COMPLIANCE

- A. Willful failure to comply with this policy on Conflict of Interest on Extramurally Funded Programs or to fully and truthfully disclose information on the Conflict of Interest Policy Disclosure Form by any individual employed or otherwise engaged by the University constitutes a serious breach of personal conduct and University Policy. Faculty members failing to comply with this policy are subject to progressive discipline, including discharge for cause. Staff members failing to comply with this policy are subject to progressive discipline, including discharge for cause.