

Meredith College Conflict of Interest Policy

Federal regulations require institutions receiving federal funding for research (directly as a primary recipient or indirectly through a subcontract) to have policies and procedures in place that ensure senior personnel of federally funded grants/contracts disclose any significant financial interest that may present an actual or potential conflict of interest in relationship to externally sponsored projects. This disclosure must be made prior to the submission of a proposal for funding. Institutions must develop specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced, or eliminated prior to award or acceptance of an award. If a new reportable significant conflict of interest arises at any time during the period after the submission of the proposal through the period of the award, then an updated disclosure must be filed.

The number and complexity of relationships between colleges and members of their faculties and staff on the one hand and private industry, the federal and state governments, and the nonprofit sector on the other hand have grown substantially in recent years. The purpose of this Conflict of Interest Policy is to provide guidelines for those relationships that will help to assure the primacy of objectivity and integrity in research. Faculty and staff are encouraged to engage in outside research relationships if the activities are compatible with the objectives of Meredith College. Such partnerships are encouraged when they produce mutual benefits to participants as well as to society.

All faculty and staff at Meredith College must maintain their commitment to the highest intellectual and ethical standards in all aspects of research, particularly where opportunities for conflict may exist. Special care must be taken when College employees involve students either directly or indirectly in their outside professional activities. Department Chairs and Deans are charged with protecting the interests of students and monitoring the potential conflicts of faculty and staff members. It is essential that Deans and Department Chairs be committed to ensuring that such conflicts do not interfere with the duties of the faculty and staff with regard to training of students.

CONFLICTS OF INTEREST

The term conflict of interest refers to situations in which financial or other personal considerations may directly and significantly affect, or have the appearance of directly and significantly affecting, a researcher's professional judgment in exercising any College duty or responsibility, including the design, conduct or reporting of research. Researchers at Meredith College may be considered to have a conflict of interest when they, or any of their family, possess a financial interest in an activity that involves their College responsibilities.

It is the policy of Meredith College that researchers are expected to avoid conflicts of interest that have the potential to directly and significantly (1) compromise objectivity in carrying out College research responsibilities; (2) affect the College's interests; or (3) otherwise compromise the performance of the College's responsibilities, unless such conflicts are managed, reduced, or eliminated in accordance with this Policy.

For some activities, a conflict is engendered by any financial interest at all, and for others only if the interest rises to a level generally considered material. Therefore, for purposes of this Policy:

Financial Interest means anything of monetary value received or held by the individual or the individual's family, whether or not the value is readily ascertainable, including, but not limited to:

- a) Salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works);
- b) Any equity interests (e.g., stocks, stock options, or other ownership interests); and
- c) Intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) Salary, royalties, or other remuneration from Meredith College;
- b) Income from the authorship of academic or scholarly works;

- c) Income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) Equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the individual does not directly control the investment decisions made in these vehicles.

Financial Interest also includes any reimbursed or sponsored travel undertaken by the individual and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the individual rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the individual's institutional responsibilities, and:

- a) If with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) If with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000; or
- c) If with a non-publicly-traded company, is an equity interest of any value during the 1- month period preceding or as of the date of disclosure; or
- d) Is income related to intellectual property rights and interests not reimbursed through the Institution.

DISCLOSURE OF FINANCIAL INTERESTS

All senior personnel, including the Principal Investigator, Co-Investigators, and any other project member who is responsible for the design, conduct or reporting of project activities on the proposed project must complete a *Conflict of Interest Research Disclosure Statement* on an annual and ad hoc basis, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

Regardless of the disclosure requirements, the individual, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.

Annual Disclosures

All senior personnel must disclose their Significant Financial Interests to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional Official, or designee, by September 30 of each year.

Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Senior Personnel must disclose their Significant Financial Interests to the Institution, through the Institutional Official, within 30 days of their initial appointment or employment on a federally-funded project.

Prior to entering into sponsored projects or applications for sponsored projects in which the individual has a Significant Financial Interest, the individual must submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the individual has submitted such ad hoc disclosures.

In addition, all Senior Personnel must submit to the Institutional official an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

Travel

Senior Personnel must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the individual's research.

CONFLICT OF INTEREST REVIEW AND DETERMINATION

If the *Conflict of Interest Research Disclosure Statement* reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the individual will be asked to submit a plan to eliminate, reduce, or manage the conflict, as appropriate. The individual may not participate in the funded research until the plan for managing the conflict is approved.

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of federally-funded research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written management plan before any related research goes forward.

To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

MANAGING CONFLICT OF INTEREST

If a conflict of interest exists that would reasonably appear to compromise the objectivity of the research, a strategy for managing, reducing, or eliminating the conflict must be adopted prior to expenditure of any part of any sponsored research award received by Meredith College.

Strategies for management of an actual or potential conflict of interest might include:

- Public disclosure of the financial interest;
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification of the individual from participation in all or a portion of the research funded by the federal agency;
- Divestiture of the financial interest;
- Severance of relationships that create actual or potential conflicts; or
- Meredith College declining the award.

The individual making the disclosure shall submit a Conflict of Interest Management Plan containing a suggested management strategy for ensuring research objectivity to the Conflict of Interest Review Committee. The Committee has the authority to modify and approve, or not approve the management strategy. A management strategy approved in writing by the individual and the Conflict of Interest Review Committee must be delivered to the Director of Sponsored Programs prior to expenditure by Meredith College of any part of the affected award. This management strategy will become part of the sponsored program record maintained by Meredith College. Monitoring compliance with the agreed strategy shall be the responsibility of the Senior Vice President and Provost. Reporting any such conflict and any plan for managing it to meet requirements of any external sponsor will be the responsibility of the Director of Sponsored Programs.

Conflict of Interest Review Committee means the Institution's committee or individual that advises the Institutional Official on conflict of interest matters. The committee consists of at least the Senior Vice

President/Provost and other administrator designated by the Dean within an academic college or the individual's supervising director or comparable position if outside of an academic department.

Institutional Official means the individual within the Institution that is responsible for the solicitation and review of disclosures of conflict of interest. This individual is responsible for ensuring implementation of this Policy and may suspend all relevant activities until the conflict of interest is resolved or other action deemed appropriate is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy. For the purposes of this Policy, the Institutional Official is designated as the Director of Sponsored Programs at Meredith College.

Institutional 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 faculty and staff outside of the immediate College 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 Duties or College Policies, Rules, and Regulations.

Senior Personnel means any individual who is responsible for the design, conduct, or reporting of federally-funded sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, technical staff regardless of classification, or graduate students. The definition may also include collaborators or consultants as appropriate.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

POLICY IMPLEMENTATION

The Senior Vice President and Provost is responsible for overseeing the implementation of this Policy, including the process and mechanism for disclosure, and the appointment of members to the Conflict of Interest Review Committee. The Senior Vice President and Provost, or his/her delegate, will review all breaches of the evaluation and review process, including:

- Failure to comply with the process (by refusal to respond, by responding with incomplete or knowingly inaccurate information, or otherwise);
- Failure to remedy conflicts; and
- Failure to comply with a prescribed monitoring plan.

Failure of the individual to comply with this policy, including but not limited to, completely and accurately disclosing Significant Financial Interests and/or complying with provisions of any approved strategy for managing conflicts of interests, shall be a violation of Meredith Colleges Policies and Procedures for Misconduct in Research and Scholarly Activities and shall be treated in accordance with that document.

Reporting to Funder

Should any reported conflict or non-compliance require reporting to the funder, the Institutional Official will report in accordance with Public Health Service regulations. If the funding for the research is made available via a subcontract from a prime awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the funder.

Disciplinary Action

In the event of an individual's failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

An Institutional Official's decision to impose sanctions on an individual because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the individual as well as the individual's immediate supervisor and appropriate other administrators.

Retrospective Review

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an individual's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an individual to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the Institutional Official may complete a retrospective review of the individual's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, name of the Principal Investigator, name of individual with the Financial Conflict of Interest, name of the entity with which the individual has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional official will update any previously submitted report to the funder or the prime awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

Training

Each senior personnel member must complete training on this Policy prior to engaging in federally-funded research, and at least every three years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of individuals, or if it is determined that the individual has not complied with this Policy or with a management plan related to their activities. For purposes of this Policy, all federally-funded researchers must complete the Conflict of Interest Basic Course provided via CITI. Individuals must complete the Conflict of Interest Refresher Course every three years. The Sponsored Programs Office will maintain on file the Investigator's Certificate of Completion.

Record Retention

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the funder or to the prime awardee.

Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may make such information available to an agency funding research of the faculty or staff member, to a requestor of information concerning financial conflict of interest related to PHS funding, or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the individual will be informed of this disclosure.

Public Accessibility

Prior to the expenditure of funds, the Institution will publish on a publicly-accessible website or respond to

any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the individual;
- b) A determination has been made that the Significant Financial Interest is related to the federally-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS policy.

Regulatory Authority

This Policy implements the requirements of 42 CFR 50 and 45 CFR 94. In instances in which there are substantive differences between this Policy and the requirements, the requirements shall take precedence.