

Minnesota State University, Mankato University Policies

Policy Name: Conflict of Financial Interest with Grants and Sponsored Programs	Effective Date August 1, 2017
Custodian of Policy: Provost and Vice President for Academic Affairs	Date of Last Review September 2016
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Policy

When the University engages in or intends to engage in a sponsored project with an external organization, or has subcontracted or intends to subcontract with an external organization under a sponsored project, a significant conflict of financial interest may occur when the affiliation of the project director/principal investigator (PI/PD) with the external organization meets any of the following criteria:

- The PI/PD is an officer, director, partner, trustee, employee, advisory board member, or agent of the external organization, agency, or corporation either funding a sponsored project or providing goods and services under a sponsored project on which the PI/PD is participating in any capacity.
- The PI/PD is the actual or beneficial owner of the voting stock or controlling interest of such organization or corporation worth more than \$5,000.
- The PI/PD has dealings with such organization or corporation from which he or she derives income of more than \$5,000 per year, exclusive of dividends and interest.
- The PI/PD's or co-applicants' spouses or dependents (dependent children or other relatives living at the same address as the PI/PD or co-applicant) meet any of the criteria stated in a. - c. above.

Per Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F (grants and cooperative agreements) and Title 45 CFR Part 94 (research contracts), the University must:

- Create and maintain a written and enforced policy stating the procedures for implementing the regulation.
- Inform each project director/principal investigator (PD/PI) of the FCOI (Financial Conflict of Interest) regulation, of the University's policy, and of the PD/PI disclosure responsibilities under the regulation and the policy.
- Require each Investigator to complete training prior to engaging in research relating to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:
 - The University revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 - An Investigator is new to the University; or
 - The University finds that an Investigator is not in compliance with the University's financial conflict of interest policy or management plan.
- Designate an institutional official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

Violations of this policy, such as willful concealment of financial interests or failure to comply with agreed-upon modifications to manage, reduce, or eliminate conflicts of financial interests, may result in sanctions being imposed upon the violating individual in accordance with the appropriate collective bargaining agreement.

Procedures

Each PI/PD and co-applicant participating in a sponsored project covered by this policy must disclose whether or not he or she has external affiliations that may constitute a conflict as described above. A disclosure form is to be completed and submitted to the Office of Research and Sponsored Programs at the same time the required Campus Approval for Externally Funded Projects form (CAEFP) is submitted for institutional approval. The form must be updated on an annual basis and whenever new significant financial interests relevant to a project are secured.

Negative Disclosure

Negative disclosures will be filed in the Office of Research and Sponsored Programs, with no further review required.

Positive Disclosure

Positive disclosure forms will be held by the Office of Research and Sponsored Programs as sealed confidential material while a proposal is pending. The AVP of Research will convene a Conflict Review Committee consisting of the appropriate Vice President (or appointed designee), one MSUAAASF representative, and one faculty representative. **The review of a positive disclosure must be completed prior to the University's acceptance of the sponsored project or issuance of purchase orders or subcontracts for the acquisition of goods and services.**

In reviewing positive disclosures, the Conflict Review Committee will be guided by the following:

- Assure adherence to relevant state law and University policies such as Minnesota Statute 43A.38, Code of Ethics for employees in the executive branch; Minnesota State University Association of Administrative and Service Faculty (MSUAAASF) bargaining agreement provisions on Ethical Standards and Outside Employment; and Inter Faculty Organization (IFO) bargaining agreement provisions on Ethical Standards related to External Employment and Other Activities, Conflict of Interest, Confidentiality, and Patents and Intellectual Property; and other University documents the Conflict Review Committee may deem appropriate.
- Review the potential conflict of interest, obtain additional information from the investigator as necessary and make a determination of whether the financial conflict of interest is significant or not.
- Consider the nature and extent of the financial interests in the relationship of the PI/PD, co-applicants, and their spouses or dependents to the external organization.
- Give special consideration to the terms and conditions of sponsored project agreements that may mitigate or complicate the given situation.
- Consult with and obtain additional information from the PI/PD or co-applicant as either the Conflict Review Committee or the PI/PD or co-applicant feel may be helpful in resolving actual or potential conflicts.
- Act in a timely manner so as not to delay unduly the conduct of a sponsored project.
- Identify possible actions the University might take to ensure that financial interests will be appropriately managed or reduced, or the conflict eliminated.

Based on the Conflict Review Committee's recommendation, the University administration may take one of the following actions:

1. Accept the sponsored project award.

2. Not accept the sponsored project award.
3. Accept the sponsored project award subject to suitable modifications in the award document or in the PI/PD's, co- applicants', or their spouses' or dependents' affiliation with the external organization. Such modifications might include:
 - Appropriate public disclosure of the financial interests.
 - Review of data and research results by in-house or external independent reviewers identified by the committee and the PI/PD(s).
 - Modification of the research plan.
 - Disqualification from participation in a portion of the research.
 - Divestiture of significant financial interests.
 - Severance of relationships that create actual or potential conflicts.

Appeals Process

If the PI/PD or co-applicant(s) are dissatisfied with the Conflict Review Committee's findings, an appeal may be made to the President, who will consult with the PI/PD and Conflict Review Committee as deemed necessary and appropriate to the particular circumstance. The decision of the President upon appeal shall be final.

The Office of Research and Sponsored Programs shall maintain records pertaining to each disclosure in accordance with the requirements of the Minnesota Data Practices Act. Access to such records will be limited to the PI/PD(s), the Conflict Review Committee, the President, and others who have a legal right to review the records, in accordance with the appropriate collective bargaining agreement. Certain sponsors, particularly federal agencies, may establish requirements that differ from this policy with regard to the timing and frequency of disclosures and other conflict considerations as well. In the case of such discrepancies, the sponsors' requirements will generally prevail.

Management Plan

Any significant financial conflict of interests determined under an NSF- or PHS-funded research shall be subject to a management plan. Management plans for significant financial conflict of interests on NSF- or PHS-funded research must be in place prior to the expenditure of federal grant dollars related to the research.

If the institutional official determines imposing conditions or restrictions would be either ineffective or inequitable and the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer or the public health and welfare, then the institutional official may allow the research to go forward without imposing certain conditions or restrictions.

Training Requirements

Financial conflict of interest training shall be provided through the Collaborative Institutional Training Initiative (CITI) required and elective courses. Investigators identifying a conflict of interest on an externally funded grant or contract or all new or existing investigators of PHS-funded research are required to complete conflict of interest training prior to engaging in the research and every four years thereafter. Training is also required when the institution finds an investigator not in compliance with the institution's financial conflict of interest policy or management plan.

Subrecipients of Federal Funds

When the university carries out federally-funded research through a subrecipient, the university must meet applicable agency requirements to ensure subrecipient investigators also comply with federal conflict of interest requirements. Unless the information is publicly available, subawardees on NSF- or NIH-funded research will be required to disclose in writing which entity's conflict of interest policy shall be followed for the duration of each entity's participation in the federally funded project. Subrecipients that do not have a conflict of interest policy in compliance with federal requirements must adhere to the conflict of interest policy established and enforced by the University.

Rationale

Introduction

This policy sets forth procedures and guidelines to be followed in resolving actual and potential conflicts of financial interests pertaining to grants and sponsored projects funded by: 1) commercial sponsors, 2) federal agencies having specific conflicts of interests requirements, such as the National Science Foundation and the Public Health Service, and 3) purchase orders and subcontracts issued by Minnesota State University, Mankato for such projects regardless of the source of funds.

Minnesota State University, Mankato benefits from faculty and staff participation in grants and sponsored projects and in other public and private activities. The University has no interest in setting forth detailed rules that may interfere with faculty and staff outside interests. However, full-time and part-time faculty and staff must ensure that their outside financial interests, and participation in outside activities, do not conflict or interfere with their obligations to the university.

This policy specifically addresses Conflicts of Financial Interests, situations in which applicants for grants and contracts may have the opportunity to influence the University's business decisions in ways that could lead to personal gain or give improper advantage to themselves or co-applicants (anyone involved in the design, conduct, and reporting of the research results), or their spouses or dependents. Such conflicts could affect the design, conduct, or reporting of research and project results.

Definitions

- *Financial Interest*: 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, royalties from such rights).
- *Significant Financial Interest*: anything of monetary value that would exceed \$5,000 (per project) in terms of income, or would represent more than 5% ownership in a given organization (42 CFR Part 50; Subpart F).
- *Negative Disclosure*: a good faith revelation of a fact (or an item of information that is not generally known) on a disclosure form that does NOT lend itself to further review.
- *Positive Disclosure*: a good faith revelation of a fact (or an item of information that is not generally known) on a disclosure form that may lend itself to further review.
- *Principal Investigator/Project Director (PI/PD)*: the investigator and any other person, who is responsible for the design, conduct, or reporting of research funded by the Public Health Service (PHS) or proposed for such funding, including investigators working for subgrantees/contractors/subcontractors/collaborators. The term Principal Investigator/Project Director includes the Principal Investigator/Project Director's spouse and dependent children.
- Public Health Service agencies mean any component of the U.S. Public Health Service, including the National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Indian Health Service (IHS), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare and Medicaid Services (CMS), Administration for Children and Families (ACF), and the Administration on Aging (AOA).

Examples of Potential Financial Conflicts of Interest

Activities that are clearly permissible:

- Outside employment, service on boards and committees of public or private organizations, service as a consultant to outside organizations, or other outside activities as allowed by the terms of the appropriate collective bargaining agreement, provided the income generated from any organization through such activities does not exceed the \$5,000 threshold.
- Acceptance of royalties for published works and patents, payment for the creation of computer software or artistic works, or of honoraria for occasional speeches.

- Acceptance of income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
- Service on boards and committees of public or private organizations and acceptance of income for service on advisory committees or review panels for public or nonprofit entities.

Activities that present the potential for conflicts:

- Relationships that might enable a PI/PD or co-applicant to influence the University's dealings with an outside organization in ways leading to personal gain or improper advantage for the PI/PD or co-applicant's spouses or dependents. (Note: Making full disclosure of such relationships and making appropriate arrangements to manage, reduce, or eliminate potential conflicts would resolve such potential problems.)

Activities that are very likely to be unacceptable:

- Use for personal profit of unpublished information emanating from sponsored agreements or confidential university sources, or assisting an outside organization by giving it exclusive access to such information, or consulting with outside organizations that impose obligations upon the PI/PD or co-applicant that conflict with the University's patents and intellectual property policies or the University's obligations under sponsored projects agreements.
- The PI/PD or co-applicant or their spouses or dependents is an officer, director, partner, trustee, employee, advisory board member, or agent of an external organization or corporation either funding a sponsored project or providing goods and services under a sponsored project on which the PI/PD or co-applicant is participating in any capacity.
- The PI/PD or co-applicant or their spouses or dependents is the actual or beneficial owner of more than five percent (5%) of the voting stock or controlling interest of such organization or corporation.
- The PI/PD or co-applicant or their spouses or dependents has dealings with such organization or corporation from which he or she derives income of more than \$5,000 per year, exclusive of dividends and interest.