This policy sets forth procedures and guidelines to be followed in resolving actual and potential grant applicants' financial conflicts of interests pertaining to grants and sponsored research projects funded by federal agencies having specific conflicts of interests requirements, such as the National Science Foundation and the Public Health Service. WSU benefits from faculty and staff participation in grants and sponsored research 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 financial conflicts of interests of the principal investigator and co-investigators (anyone involved in the design, conduct and reporting of the research results), and their spouses and dependent children in situations which could affect the design, conduct or reporting of research results. WSU must also take reasonable steps to ensure subrecipients (i.e. subcontractors or consortium members) are in compliance with this policy.

A financial interest is defined as any 1) remuneration received from an entity, 2) the value of any equity interest in the entity, and 3) income from intellectual property rights. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interests stock, stock option or other ownership interest. Intellectual property rights and interests (e.g., patents, copyrights). Financial interest does not include salary, royalties or other remuneration paid by WSU to the employee, including intellectual property rights assigned to WSU and agreements to share in royalties; nor income from seminars, lectures, or teaching assignments sponsored by a local, state or federal agency, including public institutions of higher education; nor income from service on advisory committees.

A "significant" financial interest would exist if the aggregate received from an entity exceeded $5,000 in value (in terms of income) in the 12 months preceding the disclosure. In such cases, WSU will develop a plan to manage (reduce or eliminate) the financial conflict of interest to ensure that the design, conduct, and reporting of research will be free from bias. The management plan will include descriptions of

- How the financial interest relates to the funded research and the basis for WSU’s determination that the financial interest conflicts with such research,
- Role and principal duties of the investigator or co-investigator with a financial interest,
- Conditions of the management plan,
- How the management plan is designed to safeguard objectivity in the research project,
- Confirmation of the investigator or co-investigator agreement to the management plan,
- How the plan will be monitored to ensure investigator or co-investigator compliance, and
Other information, as needed.

Each investigator and co-investigator is required to complete training on this policy at least every four years and immediately if the policy is revised, if s/he is a new investigator at WSU, or if the researcher is found not to be in compliance.

Each grant applicant 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 (Word or PDF) is to be completed and submitted to the Office of Grants and Sponsored Research at the same time the required Transmittal Form (See WSU Regulation 2-8) is submitted for institutional approval. The form must be updated on an annual basis and whenever new financial interests are secured. Negative disclosures and non-significant financial conflicts of interest (not above $5,000) will be filed in the Office of Grants and Sponsored Research, with no further review required. Positive disclosure forms will be reviewed by a Conflict Review Committee consisting of the appropriate Vice President, one MSUAASF representative, and one faculty representative. The review must be completed prior to the expenditure of funds and within 60 days of any subsequent disclosure. The Conflict Review Committee will be responsible for documenting such reviews and for filing any required annual reports or other reports with the appropriate federal agencies. 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 (MSUAASF) 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.
- Consider the nature and extent of the financial interests in the relationship of the applicant, co-applicants and their spouses or dependent children and 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 applicant or co-applicant as either the Conflict Review Committee or the applicant 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, reduced or eliminated the conflict.

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 to manage the conflict of interest in the applicant's, co-applicants', or their spouses' or dependent children’s affiliation with the entity involved. Such modifications might include:
Regulation 3-28

- Public disclosure of financial conflict of interests (e.g. when presenting or publishing the research,
- Disclosure of financial conflicts of interest directly to the participants for research projects involving human subjects,
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest,
- Modification of the research plan,
- Change of personnel or personnel responsibilities, or disqualification from participation in all or a portion of the research.
- Reduction or elimination of the financial interest (e.g., sale of an equity interest), or
- Severance of relationships that create financial conflicts.

If a financial conflict of interest is discovered which was not disclosed in a timely manner, a review will be conducted within 60 days and a management plan will be implemented. In addition, within 120 days of the determination of non-compliance, a retrospective review will be conducted to determine if the research during the time of non-compliance was biased in design, conduct, or reporting of such research.

Documentation on the retrospective review shall include:

- Project number,
- Project title,
- PD/PI or contact PD/PI, if there are multiple PD/PIs,
- Name of the investigator or co-investigator with the financial conflict of interest,
- Name of the entity with which the investigator or co-investigator has a financial conflict of interest,
- Reason(s) for the retrospective review,
- Detailed methodology used for the retrospective review (e.g. methodology of the review process, composition of the review panel, documents reviewed),
- Findings of the review
- Conclusions of the review
- An updated Financial Conflicts of Interest Report, if required, will be filed with the appropriate federal agency within 60 days specifying actions to be taken.
- If bias is found, a mitigation report, if required, will be submitted to the appropriate funding agency, including:
  - The key elements documented in the retrospective review
  - A description of the impact of the bias on the research project
  - WSU’s action plan or actions taken to eliminate or mitigate the affect of the bias impact on the research.
  - Extent of harm done, including any qualitative and quantitative data to support any actual or future harm,
  - Analysis of whether the research project is salvageable

If any grant applicant is dissatisfied with the Conflict Review Committee's findings, the applicant may appeal to the President who will consult with the applicant and Conflict Review Committee as deemed necessary and appropriate to the particular circumstance. The decision of the President upon appeal shall be final.
Violations of this policy, such as willful concealment of financial interests, or failure to comply with agreed-upon modifications to manage, reduce or eliminate financial interests, may result in sanctions being imposed upon the violating individual in accordance with the appropriate collective bargaining agreement.

The Office of Grants and Sponsored Research 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 applicant(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.

Prior to expending any agency funds on a research project, WSU, if required, will provide the appropriate awarding federal agency a Financial Conflicts of Interest Report. The report will include:

- Project number,
- PD/PI or contact PD/PI if there are multiple PD/PIs,
- Name of the investigator or co-investigator with the financial conflict of interest,
- Name of the entity with which the investigator or co-investigator has a financial conflict of interest,
- Nature of the financial interest (e.g. equity, consulting fee, honorarium),
- Value of the financial interest, and
- Description of how the financial interest relates to the funded research and the basis for the determination that the financial interest conflicts with such research.

Certain sponsors, particularly federal agencies, may have 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.

AUTHENTICATED BY:

Judith A. Ramaley
President

April 23, 2012
Date of Adoption

Authoritative References

- 42 CFR, Part 50 and 54 – Promoting Objectivity in Research
- NSF Award & Administration Guide Part II, Chapter IV
- Minnesota Statute 43A.38, Code of Ethics for Employees in the Executive Branch
- MnSCU Procedure 1C.0.1 - Employee Code of Conduct
- MnSCU Policy 1C.2 - Fraudulent or Other Dishonest Acts
- MnSCU Policy 3.26 Intellectual Property
MnSCU/Minnesota State University Association of Administrative & Service Faculty (ASF) Agreement, Article 21
MnSCU/Inter Faculty Organization (IFO) Agreement, Article 27

Initial Date of Adoption: October 1, 2002
Date of Revisions: January 3, 2012

ATTACHMENT A
Disclosure Statement (Word or PDF)