

Procedures for the Disclosure and Management of Financial Conflicts of Interest

- 1. Purpose.** The procedures described herein implement University policies related to conflict of interest disclosure and management (Board of Control Policy 4.7, Conflict of Interest; Faculty Handbook Section 3.1.1, Conflict of Interest/Effort; University Senate Proposal 38-11, Conflict of Interest Policy Changes) and insure investigator compliance with federal regulations for externally funded projects (e.g., 42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought). These procedures may be updated from time to time to insure compliance with evolving federal regulation.
- 2. Approach.** Consistent with University policy and federal regulations, it is the responsibility of the individual to disclose significant financial interests to the University, and it is the responsibility of the University to determine if a conflict of interest exists and to develop a plan to manage or eliminate the conflict. The objective is to insure a reasonable expectation that the design, conduct, and reporting of all scholarly activities, including instruction, whether or not performed under a sponsored agreement, are free from bias resulting from conflict of interest.

It is recognized and expected that members of the University community will be involved with outside activities, both public and private. The University strongly encourages outside professional activity by faculty and staff, as such efforts usually compliment the institutional responsibilities of members of the University community and assists the University in meeting the needs of society for its improvement and enrichment, including the application of new knowledge and improved technologies. Members of the University community are expected to balance their commitment of time to the university and to outside professional interests which must result in the primary professional commitment being made to the University.

3. Definitions.

3.1 Conflict of Interest. Conflicts of interest may occur in two basic categories: financial conflicts of interest, and conflicts of commitment. For employees of the University and some others who serve in compensated roles, such as many consultants, the term conflict of interest includes both financial conflicts and conflict of commitment. For volunteers, members of boards, some consultants, and others, only conflicts of a pecuniary nature are encompassed by the term conflict of interest.

3.1.1 Financial Conflict of Interest. A situation, real or perceived, in which an individual's relationships with the University may be exploited for financial or other gain, which may compromise or have the appearance of compromising professional judgment when making decisions or influencing the decisions of other employees.

3.1.2 Conflict of Commitment. A situation where an individual's professional activities, especially the allocation of time and effort to the different

institutions and organizations they serve as professionals, may take precedence over other professional responsibilities to the University.

3.2 Significant Financial Interest. A significant financial interest is:

- 3.2.1** A financial interest consisting of one or more of the following interests of the individual (and those of the individual's spouse or partner and dependent children, natural or adopted) that reasonably appears to be related to the individual's institutional responsibilities:
 - 3.2.1.1** With regard to any publicly traded entity, 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, equals or 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;
 - 3.2.1.2** With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, equals or exceeds \$5,000, or when the individual (or the individual's spouse or partner and dependent children, natural or adopted) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - 3.2.1.3** Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
- 3.2.2** Individuals must also 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 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.
- 3.2.3** The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the University to an individual 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; income from investment vehicles, such as mutual funds and retirement

accounts, as long as the individual does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by federal state or local government agencies, 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.

3.3 Institutional Responsibilities. An individual's professional responsibilities on behalf of the University, which may include, for example, activities such as teaching, research, research consultation, professional practice, University committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards. For faculty, Section 3, Faculty Rights and Responsibilities, of the Faculty Handbook provides more information on an individual's institutional responsibilities.

3.4 Investigator. The project director or principal investigator on a sponsored project and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of sponsored activities, or proposed to a sponsor. This includes principal investigators and co-investigators, and may include senior personnel, post-doctoral fellows, or graduate students. This may, in some circumstances, also include collaborators or consultants. The Conflict of Interest Coordinator should be consulted to confirm whether individuals meet this definition.

3.5 OCIS: Office of Compliance, Integrity, and Safety.

3.6 COIC: Conflict of Interest Coordinator.

3.7 HR: Office of Human Resources

4. Reporting of Significant Financial Interests.

4.1 Individuals must disclose significant financial interests to the COIC on an annual basis, within 30 days of discovering or acquiring a new significant financial interest, and prior to submitting an application for funding to a sponsor.

4.1.1 OCIS shall maintain necessary forms and software for the individual disclosures and shall make these available to the campus community. OCIS will also maintain records of disclosure dates for each individual.

4.1.2 Individual's annual disclosure or disclosure updates shall be made coincident with the submission of Annual Faculty Vita Updates, but no later than May 31 of each calendar year.

4.1.3 On the Transmittal Sheet associated with the submission of a request for funding to a sponsor, individuals shall indicate whether they reasonably

believe they have a conflict associated with the submission. The COIC shall review all positive indications, and if they concur, the COIC shall work with the individual to develop a management plan associated with the conflict.

4.2 For any reimbursed or sponsored travel subject to disclosure, the individual shall provide within 30 days of the travel the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration to the COIC. The COIC shall determine if further information is required, including the disclosure of monetary value, to determine whether the travel constitutes a conflict of interest.

5. Determination of Conflict of Interest.

5.1 The COIC will review all disclosures by individuals and determine whether any disclosed information has the potential to introduce bias or interfere with the objective conduct of any of their institutional responsibilities. In particular, the COIC must make a reasonable determination as to whether a significant financial interest could be affected by their scholarly activity, or is in an entity whose financial interest could be affected by their scholarly activity. The COIC may involve the individual in this determination, and the COIC may request additional information from the individual beyond that required in these procedures as needed in a particular case to make this determination.

5.2 The COIC will Chair a standing Conflict of Interest Review Committee, consisting of 5 members (3 selected by the University Senate and two selected by the Vice President for Research) who serve staggered 5-year terms, charged with examining the case-by-case circumstances of each case where the COIC determines a conflict to exist and providing direction aimed at insuring the amelioration of inappropriate conflicts of interest. The Committee may call on subject matter experts as appropriate to inform their deliberations.

5.3 OCIS will provide administrative support to the COIC, and shall maintain necessary forms, informational web sites, training materials, records of training, and records of findings as indicated elsewhere in these procedures.

6. Management Plan. If the COIC determines that a conflict of interest exists, the COIC is responsible for working with the individual, and others as appropriate, possibly including the individual's supervisor or the principal investigator on a sponsored project, to develop a plan to manage or eliminate the conflict.

6.1 Some conditions or restrictions that might be imposed to manage a conflict include, but are not limited to:

6.1.1 Public disclosure of the conflict (e.g., when presenting or publishing scholarly activity; to staff members or students working on a project; to the Institutional Review Board);

6.1.2 For projects involving human subjects research, disclosure of conflicts of interest directly to participants;

6.1.3 Appointment of an independent monitor, who may be the individual's supervisor, capable of taking measures to protect the design, conduct, and reporting of scholarly activities against bias resulting from the conflict of interest;

6.1.4 Modification of the research plan;

6.1.5 Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the project;

6.1.6 Reduction or elimination of the conflict (e.g., sale of an equity interest); or

6.1.7 Severance of relationships that create the conflict.

6.2 The management plan developed by the COIC and the involved individual must contain a few key elements identified below, but because there is a great deal of variability from case to case there must be allowance for the COIC to have discretion to include additional elements if warranted in a particular situation:

6.2.1 The role and principle duties of the conflicted individual in the activity;

6.2.2 Conditions of the management plan;

6.2.3 How the plan is designed to safeguard objectivity and prevent introduction of bias;

6.2.4 Confirmation of the individual's agreement to the management plan;

6.2.5 Means to monitor the management plan to ensure individual compliance, including designation of an individual to be responsible for such monitoring; and

6.2.6 Other information the COIC believes is needed.

6.3 If a sponsor requires submission of a management plan or a summary of such a plan for a conflict related to a sponsored project, OCIS is responsible for submitting the required information to the sponsor.

7. Disclosure to Sponsor. The OCIS shall be responsible for submitting any required disclosures or reports in the time and manner specified by the sponsor. Such disclosures or reports shall contain information required by the sponsor, and may require submission of the management plan developed by the COIC to address the situation. In some cases, expenditures may not be allowed on sponsored projects until these disclosures or reports have been submitted.

8. Failure to Comply.

8.1 If an individual fails to comply with the University's Conflict of Interest Policy or a management plan developed under applicable policy, the COIC shall within 120 days:

8.1.1 Complete a retrospective review of the individual's activities and any sponsored project to determine any bias in the design, conduct, or reporting of activities;

8.1.2 Document the retrospective review consistent with applicable federal regulations; and

- 8.1.3** Document the University's determination as to whether any sponsored project, or portion thereof, conducted during the period of time of the individual's non-compliance with institutional policy, these procedures, or a conflict of interest management plan, was biased in the design, conduct, or reporting of such activities.
- 8.2** If bias is found, the OCIS shall notify any project sponsors promptly and submit a mitigation report to the sponsor that shall address the following:
- 8.2.1** Impact of the bias on the research project; and
- 8.2.2** The University's plan of action or actions taken to eliminate or mitigate the effect of the bias.
- 8.3** The COIC may determine that additional interim measures are necessary with regard to the individual's participation in sponsored projects between the date that the conflict of interest is identified and the completion of the University's independent respective review, in accordance with applicable federal regulations. In addition, if a sponsor determines that activities were designed, conducted, or reported by an individual with a conflict of interest that was not managed or reported by the University, the individual involved shall disclose the conflict of interest in each public presentation of the results of the activities and request an addendum to previously published results.
- 8.4** As indicated in the Conflict of Interest Policy, the University has the authority to take action against individuals who violate conflict of interest policy. Sanctions, which may include termination, are to be graduated and reflect the seriousness of the violation. If the COIC determines that there has been a failure to disclose a significant financial interest or to comply with an agreed upon conflict mitigation plan, the COIC will report the conclusions of the retrospective review to the appropriate supervisor and HR personnel, and OCIS will work with the appropriate supervisor and HR personnel to determine an appropriate sanction.
- 9. Retrospective review.**
- 9.1** A retrospective review shall be conducted by the COIC within 120 days of discovering that a conflict of interest is not identified or managed in a timely manner, including:
- 9.1.1** Failure by an individual to disclose a significant financial interest that is determined by the COIC to constitute a conflict of interest;
- 9.1.2** Failure by the COIC or other designated individual to review or manage a conflict of interest; or
- 9.1.3** Failure by an individual to comply with a conflict of interest management plan.
- The COIC may appoint a University-level review committee on a case-by-case basis to examine the circumstances and provide direction and recommendations during a retrospective review.
- 9.2** The retrospective review shall determine whether any scholarly activities, whether sponsored or not, conducted during the time period of noncompliance was biased in the design, conduct, or reporting of such activities. The COIC shall document the

retrospective review, and this documentation must include at least the following, as well as any other information the COIC deems appropriate:

- 9.2.1** Sponsor (if a sponsored project);
- 9.2.2** University and Sponsor (if appropriate) Project Numbers;
- 9.2.3** Project title;
- 9.2.4** Principal investigator or equivalent individuals;
- 9.2.5** Name of the individual with the conflict of interest;
- 9.2.6** Name of the entity with which the individual has a conflict of interest;
- 9.2.7** Reasons for the retrospective review;
- 9.2.8** Detailed methodology use for the retrospective review (e.g., methodology of the review process, composition of the review panel (if appropriate), documents reviewed, etc.);
- 9.2.9** Findings of the review; and
- 9.2.10** Conclusions of the review.

If bias is found, OCIS must promptly notify the sponsor (if a sponsored project is involved) and submit a mitigation report to the sponsor. The mitigation report must include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the plan of action or actions taken to eliminate or mitigate the bias (i.e., impact on the research project, extent of harm done, including any qualitative or quantitative data to support any actual or future harm; analysis of whether the scholarly activity is salvageable). If a sponsored project is involved, OCIS is responsible for submission of whatever subsequent reports are required by the sponsor.

10. Training requirements.

- 10.1** All University employees are responsible for knowing and understanding the content of the conflict of interest policy and these procedures. OCIS is responsible for offering training materials to inform employees of these requirements. OCIS and the COIC are available to answer questions concerning these policies and procedures at any time.
- 10.2** All investigators on sponsored projects must complete training prior to engaging in sponsor-funded activities and at least every four years, and within 30 days under the following designated circumstances:
 - 10.2.1** University policies and procedures change in a manner that affects investigator requirements;
 - 10.2.2** The investigator is new to the institution; or

10.2.3 The University finds that an investigator is not in compliance with the individual's conflict of interest policy, procedures, or an approved conflict management plan.

OCIS is responsible for maintaining accurate records of completed training, including dates of completion of required training modules.

11. Record Retention. OCIS shall retain records of all disclosures of significant financial interests and Michigan Tech's review of, or response to, such disclosure (whether or not a disclosure resulted in Michigan Tech's determination of a Financial Conflict of Interest), and all actions under institutional policy or retrospective review for at least three years from the date of submission and, if sponsored projects are involved, for three years from the date of submission of the final expenditures report, or, if applicable, from other dates as specified in federal regulations for different situations.

12. Public Accessibility.

12.1 The OCIS shall insure that these procedures and applicable University policies are publicly available via a publicly accessible web site.

12.2 Prior to expenditure of funds under any sponsored project, the OCIS shall ensure that public accessibility, via a written response within five business days of a written request, of information concerning any significant financial interest disclosed to the institution that meets the following three criteria:

12.2.1 The significant financial interest was disclosed and is still held by investigators for the sponsored project identified in the grant application, progress report, or any other required report submitted to the sponsor;

12.2.2 The COIC determines that the significant financial interest is related to the sponsored activity; and

12.2.3 The COIC determines that the significant financial interest constitutes a conflict of interest.

12.3 Individuals requesting such information shall make a written request to the OCIS that shall specify the nature of the request, including at least the individual's name or the sponsored activity for which the information is requested and an address, electronic or actual, to send the response. The written response to such inquiries provided by the OCIS shall be postmarked or electronically dated within five business days and shall include:

12.3.1 Individual's name;

12.3.2 Individual's title and role with respect to the activity;

12.3.3 Name of the entity in which the significant financial interest is held;

12.3.4 Nature of the significant financial interest; and

12.3.5 Approximate dollar value of the significant financial interest by range: \$0-4,999; \$5,000 - \$9,999; \$10,000 - \$19,999; amounts between \$20,000 - \$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000, or a statement that the interest is one whose value cannot be

readily determined through reference to public prices or other reasonable measures of fair market value.

Such information shall be available within 60 days of disclosure and the OCIS shall note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the identification of a new conflict of interest by the COIC, which should be requested subsequently by the requestor.