Conflict of Interest Subject: Conflict of Interest Policy: Montana State University Conflict of Interest Policy Revised: August 24, 2012; November 16, 2012 Effective Date: August 24, 2012 Review Date: August 2015

Responsible Party: Office of Research Compliance

100. INTRODUCTION

The administration, faculty, and staff of Montana State University (MSU or University) all bear the responsibility of serving the teaching, research, and service mission of the University. That mission is enhanced by the sustained, active interaction of members of the University community with business, government, not-for-profit groups, professional societies, academic institutions, and other individuals and organizations. Therefore, MSU encourages entrepreneurial activities that support the University's mission through dissemination of knowledge, enhancement of educational opportunities for students, and economic development. These many interactions and activities can, however, create the potential for conflict of interest in which University employees' external activities or interests could affect—or could appear to affect—the manner or extent to which those individuals carry out their University responsibilities. Such conflicts—real or apparent—may undermine public and professional confidence in the University, diminish its ability to accomplish its mission, and violate state or federal law. Typically, conflicts of interest can be dealt with effectively through disclosure and other steps to resolve or manage the conflict. Thus, an integral part of this Policy is the disclosure and management system detailed in §§ 500-600 below.

200. POLICY

Montana State University-Bozeman is committed to fulfilling its mission with integrity and in full compliance with state and federal ethics and conflicts of interest laws and regulations and with Montana Board of Regents Policy. A conflict of interest exists when an employee's actions or decisions, are influenced by considerations of personal or financial gain. Therefore, it is the policy of the University that in all of its activities—the education of students; the design, conduct, and reporting of research; the hiring and supervision of staff; the procurement of materials and services; and all other tasks incident to its mission—it shall endeavor to be free of undue influence or bias that may result from conflicts of interests. This Policy is intended to enable employees to recognize potential conflicting interests and, thus, to protect themselves and the University from such conflicting interests through disclosure, evaluation, and, if required, management or elimination of conflicts of interest.

210. Applicable law, regulation, and policy. In addition to this Policy, MSU employees' ethical conduct is governed by:

- Montana law, Standards of Conduct—Code of Ethics, Title 2, Chapter 2, Part 1 M.C.A
- Federal regulations governing sponsored research. The National Institutes of Health requires institutions receiving funding to have a conflict of interest policy which complies with its regulations found at [http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf] (Public Health Service (PHS) FCOI regulations). This Policy is intended to comply with those regulations.
- The American Council on Education—American Association of University Professors (ACE-AAUP) statement on preventing conflicts of interest in government sponsored research at universities [/policy/faculty_handbook/fhaceaau.html].
 MSU explicitly adopts the principles contained in the statement.
- The, Conflicts of Interest. This MSU Policy is intended to implement the requirements contained therein. [].
- The , Approval of University System Employee Equity Interest and/or Business Participation
- /policy/personnel/per400.html#430.00.

Board of Regents Policy § 401.1 [] and Montana State University's Consulting Policies found at:. These policies govern faculty and staff private consulting and professional practice outside of the control of the University.

300. APPLICABILITY

This policy applies to all MSU employees. Employees are expected to review and understand their obligations under this Policy and to be familiar with their obligations under the laws, regulations and policies referenced in § 210 of this Policy.

400 **DEFINITIONS**

410. Conflict of Interest. A Conflict of Interest occurs:

- When a University employee has a personal interest that could compromise or impinge on the employee's obligation to the University to exercise the employee's best judgment in pursuit of the interest of the University and its students;
- When a non-University activity unreasonably encroaches on the time an employee should devote to the affairs of the University; or

- When an employee's non-University activities could unreasonably impinge on or compromise the loyalty or commitment to the employee's University duties and responsibilities.
- In sponsored research, when an Investigator's Significant Financial Interest could directly and significantly affect, the design, conduct, or reporting of the research.

In determining whether a Conflict of Interest exists, an important consideration is whether an independent observer might reasonably question whether the employee's professional actions or decisions are influenced by considerations of personal gain, financial or otherwise.

420. Significant Financial Interest. A Significant Financial Interest (SFI) consists of one or more of the following interests of the employee (and those of the employee's Immediate Family):

- An equity interest (including stock, stock options, or other ownership interest) of \$5,000 or greater in any publicly traded entity as determined through reference to public prices.
- Any equity interest (including stock, stock options, or other ownership interest) in any non-publicly traded entity.
- Remuneration for services including annual salary, royalties, consulting fees, honoraria, paid authorship, or anything of monetary value (regardless of whether its value is readily ascertainable) that amount to \$5,000 or more over the 12 months preceding the disclosure.
- Intellectual property rights and interest (e.g., patents, copyrights), upon receipt of income related to such interests.

Significant Financial Interest does not include:

- Salary, royalties, or other remuneration received from or through the University.
- Intellectual property rights assigned to the University and agreements to share in royalties related to such rights.
- Income from seminars, lectures, or teaching engagements sponsored by governments, institutions of higher education, academic teaching hospitals, medical centers or research institutes affiliated with institutions of higher education.
- Income from service on advisory committees or review panels for governments, institutions of higher education, academic teaching hospitals, medical centers or research institutes affiliated with institutions of higher education.
- Investments in and income from investment vehicles, such as mutual funds and retirement accounts as long as the employee does not directly control the investment decisions made in these vehicles.

430. Investigator. Principal Investigators, Project Director **and** all other MSU employees who are responsible for the design, conduct, or reporting of sponsored research.

440. Immediate Family. The employee's spouse and dependent children.

450. Sponsored Research. Research, creative activities, scholarship, training and instructional projects involving funds, materials, or other compensation from outside sources under agreement. Research in this context means a systematic investigation designed to develop or contribute to generalizable knowledge, including behavioral and social-science research.

460. Responsible Vice President. The Vice President responsible for the employee's organizational component of the University, except that in disclosures related to research, the Responsible Vice President shall be the Vice President for Research, Creativity and Technology Transfer (VPR).

470. Investigator's Institutional Responsibilities. An Investigator's professional responsibilities on behalf of the University, including, but not limited to: research, teaching, service, professional practice, and institutional review board or other institutional committee membership.**500. DISCLOSURE**

The key mechanism for implementation of this Policy is disclosure. Disclosure allows the University and the employee to evaluate personal interests to determine if they present Conflicts of Interest and to take appropriate action based on the evaluation. All employees (unless exempted as provided in § 530 below) must annually complete and submit a <u>Conflict of Interest Disclosure Statement form</u> (See § 530 below). All employees, including those exempted from the annual disclosure requirement (See § 530 below), are required to comply with this Conflict of Interest Policy and to make disclosures of any potential Conflicts of Interests (See § 510 and § 520 below) whenever they occur (using the).

510. Sponsored Research Disclosure. In Sponsored Research, all Investigators (including Graduate Research Assistants) must disclose Significant Financial Interests, including those of their immediate family:

Significant Financial Interests, including those of their immediate family, that would reasonably appear to be related to the Investigator's Institutional Responsibilities.

In addition to the above disclosure, all Investigators proposing or performing research funded by the PHS, must also disclose the following:

- The occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and immediate family) with an estimated value of \$5,000 or greater (aggregated for each paying entity), related to his/her Institutional Responsibilities; provided however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by governmental entities, U.S. institutions of higher education, academic teaching hospitals, medical center, or research institutes affiliated with an institution of higher education. The must include:
 - the purpose of the travel;
 - the identity of the sponsor;
 - the destination;
 - the duration of the travel; and
 - any additional information requested by MSU in accordance with the PHS FCOI regulations.

511. Disclosure shall be made before submitting a proposal for funding on a <u>Research Disclosure</u> Form and the included with the Proposal Clearance Form to the Office of Sponsored Programs (OSP), covering the previous 12 month period for income and travel. If the Significant Financial Interest has previously been disclosed on a Conflict of Interest Disclosure form and is up to date, a copy of the most recent disclosure may be attached in lieu of a new Research Disclosure Statement. The Research Disclosure Statement must be updated on the Annual Form as provided in §530 below.

512. In addition, for as long as the Sponsored Research continues, new Investigators and existing Investigators acquiring new interests shall disclose Significant Financial Interests or reimbursed or sponsored travel (as defined in Section 510 above) that would reasonably appear to be related to the Investigator's Institutional Responsibilities by filing a <u>Research Disclosure Form</u> and/or the with OSP. A new Investigator must make such disclosure before engaging in the sponsored research and an existing Investigator acquiring a new interest or receiving reimbursed or sponsored travel must disclose the interest or travel within 30 days.

513. OSP will provide copies of such Research Disclosure Statements to the VPR and Office of Legal Counsel.

514. Director, Office of Research Compliance, in consultation with the Investigator, the VPR and the cognizant supervisor, shall review all Investigator disclosures to determine whether or not they constitute a financial conflict of interest as defined by the PHS FCOI regulations. This review shall determine (1) whether the interest could be affected by the research or the research could affect the entity in which the Investigator has an interest, and, if so, (2) whether the interest could directly and significantly affect the research. If a financial conflict of interest exists, appropriate action to manage the conflict will be taken as provided in this policy.

515. The University through OSP will provide initial and ongoing reports of Investigator financial conflicts of interest to PHS in accordance with the PHS FCOI regulations:

- Prior to the expenditure of PHS funds;
- Within 60 days of identifying a new financial conflict of interest of an Investigator on any PHS-funded research; and
- Annually.

516. The University will make information concerning identified Financial Conflicts of Interest held by senior/key personnel on PHS-funded research (as defined in the PHS FCOI regulations) to any requestor within five business days of a request in accordance with the requirements of the PHS FCIO regulations.

517. All Investigators performing research on any PHS- funded projects shall complete financial conflict of interest training prior to engaging in such research and at least every four years thereafter and as otherwise required by PHS FCOI regulations.

520. **Disclosure**. All employees must disclose the following whenever they occur:

521. The acquisition by the employee, or a member of his/her Immediate Family, of a Significant Financial Interest in an entity engaged in commercial or research activities directly related

to the employee's University responsibilities.

522. The holding of an executive or officer position in or serving as a member of the board of directors of an entity engaged in commercial or research activities directly related the employee's University responsibilities.

523. An immediate family member holding an executive or officer position in or serving on the board of directors of an entity engaged in commercial or research activities directly related to the employee's University responsibilities.

524. The planned direct participation in a University decision which would involve a direct benefit or detriment to:A relative as defined in MSU's Nepotism Policy [/policy/personnel/per400.html#430.00]; A person in whom or with whom the employee has a financial interest; or A person with whom the employee has a consensual romantic relationship.

525. Any financial interest of the employee or an Immediate Family member in an entity involved in a University purchase or sale whenever the employee is in a position to recommend or approve the purchase or sale. Such interests must be disclosed to the Purchasing Department for purchases and to the Property Management Department for sales.

NOTE: This disclosure requirement does not include textbook adoptions when the employee is clearly identified as an author, contributor, or editor of the textbook under consideration. However, faculty members should not receive a profit as a result of recommending a specific vendor for the purchase of texts or course materials by their students, whether on-line or from other sources.

526. Participation as an employee, officer, board member, or owner in an entity which has (or wishes to have) rights to intellectual property for which you were an inventor or creator in your work for MSU as provided in Board of Regents Policy § 407 [http://mus.edu/borpol/bor400/407.htm].

527. The acquisition of any personal or financial interest which creates a Conflict of Interest.

528. The disclosures required by this Section shall be submitted on the <u>Conflict of Interest</u> <u>Disclosure Statement form</u>.

530. **Annual Disclosure**. Annually, all employees (unless exempted as provided in § 533 below) must complete and submit a <u>Conflict of Interest Disclosure Statement</u> (Disclosure Form) as follows:

531. Disclosure Forms shall be completed and filed by October 1 of each year.

532. The employee's signature on the Disclosure Form certifies that the employee has read and understands this Policy and that either (1) the employee does not have any interests which require disclosure, or 2) that the employee has appropriately disclosed any interests which create a potential conflict of interest.

533. The following groups of employees are exempt from the annual disclosure obligation, (although they remain obligated to make disclosures under § 510 and §520 above):

- Employees working less than one-half time; and
- Classified employees.

540. **Disclosure Submission**. All Disclosures shall be submitted to the Office of Research Compliance, with copies to the employee's supervisor, the appropriate dean (when applicable) or director,

and the Responsible Vice President. [Note, this may change depending on electronic submission system]

550. **Submission to President**. All disclosure forms of executive employees reporting directly to the President and employees reporting directly to the VPR, other than Research Center Administrators, shall be submitted to the President of the University and Office of Research Compliance.

560. **Optional Conflicts Management Plan Submission**. Any of the above disclosures may be accompanied, at the employee's option, by a proposed conflict management plan; a plan template is available from the Office of Legal Counsel (994-4570), and that office is available to answer questions or provide help with a plan.

600. DISCLOSURE REVIEW AND DISPOSITION

610. **Initial Review**. The Office of Research Compliance shall review each form containing a disclosure and determine, in consultation with the Responsible Vice President, or the President relative to the disclosures described in § 550 above, whether a conflict of interest exists.

620. **Waiver of Conflict**. The Office of Research Compliance, in consultation with the Responsible Vice President, or the President under § 550, may waive the conflict and the need for a conflict management plan if they make the following written determinations:

- That the conflict of interest is so remote that there is no significant probability for bias or undue influence on the employee's University duties and responsibilities;
- Any resolution of the conflict other than by disclosure and waiver would be ineffective or inequitable and the conflict is not prohibited by statute or regulation; or
- Any bias reasonably expected is outweighed by the interests of scientific progress, technology transfer or the public health and welfare, and the conflict is not prohibited by statute or regulation.

640. **Conflict Management**.

If a Conflict of Interest exists and is not waivable, Office of Research Compliance, in consultation with the Responsible Vice President, or the President under § 550, the employee, and any others deemed helpful in assessing the situation, will develop a written conflict management plan to manage, reduce, or eliminate the conflict of interest.

641. The conflict management plan may employ strategies including, but not limited to, the following:

- Public disclosure of the Significant Financial Interest;
- Monitoring of the relevant employment duties (e.g., research) by independent reviewers;
- Modification of duties of the employee, including modification of a research plan;
- Disqualification from participation in the conflicting employment activity, such as research, procurement, student advising, or employee supervision;
- Divestiture of the conflicting interest; or

• Severance of relationship that creates the Conflict of Interest.

642. Whenever a decision is made to manage rather than eliminate the conflict of interest that has not been waived, the Office of Research Compliance shall make a written statement explaining why management is in the best interest of the University. Such statement may be included in the conflicts management plan.

643. Relevant questions to consider in designing an appropriate conflicts management plan include, but are not limited to:

- What is the magnitude of the financial interest?
- What is the level of incentive created by the interest?
- How direct is the link between the interest and the duties of the employee, including research duties?
- Could the conflict compromise the objectivity of research results or their evaluation and presentation?
- Could the conflict adversely affect students?
- Could the conflict unreasonably interfere with the employee's commitment to University responsibilities?
- Can a reasonably knowledgeable person be identified to satisfactorily monitor the conflict?

644. MSU shall periodically monitor compliance with all conflicts management plans for as long as the conflict of interest exists.

700. APPEAL PROCEDURE

710. **Appeal to President**. If an employee believes the conditions or restrictions in the conflict management plan are inappropriate, the employee may appeal the decision to the President, unless the President was involved in the decision appealed, in which case the President's decision is the final decision of the University. The President may, in his/her discretion, appoint and convene a Conflict Review Committee to provide advice on an appeal. The President's decision on the appeal shall be the final decision of the University.

720. **Conflict Review Committee**. If the President wishes to have the benefit of advice from a Conflict Review Committee, the President shall appoint a three member committee. The members shall include employees or community members who have had no involvement in the decision being appealed and who have relevant experience or training to assess the conflict.

730. **Montana University System Appeal**. An employee who disagrees with the final decision of the University may appeal further as provided in the [].

800. COMPLIANCE REPORTING AND RECORD RETENTION

810. **Sponsored Research**. The VPR is responsible for the following compliance duties related to conflicts of interest in Sponsored Research, if required by the sponsoring agency:

- Compliance of subgrantees, subcontractors and collaborators.
- Submission of compliance certifications.
- Reporting concerning conflicts of interest in research.
- Notifying the sponsoring agency of financial conflicts of interest as required by the sponsoring agency.
- Notifying the sponsoring agency if non-compliance with this policy has biased the design, conduct, or reporting of the funded research and identify the corrective action taken or to be taken to address the non-compliance.
- Records of conflicts disclosure submitted with the Proposal Clearance Form and records of actions related to such disclosures shall be maintained by OSP in the grant or contract file for three years from the date of submission of the final expenditure report.

830. **Records Maintenance**. Office of Research Compliance shall be responsible for maintenance of all disclosure and conflict management records (including copies of records kept by OSP for sponsored research disclosures) for the period of time required by state and federal laws and regulations. Records will be maintained in a manner to protect sensitive and confidential information consistent with state and federal law.

900. COMPLIANCE.

910. MSU expects all employees to comply fully and promptly with all requirements of this Policy. Breaches of this Policy include, but are not limited to: intentionally filing an incomplete, erroneous, or misleading disclosure form; failure to provide additional information as required; failure to provide a disclosure form as required by this Policy; failure to comply with University requirements concerning the conflict of interest; or failure to abide by a conflicts management plan.

920. A violation of this policy may be the basis for discipline of an employee. Such discipline will be imposed consistent with the discipline policies and procedures applicable to the particular employee (Faculty Handbook, collective bargaining agreement, Personnel Policies and Procedures Manual).

930. Potential sanctions may include, but are not limited to, the following:

- Letter of warning
- Suspension or termination of participation in a Sponsored Research grant
 - Removal or suspension of privileges related to the violation, such as suspension of the privilege: to apply for Sponsored Research grants or contracts; to supervise graduate students; or to perform research which requires approval of the Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC).
- Suspension without pay

• Termination

940. If MSU discovers an Investigator conducting PHS-funded research has failed make any disclosure required in §910 or to comply with a management plan, or if MSU has failed to review or manage a financial conflict of interest as required by the PHS FCOI regulations, MSU shall within 120 days, in accordance with the requirements of the PHS FCOI regulations, complete a retrospective review of the non-compliance and determine whether the research was biased by the non-compliance. Further, MSU will document and report its review in accordance with the PHS FCOI regulations.