

Conflict of Interest Policy

Subject	Conflict of Interest
Revised	August 24, 2012; November 16, 2012; May 3, 2017; November 4, 2020, November 1, 2023, May 1, 2024; September 2025; January 2026
Web Link	https://www.montana.edu/policy/onemsu/conflict_of_interest/index.html
Effective Date	December 2023
Review Date	September 2028
Responsible Party	Research Integrity and Compliance

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Scope

This policy applies to the following MSU-affiliated Campuses:

- MSU in Bozeman (MSU) including MSU Extension, Agricultural Experiment Stations, and Gallatin College.
- MSU Billings including City College (MSUB)
- MSU Northern (MSUN)
- Great Falls College MSU (GFCMSU)

For the purpose of this policy, the term “University” means all campuses listed.

The Institutional Official for each campus is:

- MSU– Director of Research Integrity and Compliance (or designee)
- MSUB – Director Human Resources (or designee)
- MSUN – Director of Human Resources (or designee)
- GFCMSU – Executive Director of Operations (or designee)

100.00 Introduction

The administration, faculty, and staff of Montana State University and its affiliated campuses each bear the responsibility of serving the respective teaching, research, and service missions of their campuses. Those missions are 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, entrepreneurial activities are encouraged 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 influence—or could appear to influence—the manner or extent to which those individuals carry out their University responsibilities. Such influences—real or apparent—may undermine public and professional confidence in the University, diminish the University’s 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.

200.00 Policy

The University 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 the Montana Board of Regents Policy §770. This Policy is intended to implement the requirements contained therein. A conflict of interest may exist when an employee has a financial or personal interest in the outcome of an endeavor such that the employee's actions or decisions could be perceived as subject to influence in favor of the employee's interest, as more fully defined in §410. A conflict of commitment may exist when an employee's outside obligation could or could appear to encroach on the time that the employee reasonably needs to fulfill their job duties at the University.

Therefore, it is the policy of the University that in all 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 their mission—each campus and its employees shall endeavor to be free of inappropriate influence or bias that may result from conflicts of interest or conflicts of commitment. This Policy is intended to enable employees to recognize perceived or potential conflicts of interest or conflicts of commitment and, thus, to protect themselves and the University from inappropriate influence or bias through disclosure, evaluation, and, if required, management or elimination of conflicts of interest or conflicts of commitment.

210.00 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. For example, the National Science Foundation and the National Institutes of Health (and all other Public Health Service "PHS" agencies) require institutions receiving funding to have a conflict of interest policy which complies with its regulations:
 - [NSF - Grantee Standards, Award and Administration Guide](#)
 - [Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought \(42 C.F.R. Part 50, Subpart F\)](#)
 - [Responsible Prospective Contractors \(45 C.F.R. Part 94\)](#)
 - [The Board of Regents Policy § 770, Conflicts of Interest.](#)

- [The Board of Regents Policy § 407, Approval of University System Employee Equity Interest and/or Business Participation . This policy implements M.C.A. 20-25-109.](#)
- Relevant Campus , Favoritism, and Relationships Policies
 - MSU [Relationships in the Workplace Policy](#)
 - [MSU Relationships with Students Policy](#)
 - [MSUB Relationships with Students Policy](#)
 - MSUB [Billings Favoritism Policy and Procedures](#)
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 - [GFCMSU Relationships with Students Policy](#)
 - GFCMSU [Great Falls College Nepotism Policy](#)
 - MSUN Conflict of Interest Policy
- https://www.montana.edu/policy/relationships_students_policy.html Relevant Campus Consulting Policies
 - MSU [Faculty Consulting Policy](#)
 - MSU [Non-Faculty Employee Consulting Policy](#)
 - [MSUB Consulting Policy](#)
 - [GFCMSU Consulting Policy](#)
 - MSUN Compensation in Excess of Contracted Salary Policy

300.00 Applicability

This policy applies to all employees of the University. 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.

400.00 General Definitions

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

410.00 Conflict of Interest

Conflict of interest may exist:

- When a University employee has a personal interest that could or could appear to 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;
- Examples include, but are not limited to, consulting or ownership interest with a company that has contracts with MSU, or a family member or significant other who works with you.

420.00 Conflict of Commitment

A conflict of commitment may exist:

- When a non-University activity could or could appear to unreasonably encroach on the time an employee should devote to the affairs of the University; or
- When an employee's non-University activities could or could appear to unreasonably impinge on or compromise the loyalty or commitment to the employee's University duties and responsibilities.
- Examples include, but are not limited to, outside Board of Director appointments or Officer of a Professional Society where meetings require frequent trips off campus or involve a significant time commitment; or involvement with an outside company that requires a significant time commitment.

430.00 Institutional Official

Each campus will designate Institutional Official(s) or office to oversee the reporting, disclosure, and management of potential conflicts of interest.

500.00 Disclosure Procedure

The key mechanism for implementation of this Policy is disclosure. Disclosure allows the campus and the employee to evaluate personal interests to determine if they present a conflict of interest and to take appropriate action based on the evaluation. All employees, unless exempted as provided in §530, must annually complete and submit a Conflict of Interest/Conflict of Commitment Disclosure Report (§520). In addition, all employees, including those exempted from the annual disclosure requirement, are required to comply

with this Conflict of Interest and Commitment Policy and to make disclosures of any potential conflicts of interest or conflicts of commitment whenever they occur to the designated Institutional Official.

510.00 Circumstances Requiring Conflicts of Interest Disclosure

All employees must disclose the following whenever they occur. These situations apply to the employee and members of his/her family and as directly related to the employee's University responsibilities:

510.10 Related Outside Interest

The acquisition of any personal or financial interest in an entity engaged in University commercial or research activities that may create a conflict of interest. This may include but is not limited to consulting arrangements, research activities, University contracts and agreements, or other business relationships.

510.20 Related Purchase/Sale Interest

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 Procurement Services 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 or course material under consideration. However, faculty members should not receive a profit as a result of recommending a specific vendor for the purchase of textbooks or course materials by their students, whether online or from other sources.

510.30 Related Sponsored Research Interest

In Sponsored Research, acquisition of a Significant Financial Interest (see §1000).

510.40 Related Interest by Outside Position

The holding of an executive or officer position in or serving as a member of the board of directors of an entity engaged in University commercial or research activities.

510.50 Employee Inventor Equity Interest and/or Business Participation

Participation as an employee, officer, board member, or owner in an entity which has, or wishes to have, rights to intellectual property invented or created during the course of MSU employment per BOR §407 .

510.60 Favoritism and Relationships in the Workplace

The planned direct participation in a University decision which would or could appear to involve favoritism or a direct benefit or detriment to a family member, partner, , or work unit as defined by the relevant campus Relationships in the Workplace Policy. For MSU-Bozeman, Relationships in the Workplace includes:

- A spouse, domestic partner, or fiancé(e);
- A child, grandchild, parent, grandparent, sibling, uncle or aunt, nephew or niece, cousin, or the spouse domestic partner, or fiancé(e); of any such person;
- A person having a step-relationship;
- A parent-in-law or a brother- or sister-in-law;
- Any other person who resides in the same household as the employee; or
- Any other person as to whom it would reasonably appear the employee has a relationship involving an interest in such person;
- Also, for MSU-Bozeman
- Partner includes a person who has a business or personal relationship with the employee,
- Favoritism is making decisions regarding hiring, selection, promotion, wages, hours, or other conditions of employment based on relationship rather than on objective standards and the needs of the university.
- Work unit includes any sub-unit of a department or any office in which the family member or partner may be required to interact with one another on a regular basis while performing their duties.

510.70 Outside Supervisory Interest

Arrangements for the employment or use of students or employees outside the University. Such arrangements must be approved through the appropriate University channels to avoid supervisory conflicts.

510.80 Use of Personal Funds to Support Employee's Own Work

Arrangements by the employee to provide personal funds to support the employee's MSU work, laboratory, and payment of lab staff and students.

520.00 Circumstances Requiring Conflict of Commitment Disclosure

All employees must disclose the following whenever they occur. These situations apply to the employee and members of his/her family and as directly related to the employee's University responsibilities:

520.10 Outside Professional or Commercial Commitments

Outside professional or commercial commitments, whether paid or unpaid, that interfere or have the potential to interfere with the employee's University responsibilities. NOTE: This disclosure requirement does not include traditional academic responsibilities such as oral presentations, peer review, books and graphic works for publication, articles, for which royalties, honoraria, are considered a part of an employee's University responsibilities.

520.20 Consulting

Consulting of services for which remuneration in any form is received by the employee from a person, firm or corporation other than the University.

520.30 Outside Academic Appointments

Visiting appointments during an approved leave of absence or brief transitional appointments. NOTE: Employees may not have an academic appointment at another institution unless approved by the Provost.

520.40 Foreign Government or Entity Affiliations

Funding received from any foreign government or entity, any courtesy or honorary appointments that are held at other institutions and any participation with any foreign talent program and any research collaborations, affiliations, or partnerships with institutions, organizations, or individual researchers outside the United States of America.

530.00 Annual Disclosure

Annually, all employees (unless exempted under §540) must complete and submit a Conflict of Interest/Conflict of Commitment Report as follows:

530.10

Reports shall be completed upon receiving notification. Each affiliated campus shall establish a procedure for reporting.

530.20

The employee's completion of the report certifies that:

1. The employee does not have any interests or outside commitments which require disclosure;

2. The employee has a potential conflict of interest or conflict of commitment which has been duly disclosed previously and there has been no change which requires an updated disclosure; or
3. The employee has new interests which may create a conflict of interest or conflict of commitment and has disclosed them.

530.30

Each campus will submit an annual written conflict of interest report to the Board of Regents per [BOR §770](#).

540.00 Exemptions

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
- Classified employees

550.00 Disclosure Submission

All annual and new circumstantial disclosures shall be submitted to the Institutional Official or designee. Records will be made available to the employee's supervisor. Upon request, records are also available to the appropriate Department Head, Dean or Director, and any other supervisor in the line of authority when applicable.

600.00 Disclosure Review and Management

610.00 Initial Review

The Institutional Official or designee shall review all disclosures and determine whether a conflict of interest exists.

620.00 Determination of Conflict/Commitment

After the initial review, the Institutional Official or designee, along with Legal Counsel, if necessary, will provide a written resolution to determine the nature of the conflict:

1. The disclosure does not represent a conflict or outside commitment that is prohibited by statute or regulation nor is it likely to influence the actions of the employee and, therefore, requires no further action;
2. The disclosure represents a conflict or outside commitment that requires management; or
3. The disclosure represents a conflict or outside commitment that must be eliminated.

630.00 Statement of Best Interest

Whenever a decision is made to manage rather than eliminate the potential for inappropriate influence or bias in a conflict that has not been waived, the Institutional Official or designee shall make a written statement explaining why management is in the best interest of the University. Such a statement should be included in the Conflicts Management Plan.

630.10 Conflicts Management Plan

If a conflict of interest exists and is deemed manageable, the Institutional Official or designee, the employee, Conflict of Interest Committee, and any others deemed helpful in assessing the situation, will develop a written Conflicts Management Plan to manage, reduce, or eliminate the inappropriate influence or bias, or the appearance thereof. The purpose of the plan is to:

1. Accurately describe the potential conflicts in writing
2. Create explicit agreements to protect against inappropriate influence or bias
3. Facilitate oversight

630.20 Technical Partner

A Technical Partner may be assigned to monitor the plan, to ensure Research Integrity and Compliance has the technical guidance from a non-conflicted source. Any individual identified to serve as a Technical Partner must have the technical knowledge necessary to determine whether there has been inappropriate influence or bias in the results of a project and must be free from influence of the parties to the conflicts management plan, e.g., the Technical Partner must not report to the person being monitored. Technical Partners may assist in reviewing plans with employees annually to cover the upcoming year. Plans are updated as circumstances change, and the annual reviews continue until the conflict no longer exists. Additional monitoring may take place at any other time of year.

700.00 Appeal Procedure

710.00 Appeal

If an employee believes the conditions or restrictions in the Conflict Management Plan or the determinations of the Institutional Official are ineffective and unduly burdensome, the employee may appeal the decision to the institution's President, Chancellor or CEO. . The President, Chancellor or CEO or their designee may appoint and convene a Conflict Review Committee to provide advice on an appeal. The President's, Chancellor's or CEO's decision on the appeal shall be the final decision of the University whether or not the President, Chancellor or CEO was involved in the decision appealed.

720.00 Conflict Review Committee.

If the President, Chancellor or CEO wishes to have the benefit of advice from a Conflict Review Committee, the President, Chancellor or CEO 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.

730.00 Montana University System Appeal

An employee who disagrees with the final decision of the University may appeal further as provided in the [Board of Regents Appeal Policy, §203.5.2](#).

800.00 Record Maintenance

The Institutional Official or designee shall maintain all disclosure and conflict management records (both general and Sponsored Research records) 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.

900.00 Noncompliance

910.00 Breach of Policy

The University 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 as required by this policy;
- failure to comply with University requirements concerning the Conflict of Interest; or
- failure to follow a Conflicts Management Plan.

920.00 Disciplinary Action

A violation of this policy may be the basis for discipline of an employee and result in potential sanctions. Such discipline will be in accordance with the policies and procedures and collective bargaining agreements applicable to the particular employee. 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 any MSU Compliance or Institutional Review Board
- Suspension without pay

- Termination

1000.00 Sponsored Research

The Institutional Official or designee and the University office overseeing federal grant management are responsible for compliance duties related to conflicts of interest in Sponsored Research. As a University that receives U.S. Public Health Service (PHS) funding, including National Institutes of Health (NIH), the University has adopted PHS terminology and perspective for reviewing sponsored research conflicts related to any funding agency. For reporting purposes, the interest threshold at which the University must disclose varies by agency.

While acting within the law, the intent of this policy is to identify conflicts and manage them by defining the boundaries within which conflicts occur while allowing investigators to proceed with their research. The primary goal is to maintain objectivity in research by establishing standards to ensure that there is no reasonable expectation that the design, conduct, or reporting of research will be biased by a Financial Conflict of Interest of an Investigator.

1010.00 Sponsored Research Definitions

1011.00 Financial Conflict of Interest (FCOI)

A significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

1012.00 Financial Interest

Anything of monetary value, whether or not the value is readily ascertainable.

1013.00 Immediate Family

The employee's spouse and dependent children.

1013.00 Institutional Responsibilities

An Investigator's professional responsibilities on behalf of the University including activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or other institutional committees.

1014.00 Investigator

The Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of funded research, or proposed for such funding, which may include, for example, graduate research assistants, collaborators, or consultants.

1015.00 Manage

Taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

1016.00 Senior/Key Personnel

The Project Director/Principal Investigator and any other person identified as senior/key personnel by the University in the grant application, progress report, or any other report submitted to PHS.

1017.00 Significant Financial Interest (SFI)

Consists of one or more of the following interests of the Investigator (and the Investigator's Immediate Family) that reasonably appears to be related to the Investigator's Institutional Responsibilities received from an entity within twelve months preceding the disclosure. For purposes of this definition, "compensation" 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:

1. For any publicly traded entity, SFI is compensation and equity interest totaling \$5,000 or greater.
2. For any non-publicly traded entity, SFI is compensation of \$5,000 or greater and/or *any* level of equity interest.
3. Non-University intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Significant Financial Interest does not include:

- Salary, royalties, or other compensation received from or through the University if the Investigator is currently employed or otherwise appointed by 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 federal, state, or local ental agency located in the United States , United State institution of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with a United States institution of higher education.
- Income from service on advisory committees or review panels for governments, a United States Institution of higher education, United States academic teaching hospitals, United States medical centers or research institutes affiliated with United Statesinstitutions 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.

1018.00 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, study or experiment designed to develop or contribute to generalizable knowledge. 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). This may also include a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

1020.00 Sponsored Research Disclosures and Review

1021.00 Sponsored Research Disclosure

In Sponsored Research, all Investigators must disclose any SFIs and PHS Sponsored Travel prior to the University expenditure of funds.

1022.00 Disclosure Prior to Proposal Submission

Disclosure to the University shall be made before submitting a proposal for funding. On the MSU-Bozeman campus, employees will use the forms included with the e-Proposal Clearance Form (ePCF) via the Office of Sponsored Programs (OSP), covering the previous 12 months of activity. The questions contained in the ePCF shall provide the vehicle to inform Investigators of this Policy, their disclosure responsibilities, and federal regulation.

1023.00 Disclosure During Sponsored Research

For as long as the Sponsored Research continues, new Investigators and existing Investigators acquiring new interests shall disclose SFI and/or PHS Sponsored Travel to the University that would reasonably appear to be related to the Investigator's Institutional Responsibilities within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance). All disclosures must be also updated on the Annual Report per §520 during the period of the award.

1024.00 Disclosure Review

The Institutional Official or designee shall review all Investigator disclosures prior to funding expenditure to determine if the SFI is a FCOI by evaluating (1) whether the Investigator's SFI 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 design, conduct, or reporting of the research. If a FCOI exists, appropriate action to manage the conflict will be taken as provided below in §1031.

1025.00 PHS Sponsored Travel Disclosure

Travel that is paid on behalf of a PHS Investigator related to their Institutional Responsibilities; provided however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by governments, 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. The disclosure 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 the University, including monetary value, in order to determine whether the travel constitutes an FCOI

1030.00 Sponsored Research Conflicts Management

1031.00 Sponsored Research Conflicts Management Plan

If the Institutional Official determines the SFI constitutes as FCOI, a conflicts management plan may be implemented. The plan may employ safeguard strategies including, but not limited to, the following:

1. Public disclosure of FCOI (e.g., when presenting or publishing the research);
2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
3. 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;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
7. Severance of relationships that create financial conflicts.

1040.00 Sponsored Research Reporting and Records

1041.00 FCOI Reporting

As applicable by agency, the University will provide the Investigator's FCOI and implemented management reports to the funding agency. PHS FCOI Reports shall contain all the agency designated elements and will be submitted:

- Prior to the expenditure of PHS funds;
- Within 60 days of discovering or acquiring a new FCOI of an Investigator on any PHS-funded research; and

- Annually for ongoing, managed FCOI cases.

1042.00 No Reporting for Elimination of Conflict

In cases in which the University identifies a FCOI and eliminates it prior to the expenditure of awarded funds, the University shall not submit an FCOI report to the awarding agency.

1043.00 PHS Public Reporting Requirements

The University will make information concerning identified FCOI held by Senior/Key Personnel on PHS-funded research to any written request within five business days of a request in accordance with the requirements of the PHS FCOI regulations.

1045.00 Record Retention

Records of all conflicts disclosures submitted with grant proposals and records of actions related to such disclosures shall be maintained in the grant or contract file for the length of time specified by the funding agency, typically three years from the date of submission of the final expenditure report.

1050.00 Sponsored Research Noncompliance

1051.00 PHS Retrospective Review and Remedies

Within 120 days of a determination of noncompliance, the University will complete a retrospective review of the Investigator's activities and the research project to determine whether any research conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The University will document the retrospective review, retain all information, and submit a mitigation report if necessary as required by agency regulations. Such noncompliance may occur:

- When a FCOI is not identified or managed in a timely manner (including failure by the Investigator to disclose a SFI that is determined to constitute a FCOI);
- When there is failure by the University to review or manage such a FCOI; or
- When there is failure by the Investigator to comply with a Sponsored Research Conflicts Management Plan.

1052.00

The noncompliance provisions of §900 will also apply to sponsored research noncompliance.

1060.00 Training

1061.00 PHS Training

PHS Investigators must complete [Conflict of Interest Training](#) prior to engaging in research related to any PHS-funded grant and at least every four years thereafter, and immediately when any of the following circumstances apply:

1. The University revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
2. An Investigator is new to the University; or
3. The University finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

1070.00 Subrecipients

1071.00 PHS Subrecipients

When the University carries out PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the (prime awardee) institution's office overseeing federal grant management will take reasonable steps to ensure that any subrecipient Investigator complies by written agreement with the subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators in accordance with PHS regulations.