

<b>Operational Area:</b>	Academics and Research
<b>Responsible Executive:</b>	Chief Academic Officer
<b>Responsible Office:</b>	Academic Affairs
<b>Effective:</b>	July 1, 2019

# Financial Conflict of Interest for Federally Funded Research Proposals

## Academics and Research

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### I. Introduction

- A. **Authority:** C.R.S. § 23-54-102, *et seq.* (2019) authorizes the Trustees of Metropolitan State University of Denver (MSU Denver) to establish rules and regulations to govern and operate the University and its programs. The Trustees authorize the President of MSU Denver, who subsequently authorizes the Provost, to approve, administer, and interpret policies pertaining to the academic functions of the University.
- B. **Purpose:** This policy prohibits financial conflicts of interest for employees and students conducting federally funded research at the University.
- C. **Scope:** This policy applies to employees, students, and affiliates conducting federally-funded research at the University.



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### II. Roles and Responsibilities

- A. **Responsible Executive:** Chief Academic Officer
- B. **Responsible Administrator:** Associate Vice President for Curriculum and Academic Effectiveness
- C. **Responsible Office:** Academic Affairs Office
- D. **Policy Contact:** Associate Vice President for Curriculum and Academic Effectiveness, 303-615-1900

### III. Definitions

For purposes of this policy, the following definitions apply:

- A. **Investigator** means 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 research, who may include, for example, non-faculty employees, collaborators or consultants.
- B. **Investigator's Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of MSU Denver, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- C. **Significant Financial Interest (SFI)** means:
  - 1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities:

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- a. 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, 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;
  - b. 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, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must disclose any reimbursed travel or travel paid on behalf of the Investigator (i.e., not reimbursed to the Investigator), related to their MSU Denver responsibilities.
    - a. 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 as defined at 20 USC





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- 1001(a); an academic teaching hospital; a medical center; or a research institute affiliated with an institution of higher education.
- b. At a minimum, the Investigator must disclose: the sponsor/organizer of the trip, the purpose of the trip, the monetary value of the trip, the destination, and the duration.
3. The following are excluded from the definition of SFI:
- a. Salary, royalties, or other remuneration paid by MSU Denver to the Investigator if the Investigator is currently employed or otherwise appointed by MSU Denver;
  - b. Intellectual Property Rights assigned to MSU Denver and agreements to share in royalties related to such rights;
  - c. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
  - d. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
  - e. Income from service on advisory committees or review panels for a federal, state or local government agency, institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
  - f. Exclusions for NSF grants only:

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- i. An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
  - ii. Salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve-month period.
4. **Financial Conflict of Interest (FCOI)** means an SFI that could directly and significantly affect the design, conduct, or reporting of the Sponsors'-funded research.
5. **Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. This definition:
  - a. Encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
  - b. Includes any such activity for which research funding is available from the Sponsors through a grant or cooperative agreement, however authorized, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.



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6. **Small Business Innovation Research (SBIR) Program** means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of the FCOI policy, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

#### IV. Policy Statement

This document details Metropolitan State University of Denver’s (MSU Denver) policy regarding conflicts of interest in relation to research, educational, or service projects directly funded by the National Science Foundation (NSF), various Public Health Service (PHS) entities (to include the National Institutes of Health, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Food and Drug Administration, and the Agency for Healthcare Research and Quality), and any other entity adhering to NSF or PHA regulations (hereinafter, “Sponsors”). The Federal Demonstration Partnership website includes a list of agencies that have been reported as adhering to PHS financial conflict of interest regulations.

MSU Denver’s policy on Financial Conflict of Interest (hereinafter, the FCOI Policy) is designed to conform to the 2011 revised PHS regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F), as well as NSF’s Conflict of Interest Policy. The revised regulation and policy promote objectivity in research by establishing



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standards designed to provide a reasonable expectation that the design, conduct, and reporting of research funded by the Sponsors will be free from bias resulting from Investigator financial conflicts of interest.

Individuals subject to this policy are required to disclose financial interests related to federally funded proposals and to meet institutional and Sponsor requirements for COI training. An Investigator will not be eligible to submit an application in response to a Sponsor's funding announcement until she/he has met these requirements. 1.4. For ongoing research, the FCOI Policy applies to every project with a Notice of Award issue date on or after August 24, 2012. Additionally, all Investigators who received an award prior to August 24, 2012, for which Progress Reports were due subsequent to that date, must comply with the FCOI Policy.

### **V. Procedures**

#### **A. Mandatory COI Training**

1. MSU Denver provides online COI training through the Collaborative Institutional Training Initiative (CITI). The training is administered by the Center for Faculty Excellence and is available to all faculty, staff, and
2. Each investigator must complete COI training:
  - a. Prior to submitting, or being listed as an investigator on, an application in response to a Sponsor's funding announcement, and
  - b. At least every four years afterward, and
  - c. Immediately under the following circumstances:
  - d. For new Investigators, before beginning work on a currently-funded project to which this COI policy applies.

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- e. MSU Denver FCOI policies change in a manner that affects Investigator requirements.
  - f. MSU Denver identifies an Investigator noncompliant with this FCOI policy.
  - g. MSU Denver identifies an Investigator noncompliant with a previously instituted management plan.
3. Investigators must complete the required COI training and forward proof of completion to the Executive Director of the Office of Sponsored Research and Programs.
- B. COI Disclosure Procedures and Forms**
- 1. A completed Financial Conflict of Interest Disclosure Form, or a Collaborator Financial Conflict of Interest Certification, is required to be submitted from each Investigator, including sub-recipient Investigators, if applicable, planning to participate in the Sponsors' funded research:
    - a. At the time of application for federal funding
    - b. At least annually, during the period of the award, beginning with the anniversary date of the award.
    - c. Within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
  - 2. Completed disclosure forms should be provided to the Executive Director of the Office of Sponsored Research and Programs.
- C. Review of Disclosure Forms**
- 1. OSRP will refer any potential financial conflicts (positive disclosures) to the Associate Vice President for Administration, Finance and



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Facilities/Controller, or designee, to make an initial determination whether an Investigator's significant financial interest (SFI) is related to the Sponsors' funded research, i.e. reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the Sponsor funded research.

2. The Associate Vice President for Administration, Finance and Facilities/Controller, or designee, in consultation with appropriate University officials, shall appoint a Conflict of Interest Committee (COIC) with the appropriate expertise to evaluate any potentially positive determinations. A Financial Conflict of Interest (FCOI) exists in those circumstances where the COIC determines that the SFI is related to the Sponsors-funded research.
3. Where a FCOI has been found to exist, a management plan will be established to address the SFI, as detailed in the Management of FCOI's section, and the Sponsor will be notified, as detailed in the Reporting of FCOI's section of this policy statement

#### D. Management of Financial Conflict of Interest

1. All management plans must include, at a minimum, the following elements:
  - a. Sponsor Project Number;
  - b. Project Title;
  - c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
  - d. Name of Investigator with the Financial Conflict of Interest (FCOI);
  - e. Name of the entity with which the Investigator has a FCOI;
  - f. Nature of the FCOI;

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- g. Value of the FCOI (dollar ranges are permissible: \$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;
- h. A description of how the financial interest relates to the Sponsor-funded research and the basis for the Institution's determination that the financial interest conflicts with such research;
- i. Detailed methodology of the review process to include composition of the review panel, and documents reviewed;
- j. Findings of review; and
- k. A description of the key elements of the Institution's management plan, including:
  - i. Role and principal duties of the conflicted Investigator in the research project;
  - ii. Conditions of the management plan;
  - iii. How the management plan is designed to safeguard objectivity in the research project;
  - iv. Confirmation of the Investigator's agreement to the management plan;
  - v. How the management plan will be monitored to ensure Investigator compliance; and
  - vi. Other information as needed.

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2. Where a Financial Conflict of Interest (FCOI) has been identified, the Office of Sponsored Research and Programs (OSRP) in conjunction with the Conflict of Interest Committee (COIC), will work with the Investigator to develop a resolution plan to manage, reduce, or eliminate any actual or potential FCOI. Possible approaches include, but are not limited to the following:
  - a. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research). If the Sponsors' determine that a Sponsor-funded project to evaluate a drug, medical device or treatment was conducted by an Investigator with a conflict that was not disclosed or managed, the Investigator(s) is required to disclose the conflict in each public presentation of the results of the research;
  - b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
    - i. COI determinations and management plans must be included in the submission of human subjects research to the Institutional Review Board (IRB) for review. The IRB may require modifications to the research or to the management plan for the protection of subjects, per HSPP/IRB policies.
  - c. 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;
  - d. Modification of the research plan;





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- e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - f. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
  - g. Severance of relationship(s) that create financial conflicts.
3. Whenever MSU Denver identifies an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the University, within 60 days OSRP or the COIC will: review the SFI; determine whether it is related to the Investigator's institutional responsibilities; determine whether a financial conflict of interest exists; and, if so
- a. Implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
  - b. Within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. If necessary, MSU Denver will update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, MSU Denver is required to notify the Sponsors promptly and submit a mitigation report to the appropriate Sponsor point-of-contact. MSU Denver may determine that additional interim measures are necessary.

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4. No less than once a year, OSRP and the COIC will meet to monitor Investigator compliance with management plans for the duration of the project period, including extensions with or without funds.
- E. Resolution of FCOI Disputes. Any dispute, controversy, sanction or appeal in relation to disclosure, management or elimination of financial conflicts of interest shall be resolved by the Conflict of Interest Committee (COIC). COIC decisions shall be considered final subject to review and modification by the Provost, President and/or the Board of Trustees.
- F. Reporting a Financial Conflict of Interest
1. Prior to the University's expenditure of any funds under the Sponsors' research project, the University is required to provide to the Sponsors a financial conflict of interest (FCOI) report regarding any Investigator's FCOI and ensure that MSU Denver has implemented a management plan in accordance with this policy. If MSU Denver identifies a FCOI and eliminates it prior to the expenditure of the Sponsors' awarded funds, the University is not required to submit an FCOI report.
  2. Once a FCOI has been reported, MSU Denver must submit an annual FCOI report to the Sponsor for the duration of the project period, including extensions with or without funds. The report must specifically state whether the FCOI is still being managed, why it no longer exists, and/or detail any changes in the management plan.
  3. For any significant financial interest (SFI) that MSU Denver identifies as conflicting subsequent to its initial FCOI report during an ongoing Sponsor-funded research project (e.g., upon the participation of an Investigator who is new to the research project), within 60 days MSU Denver must provide to

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the appropriate Sponsor point-of-contact an FCOI report regarding the financial conflict of interest and ensure that MSU Denver has implemented an FCOI management plan.

- a. If the FCOI report involves an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed or managed by the University, MSU Denver must complete a retrospective review to determine whether any Sponsor-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. If bias is found, MSU Denver is required to notify The Sponsor promptly and submit a mitigation report to the appropriate Sponsor point-of-contact.
- G. Sub-Recipient Monitoring. When MSU Denver carries out any Sponsor-funded research with the involvement of a sub-recipient or contractor, the University will take reasonable steps to ensure that any sub-recipient Investigator complies with the Sponsor's FCOI mandates by:
1. Incorporating terms as part of a written agreement with the sub-recipient that establish whether MSU Denver's FCOI policy or the sub-recipient's policy will apply to the sub-recipient's Investigators.
  2. If the sub-recipient's Investigators are to comply with the sub-recipient's FCOI policy, the sub-recipient must certify that its policy complies with the Sponsors regulations and the agreement will specify the time period(s) for the sub-recipient to report all identified FCOIs to MSU Denver. If the sub-



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recipient cannot provide such certification, its Investigators must comply with MSU Denver's FCOI policy.

3. If the sub-recipient's Investigators are to comply with MSU Denver's FCOI policy, the agreement will specify the time period(s) for the sub-recipient to submit all Investigator disclosures of significant financial interests to MSU Denver.
- H. Public Disclosure of PHS-Funded Financial Conflicts of Interest. Pursuant to the 2011 revised FCOI regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F), as well as NSF's Conflict of Interest Policy, prior to the expenditure of any funds under Sponsor-funded research project, MSU Denver will ensure public accessibility, via a publicly accessible website or written response to any requestor within five business days of a request, of information concerning any significant financial interest (SFI) disclosed to the University that meets the following three criteria:
1. The SFI was disclosed and is still held by the Investigator;
  2. MSU Denver determines that the SFI is related to the Sponsor-funded research; and 3.8.1.3. MSU Denver determines that the SFI is a FCOI.
- I. Records Management. Records of all FCOI disclosures, review notes, and actions taken will be maintained for at least three years from the date of submission of the final expenditures report.

## **VI. Policy History**

- A. **Effective:** July 1, 2019
- B. **Enacted:** September 2015
- C. **Review Schedule:** This policy will be reviewed every three years or as deemed necessary by University leadership.



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### VII. Policy Approval

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**Vicki Golich, Ph.D.**  
*Provost and Executive Vice President for Academic Affairs  
Metropolitan State University of Denver*