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|  <p>Research & Sponsored Programs UNIVERSITY OF DENVER</p> | <p>Office of Research and Sponsored Programs Policy Manual</p> <p>Disclosure and Management of Conflicts of Interest, (COI) in Externally Funded Research Awards</p> |
| <p>Supersedes Document Dated: 02/01/2012; 8/23/2012</p> | <p>Policy Number: ORSP-03</p> |
| <p>Recommended By: Director of Research Integrity and Education; Director of Sponsored Programs Administration Approved By: Senior Vice Provost for Research and Graduate Education</p> | <p>Effective Date: 04/01/2023</p> |

1. PURPOSE

The University of Denver’s academic vision is regularly served by participation of its representatives in activities outside the University. The interactions with external organizations contribute to the enrichment of University programs. While such interaction is encouraged, these activities may result in a real or perceived financial conflict of interest. It is necessary to assess and manage financial conflicts of interest, so that the integrity of federally funded awards and the interests of the University and its representatives are protected.

This policy seeks to Provide guidelines for identifying and addressing perceived, potential, and actual financial conflicts of interest in federally funded awards to which faculty and staff engage. Protect federally funded investigators and the University from the appearance of bias in the creation, analysis, interpretation, and publication of data. Protect human participants who participate in research from risks and provide information which can be used in reaching decisions about entering or remaining in research protocols.

This policy applies to all federally funded awards managed by the Office of Sponsored Program Administration and reviewed and approved by the compliance boards managed through the Office of Research Integrity and Education.

2. DEFINITIONS

- 2.1. Conflict of Interest (COI): A conflict of interest (COI) exists when the recipient’s designated official(s) determines that an investigator’s significant financial interest could directly and significantly affect the design, conduct, or reporting of externally funded research.
- 2.2. Institutional Conflict of Commitment & Interest: Institutional conflict of commitment and interest exists in situations when a University Representative (employees who are deans, directors, and/or officers of the University) engages in external activities, either paid or unpaid, that is compromised by a personal, financial, or business interests that interferes with his/her primary obligation and commitment to the University.
- 2.3. Related Party: A related party is defined as a spouse; descendant; an ancestor; a sibling; the spouse or descendant of a sibling; an estate or trust in which a trustee, officer, faculty or staff of the University or a party related to a trustee, officer, faculty, or staff of the University has a beneficial interest; or an entity in

which a party related to the trustee, officer, faculty, or staff of the University is a director, officer, or has a financial interest.

- 2.4. Research: As used in this Policy, any activity for which research funding is available from a federal-awarding agency, including research grants and cooperative agreements.
- 2.5. Investigator: As used for this Policy, an Investigator is a University employee serving as the principal investigator or co-investigator, or any other person at DU who is responsible for a portion of the design and conduct of a federally funded research activity, or proposed for funding, through a federally-funded award.
- 2.6. Externally Funded Activity: A research projects involving funds, materials, or other compensation from external (i.e., outside of the University) sponsors under special agreements.
- 2.7. Federally Funded Activity: Research projects involving federal funds, materials, or other compensation from federal sponsors under special agreements.
- 2.8. Institutional Official: The Institutional Official (IO) is a University senior level administrator who is legally authorized to exercise administrative and operational authority to commit institutional resources, enforce policies, authorize necessary administrative or legal action, and otherwise ensure that the University maintains a strong and effective compliance program.
- 2.9. Significant Financial Interest (SFI): Consistent with federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), a “Significant Financial Interest” (SFI) is defined as the receipt of you, your spouse, or your dependent children of any of the following:
 - Income that exceeds \$5,000 from any outside entity, measured on a rolling 12-month basis. This may be one payment from a company of more than \$5,000 or multiple payments from the same company that in the aggregate exceed \$5,000 and are received within the previous 12 months.
 - Acquisition of equity in a public company that exceeds \$5,000 in value.
 - Aggregated income and equity/ownership interest from a public company that exceeds \$5,000, as measured on a rolling basis.
 - ANY equity/ownership interest in a privately held company.
 - An income that exceeds \$5,000 from rights in intellectual property, as measured on a rolling 12-month basis;
 - All reimbursed and “sponsored” travel that exceeds \$5,000, as measured on a rolling 12-month basis.
- 2.10. Excluded from this definition are payments (including travel) received from the University. Also excluded from this definition are payments received from any of the following entities, provided these payments are received for teaching engagements, lectures, seminars, or services on advisory committees or review panels:
 - Government agencies.
 - U.S. institutions of higher education and research institutes affiliated with them.
 - Academic teaching hospitals.
 - Medical centers.
- 2.11. Further, you need not report income from investment vehicles over which you need not exercise control, such as mutual funds and retirement accounts.
- 2.12. Research Financial Conflict of Interest Review Committee: A Committee appointed by the Institutional Official (or designee) to review Investigators’ significant financial interests (SFIs) related to federally funded awards to determine whether any of the SFIs constitutes a financial conflict of interest (COI), and whether a management plan must be implemented. Committee members will be comprised of a faculty member from the Sponsored Programs Academic Research Council and leaders (or designees) from the Offices of Research Integrity and Education, Intellectual Property and Technology Transfer, and Sponsored Programs Administration.

3. POLICY

3.1. All Externally Funded Research Awards

Any University employee responsible for the design, conduct, or reporting of an externally or federally funded project at the University must disclose to the Office of Research and Sponsored Programs (ORSP) any significant financial interests at least annually, and within 30-days of receiving a new funding award. ORSP determines if such interests reasonably appear to be directly and significantly affected by the externally funded project. ORSP, as an agent of the University, will take steps either to manage, reduce, or to eliminate financial conflict of interest before funds are spent.

The COI policy applies to ongoing and future externally funded activities, research grants, projects or programs, but not to past transactions or past research grants. The latter are subject to applicable University policies in place at the time these activities were undertaken. If an individual is also a member of and has duties and responsibilities to another institute or agency that conflict with the policies of the University, the most restrictive of the conflicting policies will prevail.

The Office of Sponsored Programs will obtain assurances from sub-recipients (subcontractors and subgrantees) on federally funded activities who are compliant with current financial conflict of interest regulations and University policies.

The Office of Research & Sponsored Programs will verify and ensure all federally funded investigators are compliant with current Financial Conflict of Interest regulations and University policies.

3.2. Research Compliance Board or Committee Membership

Institutional Research Compliance Board or Committee relationships shall be done transparently and disclosed as initiated.

3.3. University Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Institutional Biosafety Committee (IBC) Commitments

No regular or alternate member may participate in the initial or renewal of any research project in which the member has a financial conflict of interest, except to provide information as requested. It is the responsibility of each voting member or alternate member to disclose any COI in a study submitted to these institutional committees and recuse themselves from deliberations and voting. Institutional staff whose job status or compensation is affected by research reviewed by the committees must recuse themselves from any meeting at which such a protocol is reviewed.

3.4. Reporting

The University must report any conflicting significant financial interests (SFI) to the awarding agency that issued the award prior to expending any funds, AND any SFI identified as conflicting to the initial report within 60 days of that identification.

Upon request, the University will make information available to the Department of Health and Human Services (DHHS) regarding all conflicting research financial interests and how those interests have been managed, reduced or eliminated. Federal requirements are in addition to other provisions by the University including:

- University of Denver policies 3.20.060
- 42 CFR 50 Subpart F and 45 CFR 94
- PHS Policy
- NSF Proposal & Award Policies & Procedures Guide Part II, Chapter IX, Section A
- DU HRPP Policy 301, Section 3.8, version 3.0

4. PROCESS

4.1. Disclosures and Documentation of Research Financial Conflict of Interest

Any Investigator who wishes to submit a proposal for an externally funded award shall disclose fully any potential financial conflict of interest (as defined above) to the Office of Research and Sponsored Programs annually, and within 30-days of a new award.

Any Investigator who submits a proposal for Institutional Compliance Committee or Board review shall disclose fully any potential financial conflict of interest (as defined above) to the Office of Research and Sponsored Programs.

4.2. Annual Disclosures

Disclosures of significant financial interests shall be made by filing an annual financial COI disclosure form. All forms should be submitted annually as designated by ORSP. Disclosure and review of the disclosure should take place before acceptance of any external funding from the sponsor, before commencing any sponsored project, or issuing final approval for a research proposal from an Institutional Research Compliance Board or Committee.

4.3. Ad hoc Disclosures

In addition to the annual disclosure, certain situations require the submission of an ad hoc COI disclosure. Prior to receiving a new externally funded project award, the Investigator must affirm the accuracy of the annual disclosure or indicate if a new Significant Financial Interest exists by updating the previously submitted Financial Conflict of Interest Disclosure Form.

When an Investigator is not aware at the time of the proposal of the existence of provisions that might be a potential financial conflict of interest or such provisions arise thereafter, the Investigator(s) shall notify the Office of Research and Sponsored Programs within 30 days of learning of such arrangement.

Whenever a Sponsored Programs representative believes a conflict exists, they shall immediately refer the matter to the Research COI Review Committee for review and recommendation.

Whenever a federally funded research proposal is submitted to an Institutional Compliance Board or Committee and a potential financial a conflict of interest is identified, the matter may be referred to the Research COI Review Committee for review and recommendation.

4.4. Travel

Investigators must disclose reimbursed or federally funded travel, as defined above in the definition of Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/ organizer, the destination, the duration, and if known, the monetary value. Investigators should complete a COI disclosure for review to determine whether the travel constitutes a

conflict or potential financial conflict of interest with the Investigator's research. This will be done through annual disclosure or an updated disclosure as appropriate.

4.5. Sub-recipients

Prior to initiating a subcontract or subaward under a Prime award, Sponsored Programs will request a certification from the sub-recipient as to one of the following:

- Sub-recipient has a Financial Conflict of Interest (COI) policy in compliance with DHHS regulations.
- Sub-recipient will either provide or provide access to their policy for COI Review Committee review.
- Sub-recipient does not have a compliant COI policy and agrees to abide by the University Disclosure of Financial Interests & Management of COI, Federally Funded Research Awards Policy.
- The sub-recipient will be required to submit a financial COI disclosure form for all key personnel to ORSP for review in the same methods discussed herein.

4.6. Resolution of Conflicts

In the event an SFI disclosure by an Investigator reveals a potential, apparent or actual conflict, the COI disclosure will be forwarded to the Research COI Review Committee to review the facts and determine whether a financial conflict of interest exists. The Research COI Review Committee shall determine the appropriate steps to take to manage the financial conflict of interest, including the reduction or elimination of the conflict, as appropriate. The committee will attempt to resolve the matter informally and privately with the party involved, if possible.

A Financial Conflict of Interest will exist when the Institutional Official or Research COI Review Committee determines that a Significant Financial Interest could directly and significantly impact the design, conduct, or reporting of an externally funded award. If determined that there is a Financial Conflict of Interest that can be managed, the Research COI Review Committee will develop and implement a written management plan. The Investigator must formally agree to the proposed management strategies before the funded activity goes forward.

If the Investigator objects to the management plan, the Institutional Official will review or may appoint an independent advisory committee. In cases involving a member of the faculty, at least one of these committee members shall be a senior faculty member. The advisory committee shall evaluate the severity of the conflict and recommend to the Institutional Official the steps necessary, in its view, to resolve the conflict.

ORSP will periodically review the ongoing activity, monitor the conduct of the activity, and oversee compliance with the management plan.

4.7. Mechanism for Ongoing Disclosure

Any University employee engaged in an externally funded project shall have an ongoing duty to complete and file an COI disclosure form annually and whenever a new reportable financial interest develops for their current or future externally funded awards.

The employee shall also attest to the Office of Research and Sponsored Programs that provisions have been made for maintenance of records, identifiable to each award, of all disclosures of significant financial interests or potential conflicts of interest.

Federally funded research records of all COI disclosures and all actions taken by the institution will be maintained by ORSP for at least three years from the date of submission of the final expenditure report.

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the University of Denver may be requested or required to make such information to a government agency, the sponsor, or to a requestor of information concerning financial conflict of interest related to federal funding. If the University is requested to provide any of this information to an outside entity, the Investigator will be informed of the disclosure.

The Institutional Official with signature authority shall make such certifications relating to conflicts and the University's management of those conflicts as required by governmental or other sponsors.

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The Institutional Official with signature authority shall make such certifications relating to conflicts and the University's management of those conflicts as required by governmental or other sponsors.

4.9. Education and Training in Conflict of Interest

Any University faculty or staff who are directly and could significantly affect the design, conduct, or reporting of externally funded research must complete education related to conflict-of-interest issues. Investigators obtaining federally funded awards through the National Science Foundation (NSF) must also complete responsible conduct of research (RCR) education. These training requirements must be met by completing coursework provided through the Office of Research and Sponsored Programs via The Collaborative Institutional Training Initiative (CITI Program). Education requirements must be completed before initial receipt of funds and renewed every 4 years.

4.10. Responsibility and Non-Compliance

The Institutional Official and ORSP are responsible for articulating and enforcing the Disclosure of Financial Interests & Management of COI, Externally Funded Research Awards Policy at the University. ORSP is responsible for monitoring the COI status, disclosures, and training profiles of faculty and staff.

4.10.1. Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented. An Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official will be described in written explanation of the decision of the investigator. If required, ORSP will promptly notify the Sponsor of the action to be taken.

4.10.2. Retrospective Review

If the University determines that a COI was not identified or managed in a timely manner, including, but not limited to, an Investigator's failure to disclose a financial conflict of interest, or failure by an Investigator to materially comply with a management plan, an advisory committee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and the sponsored project to determine whether the activities conducted during the period of non-compliance were biased in the design, conduct or reporting of the research or activities.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the COI, name of entity with which the Investigator has the COI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

ORSP will update any previously submitted report to the sponsor, specifying actions that will be taken to manage the COI going forward. This retrospective review will be completed in the manner and time frame established in regulations. If bias is found, the institution will promptly notify the sponsor and submit a mitigation report. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

4.11. Public Accessibility

The ORSP at the University shall identify a campus email address and one office address as the recipient address for public requests for information under the DHHS regulation and this policy and shall take the necessary action to provide this address to the public, including prominently posting this information on the campus website. In accordance with DHHS regulations, this policy is posted on a publicly accessible website at <https://www.du.edu/orsp/research-compliance/conflict-interest>.

Prior to the expenditure of funds, the University of Denver will respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- The Significant Financial Interest was disclosed and is still held by the senior and key personnel.
- A determination has been made that the Significant Financial Interest is related to the

externally funded research.

- A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

Annual Disclosure forms, ad hoc disclosure forms, and management plans including determinations of Financial Conflicts of Interest are public records open to public inspection, under federal and state law.

