

 Research & Sponsored Programs UNIVERSITY OF DENVER	Office of Research and Sponsored Programs Policy Manual Conflicts of Interest in Research
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Recommended By: Director of Research Integrity and Education; Director of Sponsored Programs Administration; Regulatory Compliance Officer Approved By: Senior Vice Provost for Research and Graduate Education	Effective Date: 04/01/2024

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 or COI is when a Researcher has a personal, professional or financial interest that could directly and significantly affect the design, conduct, or reporting of research results resulting from an externally funded research project.
- 2.2. Institutional Conflict of Commitment & Interest is a situation in which a Researcher engages in external activities outside the University, either paid or unpaid, that is compromised by a personal, professional financial, or business interest that interferes with their primary obligation to the University.
- 2.3. Related Party is 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 is any activity for which research funding is available from a federal-awarding agency, including research grants and cooperative agreements.
- 2.5. Researcher is University employee serving as the Principal Investigator, investigator, research associate, research assistant or any other person 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 is a Research project that involves funds, materials, or other compensation from entity other than the University through a written agreement.
- 2.7. Federally Funded Activity is a Research project involving funding materials, or other compensation that originates from an agency of the Government of the United States through a written agreement or other notification.
- 2.8. Significant Financial Interest or SFI, pursuant to 42 CFR Part 50.603 and 45 CFR Part 94.3, is the receipt by the Researcher, Researchers spouse, or Researchers dependent children of any of the following:
 - 2.8.1. Any income that exceeds one thousand dollars (\$1,000.00) from any entity other than the University.
 - 2.8.2. Acquisition of equity in any company that exceeds \$5,000 in value.
 - 2.8.3. An income that exceeds one thousand dollars (\$1,000.00) from rights in intellectual property in any twelve-month period.
 - 2.8.4. Any travel paid for by an entity other than the Researcher or the University that exceeds one thousand dollars (\$1,000.00) in any twelve-month period.

Excluded from this definition are any compensation (including travel) received from the University. Also, excluded from this definition are payments received from any government agency, provided these payments are received for teaching engagements, lectures, seminars, or services on advisory committees or review panels. You also need not report income from investment vehicles over which you exercise no control, such as mutual funds and retirement accounts.

- 2.9. Research Conflict of Interest Review Committee is committee appointed by the Vice Provost for Research (VPR) to review conflicts or potential conflicts of interest disclosed by a Researcher, and whether a management plan must be implemented to mitigate such conflict.
- 2.10. Principal Investigator is the University employee that leads an externally funded program or project and is responsible for the proper conduct of research, financial management, and other activities described in the proposal, grant, contract or other instrument of agreement.
- 2.11. Personal or Professional Relationship is a situation or circumstance in which an individual has a relationship that could impair their ability to act impartially and in the best interest of the Research they are responsible for performing or overseeing.
- 2.12. Country of Concern is nation state that is listed by the United States Department of State as a Country of Particular Concern pursuant to the [International Religious Freedom Act of 1998 \(Pub. L. 105-292\)](#) and Frank R. Wolf International [Religious Freedom Act of 2016 \(Pub. L. 114-281\)](#). This includes nation states designated by the United States Department of State as Special Watch List Countries and Entities of Particular Concern.

3. POLICY

- 3.1. All active Researcher will disclose to the Office of Research and Sponsored Programs (ORSP) in a form and format produced by ORSP any and all SFI, Personal or Professional Relationship that may affect Research and, any collaboration with a foreign person, entity or government. If ORSP determine that any such disclosure reasonably appears to directly and significantly affect the externally funded project, ORSP, as an agent of the University, will take steps to either manage, reduce, or to eliminate conflict of interest before Research is begun.
- 3.2. This policy applies to ongoing and future externally funded Research activities, Research grants, projects or programs, but not to past transactions or past Research grants. If a Researcher is also a member of or has duties and responsibilities to another institution or agency that conflict with this policy, the most restrictive of the policies will prevail.
- 3.3. ORSP 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. ORSP will verify all federally funded Researchers are compliant with all federal conflict of interest regulations and University policies.
- 3.4. No regular or alternate member of the University's Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), or Institutional Biosafety Committee (IBC) may participate in the initial or renewal application or review of any Research project in which the member has a conflict of interest, except to provide information as specifically requested by such body. It is the responsibility of each member or alternate member to disclose all conflicts of interest related to study submitted to these committees and recuse themselves from deliberations and voting. A University employee whose job status or compensation is affected by Research reviewed by the committees must recuse themselves from any meeting at which such a study is reviewed.
- 3.5. Upon request, the University will make information available to the United States Department of Health and Human Services (HHS), the National Science Foundation (NSF), the United States Department of Defense (DoD) and the United States Department of Energy (DoE) regarding all information disclosed to it regarding the actual and potential conflicts of interest disclosed by the Researcher and how such conflicts have been managed, reduced or eliminated.
- 3.6. This policy applies to all Researchers engaged in externally funded Research regardless of the entity funding such research. This policy requires disclosure of information that meets and exceeds the requirements set by federal regulation.
- 3.7. Researchers must disclose any travel that is not paid for by the Researcher or the University and if such travel is to an international location, register the travel pursuant to [University Policy RISK 2.50.070 – International Travel](#). Such disclosures must include, at a minimum, the purpose of the trip, the identity of the organizer, the destination, the duration, and if known, the monetary value. Researchers will complete a conflict-of-interest disclosure to determine whether the travel constitutes a conflict or potential conflict of interest with the Research. This will be done through annual disclosure or an updated disclosure as appropriate.
- 3.8. All Researchers have an ongoing duty to complete and submit COI disclosure form whenever a new reportable SFI or other potential conflict of interest develops related to current or future externally funded Research.

- 3.9. All Researchers will attest to ORSP 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.
- 3.10. To the extent permitted by law, all disclosure forms, management plans, and related information will be confidential. However, the University may be required to make such information available to a government agency, the sponsor, or to a legitimate requestor of information concerning the conflict of interest. If the University is turns over any information to an outside entity, the subject of the records will be notified of the disclosure. The VPR has authority to make such certifications relating to conflicts and the University's management of those conflicts as required by governmental or other external funding entities.
- 3.11. Researchers must disclose if any research collaborator is a citizen of a foreign nation and if so which foreign nation the collaborator is citizen of.
- 3.12. Researchers must disclose the name and location of any foreign government or foreign owned business entity or person with which they have in the past or plan in the future to do business with regardless of if such business is related to University research. If the foreign nation is a Country of Concern the Researcher must also disclose the names and contact information for all individuals with whom they have had contact with in the Country of Concern.
- 3.13. The University will submit a Researchers COI disclosure form to the applicable external funding entity as evidence of compliance with the external funding entities conflict of interest policies. This includes submitting any supplementary information as may be required by the National Science Foundation, United States Department of Deference, United States Department of Energy and United States Department of Health and Human Services including all Public Health Service (PHS) agencies including the Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH - including all Institutes and Centers), and Substance Abuse and Mental Health Services Administration (SAMHSA).
- 3.14. The completion of the COI disclosure form by Researchers is in addition to the requirements for COI disclosure outlined in [University Policy RISK 3.20.060 – Conflict of Interest](#).
- 3.15. The University, including its, officers, employees, trustees, students, volunteers, agents and other affiliates, must balance many competing pressures. The University engages in relationships with a variety of external entities and individuals that may lead to financial benefit to the University including gifts, business ventures, royalty payments and equity from licensing intellectual property, as well as sponsored educational and research agreements. Understanding the competing pressures the University will not permit any external relationship to compromise or appear to compromise the integrity of University Research.

4. PROCESS

- 4.1. Any Researcher who seeks to submit a proposal for an externally funded Research award will completely and accurately disclose any and all potential conflict of interest to the ORSP no less than every twelve months, and within thirty days of receiving a new funding award.
- 4.2. Prior to initiating a subcontract or subaward under ORSP will request a certification from the sub-recipient as to one of the following:
 - 4.2.1. That the sub-recipient has a COI policy in compliance with the applicable federal regulations.
 - 4.2.2. That the sub-recipient will either provide or provide access to their COI policy for ORSP review.
 - 4.2.3. That if the sub-recipient does not have a compliant a COI policy that is complaint with federal regulation the sub-recipient agrees in writing to comply with this policy.
 - 4.2.4. That the sub-recipient will to submit a COI disclosure form for Researchers to ORSP in a from and format prescribed by ORSP.
- 4.3. In the event a disclosure reveals a potential, apparent or actual conflict, the disclosure form will be forwarded to the Research Conflict of Interest Review Committee to review the disclosure and determine whether a conflict of interest exists. The Research Conflict of Interest Review Committee will determine the appropriate steps to take to manage the conflict of interest, including the reduction or elimination of the conflict, as appropriate. The Research Conflict of Interest Review Committee will attempt to resolve the matter informally and privately with the party involved, if possible.
- 4.4. A Conflict of Interest will exist when the Research Conflict of Interest Review Committee determines that a SFI or other disclosure could directly and significantly impact the design, conduct, or reporting of results from an externally funded award. If determined that there is a Conflict of Interest that can be managed, the Research Conflict of Interest Review Committee will develop and implement a written management plan. The Researcher must formally agree to the proposed management plan before the funded activity make continue.
- 4.5. If the Researcher objects to the management plan, the VPR will review the proposed management plan and may appoint an independent advisory committee to assess the proposed management plan. The Researcher will be bound by a management plan directed to them by the VPR over their objections in order to continue with the externally funded Research. ORSP will periodically review the ongoing activity, monitor the conduct of the activity, and oversee compliance with the management plan.
- 4.6. Any University employee who are directly or could significantly affect the design, conduct, or reporting of externally funded research to a funding entity will complete education related to COI issues, Responsible Conduct of Research, Foreign Interference, Research Security and Export Control. Training requirements will be met by completing coursework provided through the ORSP utilizing the Collaborative Institutional Training Initiative Program (CITI Program). Education requirements must be completed before initial receipt of funds and renewed every two (2) years.
- 4.7. The VPR is responsible for articulating and enforcing this Policy at the University. ORSP is responsible for monitoring the COI status, disclosures, and training profiles of faculty and staff. The VPR may delegate responsibility for enforcement of this policy to another University employee or appropriate contractor.
 - 4.7.1. In the event of Researchers failure to comply with this policy, the VPR may suspend all relevant Research activities or take other disciplinary action until the matter is resolved or other action deemed appropriate. A VPRs decision to impose sanctions because of failure to comply with this policy, or failure to comply with the decision of VPR will be described in written.

- 4.7.2. If the University determines that a COI was not identified or managed in a timely manner, including, but not limited to, a Researchers failure to disclose a Conflict of Interest, or failure by a Researcher to materially comply with a management plan, ORSP will complete a retrospective review of the Researchers activities and the Research 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. ORSP will update any previously submitted report to the sponsor of the externally funded Research, specifying actions that will be taken to manage the COI in the future. This retrospective review will be completed in a manner and timeframe required by federal regulations. If bias is found, the University will promptly notify the sponsor of the externally funded Research and submit a mitigation report.
- 4.8. The ORSP will identify a campus email address and one office address as the recipient address for public requests for information pursuant to federal regulation and this policy and will take the necessary action to provide this address to the public, including prominently posting this information on the ORSP website.
- 4.9. Prior to the expenditure of funds, the University will respond to any request for information, within five business days, concerning any SFI or other Conflict of Interest that meets the following criteria:
- 4.9.1. The SFI was disclosed and is still held by the senior Researcher.
 - 4.9.2. A determination has been made that the SFI is related to the externally funded Research.
 - 4.9.3. A determination has been made that the SFI is a Conflict of Interest.
- 4.10. With respect to any funding award from a PHS agency, prior to expenditure, the University will review the annual COI disclosure for all participating Researchers to assess whether any SFI is related to the PHS agency funded research. A SFI is related to the PHS agency funded research when it:
- 4.10.1. Could be affected by the relevant PHS agency funded Research; or
 - 4.10.2. is in an entity whose financial interest could be affected by such Research.
- 4.11. Factors that indicate relatedness to a PHS agency include but are not limited to whether the SFI is in an entity that:
- 4.11.1. Funds the PHS Research in whole or in part, whether through a research agreement, gift, or other arrangement.
 - 4.11.2. Supplies drugs, devices or other goods that are the subject of such Research, or services or other deliverables in connection with the research, pursuant to a material transfer agreement, a research agreement or otherwise.
 - 4.11.3. Holds an Investigational New Drug application or Investigational Device Exemption for a Technology being investigated in such Research.
 - 4.11.4. Owns, licenses, or has any other contractual interest in a Technology being investigated in such Research.
- 4.12. Violations of this policy will be investigated by the VPR or their designee. Conduct that the VPR determines has violated this policy will, if not resolved, subject an employee to appropriate corrective action up to and including termination or employment. Prohibited conduct committed by a student will be referred to the Office of Student Rights and Responsibilities for determination of outcomes under the University's Honor Code.

5. Resources

- 5.1. [Promoting Objectivity in Research - 42 CFR Part 50 Subpart F](#)
- 5.2. [Responsible Prospective Contractor – 45 CFR Part 94.3](#)
- 5.3. [Grantee Standards - National Science Foundation Proposal & Award Policies & Procedures Guide Part II, Chapter IX, Section A](#)
- 5.4. Human Subjects Research Protections General Policies and Procedures – Policy 301, Section 3.8
- 5.5. [International Religious Freedom Act of 1998 - Pub. L. 105–292](#)
- 5.6. [Religious Freedom Act of 2016 - Pub. L. 114-281](#)
- 5.7. [University Policy RISK 2.50.070 – *International Travel*](#)
- 5.8. [University Policy RISK 3.20.060 – *Conflict of Interest*](#)