1.0 POLICY

The University of Denver 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 conflict of interest. It is necessary to assess and manage conflicts of interest, so that the integrity and the interests of the University and its representatives are protected.

This policy applies to all sponsored projects managed by the Office of Research and Sponsored Programs.

1.1 Purpose

- Provide guidelines for identifying and addressing perceived, potential, and actual conflicts of interest in research and activities to which faculty and staff engage, by assisting employees and officials in a way that encourages professional and personal development as long as their personal or financial gain does not affect their objectivity, integrity, or professional commitment to the University.
- Protect investigators, staff, students, and the University from even 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.

1.2 Definitions

**COI:** A conflict of Interest (COI) arises when an employee, or related party has a significant financial interest in an outside funding source, which interest could directly and significantly affect decision making in the design, conduct, or reporting of externally funded instruction, research, or service activities performed on behalf of the University. A COI also refers to other personal considerations that may compromise, or have the appearance of compromising, an employee's professional judgment in administration, management, instruction, research and other professional activities.
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, as defined in the University of Denver Conflict of Commitment and Interest policy (3.20.060).

Investigator: 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 instructional, research, service activities, or any other sponsored activity funded or proposed for funding by an external sponsor, agency or organization.

A sponsored activity is defined as research, training, instructional or service projects involving funds, materials, or other compensation from outside sponsors under special agreements.

Institutional Official: Associate Provost for Research.

COI Officer: Representative from the Office of Research and Sponsored Programs.

PHS: The Public Health Service of the U.S. Department of Health and Human Services, and any component of the PHS to which PHS authority may be delegated.

Significant Financial Interest: means anything of monetary value (or potential monetary value), whether or not the value is readily ascertainable, including but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks) upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial interest also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available.

Significant Financial Interest does not include:

(1) Salary, royalties, or other remuneration from the applicant institution;

(2) Income from authorship of academic or scholarly works;

(3) Income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels from public or non-profit entities;

(4) Equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Employee does not directly control the investment decisions made in these vehicles.

(5) Travel reimbursed or sponsored by public or non-profit entities

(6) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the preceding twelve months that did not exceed $5,000.
2.0 SPECIFIC POLICIES

2.1 ALL Sponsored Projects

Any University employee responsible for the design, conduct, or reporting of a sponsored project at the University must disclose to ORSP significant financial interests before submission of an application for funding. ORSP determines if such interest reasonably appear to be directly and significantly affected by the sponsored project. ORSP as an agent of the University will take steps either to manage, reduce, or to eliminate the conflict of interest before funds are spent.

The COI policy applies to ongoing and future activities, research grants, projects or programs, sponsored activities funded by external agencies, 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.

ORSP will obtain assurances from sub-recipients (subcontractors and subgrantees) that they are in compliance with current Conflict of Interest regulations.

2.2 Board or Committee Membership

External Board or Committee relationship shall be carried out in a transparent manner and disclosed as initiated. University of Denver IRB, IACUC, and IBC Commitments: No regular or alternate member may participate in the initial or continuing review of any research project in which the member has a 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 that is reviewed by the committees must recuse themselves from any meeting at which such a protocol is reviewed.

3.0 APPLICABLE REGULATIONS AND GUIDELINES

This policy applies to all sponsored projects.

NSF and PHS-funded research: the University must report any conflicting interest to the awarding agency that issued the award prior to expending any funds, AND any interest identified as conflicting subsequent 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 (HHS) regarding all conflicting interests and how those interests have been managed, reduced or eliminated. Federal requirements are in addition to other provisions by the University of Denver.

University of Denver policies 3.20.060 and 3.01.005.

42 CFR 50 Subpart F and 45 CFR 94;

National Science Foundation Grant Policy Manual Section 510
4.0 PROCEDURES

4.1 Disclosure and Documentation of Financial Interest and COI

Any investigator who wishes to submit a proposal for sponsored research shall disclose fully any potential conflict of interest (as defined above) to ORSP prior to submission.

a) Annual Disclosures
Disclosures of significant financial interests and potential COI shall be made by filing an annual COI form. All forms should be submitted to ORSP annually as designated by ORSP. Disclosure and review of the disclosure should take place before acceptance of funding from the sponsor and before commencing any sponsored project.

b) Ad hoc Disclosures
In addition to the annual disclosure, certain situations require ad hoc disclosure. Prior to applying for a sponsored project, the investigator must affirm the currency of the annual disclosure or indicate a new Significant Financial Interest exists and submit an ad hoc updated disclosure of the interest.

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

Whenever an ORSP representative believes that a conflict exists, he or she shall immediately refer the matter to the Institutional Official for review and recommendation.

c) Travel
Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, 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. The ORSP representative will determine whether the travel constitutes a conflict or potential conflict of interest with the Investigator’s research. This will be done through annual disclosure or ad hoc disclosure as appropriate.

d) Sub-recipients

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

- Sub-recipient has a Financial Conflict of Interest (FCOI) policy in compliance with PHS regulations. Sub-recipient will either provide or provide access to their policy for ORSP review.
- Sub-recipient does not have a compliant FCOR policy and agrees to abide by the University of Denver’s Conflict of Interest policy. The sub-recipient will be required to submit a COI disclosure form for all key personnel to ORSP for review in the same methods discussed above.
4.2 Resolution of Conflicts

In the event that a disclosure by an Investigator reveals a potential, apparent or actual conflict, the responsible Institutional Official, ORSP representative, or designee shall review the facts and determine whether a conflict of interest exists. He or she shall determine the appropriate steps to take in order to manage the financial conflict of interest, including the reduction or elimination of the conflict, as appropriate. He or she shall 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, ORSP representative, or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of a sponsored activity. If determined that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies before the sponsored activity goes forward.

If the Investigator objects to the resolution plan, the Institutional Official 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 consider whether a conflict exists, 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.

4.3 Mechanism for Ongoing Disclosure

Any University employee engaged in a sponsored project, whether funded by the University; externally sponsored from federal sources, state sources, or foundation, industry, or other private sources; who wishes to be eligible to engage in a particular sponsored project shall have an ongoing duty to complete and file a COI form whenever a new reportable financial interest develops.

The employee shall also attest to the ORSP representative 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.

Records of all financial disclosures and all actions taken by the institution will be maintained by ORSP for at least three years beyond the termination or completion of the award or until resolution of any action by any governmental agency involving the record, whichever is longer. For NIH and NSF funded research records of all financial disclosures and all actions taken by the institution will be maintained 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 NIH funding. If the University is requested to provide any of this information to an outside entity, the Investigator will be informed of the disclosure.
An 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.

4.4 Education and Training in COI

University faculty, staff and students shall complete education related to conflict of interest issues. This requirement must be met by completing coursework provided through the Office of Research and Sponsored Programs. Education requirements must be completed prior to initial receipt of funds, or project initiation if unfunded, and renewed every 4 years.

4.5 Responsibility and Non-Compliance

Institutional Official and ORSP are responsible for articulating and enforcing the conflict of interest policy (COI) at the University of Denver. ORSP is responsible for monitoring the COI status and disclosures of faculty and staff.

a) 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, and, where applicable, the IRB, and will notify the Investigator of the right to appeal the decision. If required, ORSP will promptly notify the Sponsor of the action to be taken.

b) Retrospective Review

If the University determines that a FCOI 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, a 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 FCOI, name of entity with which the Investigator has the FCOI, 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 FCOI 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 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.
4.6 Public Accessibility

In accordance with PHS regulations, this policy is posted on a publicly accessible website at www.du.edu/orsp.

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:

a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;

b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and

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