

UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

**PROCEDURES FOR EVALUATING  
CONFLICTS OF INTEREST  
AND  
COMMITMENT**

(Effective August, 12 2019)

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## **Procedures for Evaluating Conflicts of Interest and Commitment**

Maintenance of the public trust is critical to the mission and reputation of the University of Colorado Denver | Anschutz Medical Campus (“the University” or “University”), which is committed to upholding the principles of transparency, integrity and accountability. The University encourages its employees to interact with business and industry, public and private organizations, and government agencies in ways that support the institution’s missions. Notwithstanding the foregoing, teaching, research, outreach and other activities shall not be compromised, or perceived as compromised, by financial and/or personal benefit.

The procedures outlined herein supplement the Administrative Policy Statement at <https://www.cu.edu/ope/aps/5012>. The University encourages and supports outside interactions of its faculty and student employees with federal, state, and local governments, and with business and industry as important parts of their research, education and public service activities. In limited cases, similar opportunities are encouraged for University staff members as well.

### **1. Overview: Conflict of Interest and Commitment**

#### **1.1. Conflict of Interest Official**

Federal regulations require PHS-funded institutions to appoint a COI Official to review financial interests in sponsored research. The Chancellor for the University shall appoint such an official for the COIC Committee. The COI Official will report to the Vice Chancellor for Research regarding all COI activities. The COI Official will serve on the COIC Committee and also as a liaison to COMIRB.

#### **1.2. Conflict of Interest**

Situations in which financial or other personal considerations may adversely affect, or have the appearance of adversely affecting, an employee’s professional judgment in exercising any University duty or responsibility in administration, management, instruction, research and other professional activities. The bias that such conflicts could conceivably impart may inappropriately affect the goals of research, instructional or administrative programs. The education of students, the methods of analysis and interpretation of research data, the hiring of staff, procurement of materials and other administrative tasks at the University must be free of the undue influence of outside interests.

The mere appearance of a conflict may be as serious and potentially damaging as an actual distortion of instructional, research, or administrative goals, processes, or outcomes. Reports of conflicts based on appearances can undermine public trust in ways that may not be adequately restored even when the mitigating facts of a situation are brought to light. Apparent conflicts, therefore, should be disclosed and evaluated with the same vigor as actual conflicts.

#### **1.3. Conflict of Commitment**

The term "conflict of commitment" refers to situations in which outside relationships or activities (such as professional consulting for a fee) adversely affect, or have the appearance of adversely affecting, an employee's commitment to his/her University duties or responsibilities. Such activities are encouraged insofar as they are conducted in accordance with University

policy (including the One-Sixth Rule); promote professional development of faculty and student employees and enrich their contributions to the institution, to their profession and to the community. Consulting relationships, for example, may serve to create conduits for the exchange of information and technologies that enhance the University environment and permit faculty to test the soundness of their ideas (Regent Action 6/12/48). Separate policies apply to faculty in the School of Medicine (“SOM”), who are subject to separate guidelines and are required to direct all outside professional activities through CU Medicine.

Conflicts of commitment that are not appropriate could occur, for example, in the following areas:

- **Disproportionate Compensation.** If the aggregate amount of honoraria or consulting compensation to a faculty or staff member from outside entities exceeds thresholds established by the Office of Regulatory Compliance or the COIC Committee, a potential for a conflict of commitment exists.
- **Conflict of Time.** When the commitments for external activities, whether related to professional competence or not, encroach upon a faculty or staff member’s ability to contribute to the level expected of other staff members in the same specialty, a potential for a conflict of time commitment exists. Refer to Regent’s One-Sixth Rule, <https://www.cu.edu/regents/policy-5e-additional-remuneration-consultative-services>.
- **Conflict of Business or Mission.** Faculty and staff members may not engage in consulting or other external activities that compete or conflict with University business activities or mission. Additionally, they must not divulge proprietary University business information.
- **Conflict of Resources/Intellectual Property.** Faculty and staff members may not utilize University resources or share intellectual property developed or acquired during their Faculty appointment for the betterment of an external entity without prior approval.

Refer to the following policies for additional information:

- *Intellectual Property Policy on Discoveries and Patents for Their Protection and Commercialization*, Administrative Policy Statement 1013, <https://www.cu.edu/ope/aps/1013>. <https://www.cu.edu/policies/aps/academic/1013.html>
- *Intellectual Property That Is Educational Materials*, Administrative Policy Statement 1014, <https://www.cu.edu/ope/aps/1014>.
- *Facilities Use by Employees and Students*, [http://www.ucdenver.edu/faculty\\_staff/employees/policies/Policies%20Library/Admin/UsingUCDFacilities.pdf](http://www.ucdenver.edu/faculty_staff/employees/policies/Policies%20Library/Admin/UsingUCDFacilities.pdf).

#### 1.4. Definitions.

**Administrator** A dean, assistant or associate dean; assistant or associate vice-chancellor; department chair; administrative director; department head or any individual who has supervisory authority at the division or department level for faculty and/or staff.

**Business** Any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business trust, real estate trust or any other legal entity organized for profit or charitable purposes. This excludes University-related entities.

**Compelling Circumstances** The facts considered by the COIC Committee to determine if a financially interested individual should be permitted to conduct human subject research involving greater than minimal risk. When considering a request by a financially interested individual to conduct research, the circumstances that the COIC Committee should evaluate include the nature of the research, the extent to which the interest could be directly and substantially affected by the research, and the degree of risk to the institution or to a human subject involved that is inherent in the research protocol. The Committee should also consider the extent to which the interest is amenable to effective oversight and management.

**Compensation** Income or monetary value given in return for services, including but not limited to wages, salaries, commissions paid salesmen, compensation for services on the basis of a percentage of profits, commissions on insurance premiums, tips, bonuses (including Christmas bonuses), termination or severance pay, rewards, jury fees, marriage fees and other contributions received by a clergyman for services, pay for persons in the military or naval forces of the United States, retirement pay of employees, pensions and retirement allowances are income to the recipients unless excluded by law.

**Conducting Research** With respect to a research protocol, designing research; directing research; serving as the Principal Investigator, co-investigator, and/or research coordinator enrolling research subjects (including obtaining subjects' informed consent); making decisions related to eligibility to participate in research; analyzing research data; reporting research data or submitting manuscripts concerning the research for publication.

**Confidential or Privileged Information** Information contained in documents so designated; medical, educational, personnel, or security records of individuals; anticipated material requirements or price action knowledge of possible new sites for University-sponsored operations; knowledge of forthcoming program selections of contractors or subcontractors in advance of official announcements; or any other information that is private or sensitive in nature.

**Conflict of Commitment** Situations in which outside relationships or activities interfere with, or have the appearance of interfering with, an employee's commitment to his/her university duties or responsibilities.

**Conflict of Interest** Situations in which financial or other personal considerations may adversely affect, or have the appearance of adversely affecting, an employee's professional judgment in exercising any University duty or responsibility in administration, management, instruction, research and other professional activities. This can include interests that bias the nature or direction of scholarly research or influence decisions with respect to teaching and students, appointments and promotions, use of university resources, interactions with human subjects or other matters of interest to the University.

The mere appearance of a conflict may be as serious and potentially damaging as an actual distortion of instructional, research, or administrative goals, processes, or outcomes. Reports of conflicts based on appearances can undermine public trust in ways that may not be adequately

restored even when the mitigating facts of a situation are brought to light. Apparent conflicts, therefore, should be disclosed and evaluated with the same vigor as actual conflicts.

**Consulting** A relationship with an individual or a business (as defined above) or with an agent or other representative of such individual or business, service on advisory boards, and any other relationship whereby the individual receives or has the right or expectation to receive, remuneration from such individual or business in exchange for services. Examples of consulting include service on a business' board of directors; professional services rendered for a business, industry, private individuals, government, other academic institutions, or foundations; and, in limited circumstances, services for a colleague holding a sponsored research contract or grant at the same institution.

**Covered Individual** Faculty, staff, affiliates, and others as noted below, who are required to submit a COI disclosure.

- All faculty (assistant professor or higher).
- The project director/ Principal Investigator (“PI”) and any other key personnel, regardless of title or position who are responsible for the design, conduct and reporting of basic, animal or clinical research. This includes anyone who is substantively involved in research-related activities such as obtaining informed consent, determining subject eligibility, reviewing data or conducting data analysis.
  - This includes the PI and Co-PI, anyone listed on the IRB application form, IACUC protocol and OGC grant/contract or reporting of research funded by the NIH, which may include, for example, collaborators or consultants (as required by the OGC Policy).
- Research Committee Members (i.e., IRB members, Data Safety Monitoring Board members and/or members of other research review committees).
- Staff who negotiate or execute research agreements on behalf of the University (i.e., staff from OGC), and area/program administrators, and University campus officers (excluding chancellor and legal counsel).
- Consultants, subrecipients, or subcontractors who are employees of an external entity collaborating on research, when such entity does not have a PHS-compliant Conflict of Interest Policy.

Exception: This does not apply to the individuals who hold the ranks of instructor, lecturer, adjunct professor, retiree, clinical faculty, unless they are conducting research.

**Disclosure** A release of relevant information about significant financial interests to parties outside the institution’s COI review and management processes (e.g., to research subjects or journal editors).

**Family Member** The spouse/domestic partner and dependent child/children of a faculty member or a University employee.

**FCOI Report** The report of a financial interest made by the University to a PHS Awarding Component, to a lead institution if required under the terms of the sub-recipient agreement, or to a sponsor if required under the contract.

**Financial Conflict of Interest (“FCOI”)** A significant financial interest that could directly and significantly affect the design, conduct or reporting of research. Also, a significant financial interest that could directly and significantly affect an individual’s institutional responsibilities as determined by COI Compliance Office.

**Financially Interested Company** A commercial entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the research. This term includes but is not limited to companies that compete with the sponsor of the research or the manufacturer of the investigational product, if the covered individual actually knows that the financial interests of such a company would reasonably appear to be affected by the research. The term also includes any entity acting as the agent of a financially interested company (e.g., a CRO).

**Financially Interested Individual** A covered individual who holds a significant financial interest that would reasonably appear to be affected by the individual’s research or other activity.

**Financial Investment Firm** An entity that provides investment services to the public, including brokerage firms and hedge funds. Consulting for financial investment firms or the investing public can involve inadvertent violation of insider trading laws or obligations of tax-exempt organizations. Faculty members are prohibited from serving as consultants for financial investment firms or the investing public – regardless of the amount of compensation – without both prior approval by the COIC Committee and a contract review by the Office of University Counsel. (Private equity or venture capital firms that evaluate new technologies for their own benefit are not considered financial investment firms. Consulting for such firms involves the University’s pre-approval process that is required when consulting for entities other than financial investment firms)

**Honoraria** For schools that do not follow a specific definition, honoraria includes one-time payment for presentations, lectures, articles, visiting professorships, article reviews, editing services, and/or expert witness testimony by accomplished faculty who have achieved a level of expertise sought by others outside of the University. If there is a contract or other formal agreement, or if there is an established reward, those payments are not considered honoraria.

Other schools as noted use the following definitions:

- **School of Medicine** Honoraria are generally one time payments of modest amounts of money which are provided in exchange for presentations by accomplished faculty who have achieved a level of expertise sought by others outside the University. Honoraria include one-time payment for lectures.
- **College of Nursing** Exempt Honoraria is not required to be assigned to the Faculty Practice Plan. Exempt Honoraria include one-time payment for lectures, articles, visiting professorships, NIH study sections and service on boards for non-profit corporations.
- **School of Pharmacy** Token payment for a one-time activity which includes but is not limited to speakers' bureaus, Continuing Education (“CE”) and other presentations, article reviews, editing services, expert witness testimony. If there is a contract, other



formal agreement or an established reward, those payments are not considered honoraria.

**Human Subject Research** All research meeting the definition of “research” performed with “human subjects” as these terms are defined in the federal Common Rule (45 CFR 46 and 21 CFR 50 and 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation. In the event that the Common Rule definitions of “human subject” or “research” are modified through rulemaking, any such revisions shall apply for the purpose of this guidance.

**Insider Trading** Securities law broadly prohibiting fraudulent activities of any kind in connection with the offer, purchase or sale of securities. These provisions are the basis for certain types of government enforcement activities, including actions against illegal insider trading. Insider trading is illegal when a person trades a security while in possession of material, non-public information, including information from clinical research trials, in violation of a duty to withhold the information or refrain from trading in the security. Providing non-public information, or a “tip,” to other traders who trade a security affected by the tip is illegal as is considered an illegal tip.

**Institutional Conflicts of Interest** Institutional conflict of interest are situations in which the teaching, research, outreach, administrative, financial, operational or other activities of the University could be compromised because of external financial interests and/or business relationships held by the institution as a body corporate, by the University or a campus official acting within his/her authority on behalf of the University, or a campus, that could bring financial gain to the University, a University campus, any of the University’s units and the individuals covered by this policy.

Institutional financial conflicts of interest include:

- Licensing, technology transfer, and patents
- Investments
- Gifts
- Other financial interests

**Institutional Responsibilities** An investigator’s professional responsibilities conducted on behalf of the University, which can include the following: research, research consultation, teaching, professional practice, purchasing, University committee memberships and service on panels such as IRBs or DSMBs.

**Institutional Review Board** The Institutional Review Board (“IRB”) is the group charged with and responsible for the protection of human subjects or any other committee or group that is charged with responsibility for compliance with federal regulations for the protection of human subjects in research and/or reviews all research proposals and related activities involving human subjects in order to protect their rights and welfare.

**Intellectual Property and Publication Rights** Any discovery for which legal protection is sought. For example, a patent, copyright, know-how, mask work, tangible research property, trademark, trade secret, and other forms of intellectual property legally recognized now or in the future. See, *Administrative Policy Statement for Intellectual Property Policy on Discoveries and Patents for Their Protection and Commercialization* at <https://www.cu.edu/ope/aps/1013>.

**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 research.

**Key/Senior Personnel** Project director or Principal Investigator and any other person who is responsible for the design, conduct and reporting of basic, animal or clinical research. This includes PRAs as well as those who obtain informed consent, those who determine eligibility, those who review data and those who conduct data analysis.

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

**Mutual Funds** Equity interest which is diversified and independently managed by an outside entity. Includes funds that are in a sponsored 401k, 403a, 403b, etc. that are not self-directed.

**Non-Human Subject Research** Basic research, animal research or other research that is not human subject research.

**Officers** University officials or senior management who fall under external regulations to which the University is subject.

**Officers of the Administration** Individuals who hold the title or interim/acting title of vice president, chancellor, associate vice president, assistant vice president, vice chancellor, associate vice chancellor, associate university counsel, and deans of the schools, colleges, and libraries.

For purposes of this policy, “Officers” and “Officers of the Administration” may be used interchangeably and refer to University officials. All Officers must annually disclose the following:

- Outside employment;
- Outside professional association, nonprofit or business board service;
- Outside financial interests; however, this excludes the value of managed investment accounts (i.e., mutual funds);
- Immediate family members’ professional services to the University;
- Other interests related to the University; and
- Conflicts of interest

Additionally, officers are also required to disclose, in good faith, any other outside interests or activity which may give rise to a perceived conflict of interest, regardless of dollar amount.

Note: Disclosures that do not involve doing business or competing with the University are considered to be confidential personnel matters. Disclosures that involved doing business or competing with the University are considered to be matters of public record. The disclosure of outside financial interests and activities is deemed to be included in the personnel file of the individual who submitted it.

**Outside Income** Consulting; speaking or other fees; honoraria; gifts; licensing revenues (royalty income); equity interests (including stocks, stock options, warrants, partnership and other equitable ownership interests).

Outside Income DOES NOT include:

- Salary, compensation and royalties from the University or its affiliates;
- Income from seminars, lectures, or teaching engagements sponsored by public entities (e.g., Denver Public Schools, income from review boards and NIH peer review boards);
- Income from service on advisory committees or review panels for public entities (e.g., Denver Public Schools, income from review boards and NIH peer review boards);
- Interest in mutual funds where the individual has no control over the selection of holdings.

**Participate** Taking part in a described activity in any capacity including but not limited to designing or directing research and/or serving as the Principal Investigator, research collaborator, expert witness, or provider of direct patient care. The term is not intended to apply to individuals who provide primarily technical support; who are purely advisory with no direct access to the data (e.g., control over its collection or analysis) or in the case of research, to the trial participants, unless they are in a position to influence the study's results or have privileged information as to the outcome (e.g. in community participatory research).

**PHS** Public Health Service of the U.S. Department of Health and Human Services ("PHS") and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health ("NIH").

**PHS Awarding Component** The organizational unit of the PHS that funds the research subject to 42 CFR 50 Subpart F, *Promoting Objectivity in Research*.

**Public Health Service Act** The statute codified at 42 U.S.C. 201 et seq.; also referred to as PHS Act.

**Research** A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. 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). For the purposes of this process the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.

**Reporting** The provision of information about significant financial interests by a covered individual to responsible University officials and to the COIC Committee, the transmission of such information within University channels (e.g., from the COIC Committee to COMIRB), or the reporting of a significant financial interest to an awarding component as required (e.g., ERA Commons for NIH granting mechanisms).

**Reasonable Circumstances** The circumstances that a reasonable, prudent layperson would expect a covered individual to maintain given the need to accomplish a specific task related to

University activities which also has a significant financial interest. Reasonable Circumstances might include the extent of the conflict to the University and the potential effect of the conflict upon the research or activity itself, the University, the sponsor or external party.

**Reasonable Research Costs** Payments to the University on behalf of a staff member or employee that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and the University. Reasonable Research Costs are not considered significant financial interests.

**Royalties** Royalty income or the written contractual right to receive future royalties, either directly or indirectly under a patent, license or copyright, where research is directly related to the licensed technology or work.

**Scientific Advisory Committee** A scientific advisory board, data safety monitoring board, steering committee for a clinical trial, executive committee for a clinical trial, or other committee of a pharmaceutical or biotechnology company. Service on a scientific advisory committee is not fiduciary service.

**Significant Financial Interest (“SFI”)** Anything of monetary value (can be cumulative totals), including, but not limited to:

- Salary or payment for services;
- Consulting fees;
- Honoraria (including honoraria from a third party as well as honoraria routed through the faculty practice plan, if the original source is a financially interested company);
- Gifts or other emoluments or “in kind” compensation from a financially interested company including reimbursement for professional meetings or non-governmental organizations (or entitlement to the same), whether for consulting, lecturing, travel, service on an advisory board, paid authorship or for any other purpose not directly related to the reasonable costs of conducting research or activity (as specified in the research agreement) that in the aggregate have in the prior calendar year exceeded the *de minimus* amount of a value equal to or greater than \$5,000, or are expected to exceed that amount in the next twelve months.

This compensation includes:

- Equity value greater than \$5,000 or 5% ownership in a single publicly traded entity;
- Equity interests, including stock options, of any amount in a non-publicly traded company;
- Royalty income or the right to receive future royalties under a patent, license or copyright, where the research is directly related to the licensed technology or work of any amount;
- Receiving compensation for services as a consultant or advisor to a commercial sponsor of research in excess of \$5000 annually;
- Serving as a director, officer or other decision-maker for a commercial sponsor;
- Personally accepting payment from the research sponsor, for non-research related gifts equal in value to more than \$5,000.

What is NOT considered a “significant financial interest”?

- Salary, royalties, or other compensation from the University or its affiliates if the investigator is currently employed or otherwise appointed by the University, including 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 government agency, an institute of higher education, academic teaching hospital, a medical center or a research institute that is affiliated with an Institution of higher education;
- Income from service on an advisory committee or review panels for a federal, state or local government agency, an institute of higher education, academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education entities (e.g., Denver Public Schools, income from review boards and NIH peer review boards); or
- Interest in mutual funds or similar investment vehicles where the individual has no control over the selection of holdings.

**Small Business Innovation Research (“SBIR”)** The extramural research program for small businesses 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 the purposes of this policy, the term SBIR also includes the Small Business Technology Transfer (“STTR”) Program, which was established by Public Law 102-564.

**Speakers Bureau** Under the SOM policy, *Policy to Limit Conflicts of Interest Between Health Care Professionals and Industry Representatives*, activity on speaker’s bureaus is prohibited. Speakers’ Bureaus activities are defined as:

“Compensation by any pharmaceutical company, medical device manufacturer or manufacturer of other health or nutrition-related products, or their subsidiaries, for speaking engagements whether on a one-time or recurring basis.”

This definition does not include compensation for research consulting.

**Sponsored Research or Sponsored Projects** Awards that are exchange transactions between an external sponsor and the University under a grant, contract, cooperative agreement, purchase order, or any other mutually binding award that restricts the use of funds or property and stipulates conditions with which the University must comply. Typical sources of sponsored projects include organizations at all levels of government (local, state, federal, or international) as well as private corporations and foundations.

**Stock** Equity interest, security or capital investment that represents ownership in a publicly traded or privately held corporation.

**Stock Options** The right to purchase stock in the future at a price set at the time the option is granted (by sale or as compensation by the corporation). In order to obtain the shares of stock, the owner of the option must “exercise” the option by paying the agreed upon price and requesting issuance of the shares.

**Subrecipient relationship** A relationship that exists when another entity performs substantive programmatic work or undertakes an important or significant portion of the research program or project. The other entity participates in a creative way in designing and/or conducting the research, retains some element of programmatic control and discretion over how the work is conducted.

**Subcontractor relationship** A relationship that exists when another entity provides specific services in support of the research program but does not significantly participate in the design of the research and has little independent decision-making in the how the research program or project is to be completed. The subcontractor relationship is characteristic of a vendor relationship.

**Technology** Any process; method; product; compound; drug; device; or any diagnostic, medical or surgical procedure developed using University facilities, equipment or funds, whether intended for commercial use or not.

**University** Term of art which refers to the University of Colorado System.

## **2. Conflict of Interest and Commitment Office**

The Conflict of Interest and Commitment Office (“COI Office”) exists to implement and enforce University policies and procedures concerning conflict of interest and commitment as outlined in this document. This includes creating and maintaining policies and procedures that comply with applicable regulations; ensuring that the University COI policies and procedures document is posted on the University website; collecting the annual conflict of interest disclosures; establishing the interconnections between projects, protocols and technology within the University; administering or facilitating the review process; creating the COIC Committee minutes; maintaining appropriate documentation and coordinating training.

The COI Office staff consists of staff employed within the Office of Regulatory Compliance (“ORC”).

The COI Official or their designee serves as the signature authority for communication from the COIC Committee.

### **2.1. Education and Training**

**Information.** Letters, email notifications and articles in University publications regarding the Conflict of Interest and Conflict of Commitment Policy will be distributed to employees. The content of these publications may be related to specific, and/or general conflict of interest issues and other elements of the Conflict of Interest and Conflict of Commitment Policy.

Individuals must acknowledge their understanding of this policy as part of submitting the annual Conflict of Interest Disclosure Form.

Communication will be sent to all faculty and staff when University makes material revisions to its FCOI policy.

**Training.** All covered individuals are required to complete training within 60 days of joining the University, prior to engaging in any funded research and at least annually during the annual financial disclosure. Training is a mandatory portion of the COI Disclosure Form and must be completed before a new or updated COI Disclosure Form can be submitted.

Training topics may include information on University COI policy, investigators' disclosure responsibilities and federal regulations relating to COI.

Training materials will be updated whenever University COI policy is updated in a manner that affects requirements for any covered individuals.

The required training materials will be linked to the COI Disclosure Form. Training will be a mandatory part of each COI Disclosure Form submitted to the COI Office; therefore, mandatory training will occur at least annually.

The University is committed to communicating its standards for ethical conduct and University policies to all employees. The University provides education and training to develop awareness and stress compliance with this Conflict of Interest and Conflict of Commitment Policy through individual guided study. Materials and resources are also available at [ucdenver.edu/coi](http://ucdenver.edu/coi).

## **2.2. Disclosure Requirements**

All personnel who meet the definition of a covered individual must submit a COI Disclosure Form according to the following requirements:

- Within 60 days of being hired;
- No later than at the time of application for research funding (i.e., one cannot submit a grant if a current disclosure is not on file with the COI Office);
- Annually between mid-August and October or upon request by the COI Official;
- Within 30 days of a change, addition, or elimination of a previously disclosed interest ; or
- Within 30 days of the occurrence of any trip for which there is reimbursement or sponsored travel.

### **What has to be disclosed?**

For covered individuals, the University has a zero dollar threshold for disclosure of financial interests that reasonably appear to relate to the covered individual's University responsibilities. This includes but is not limited to the financial interest of a covered individual's spouse/domestic partner and/or dependent children.

Faculty who receive NIH extramural funding are subject to 42 CFR Part 50, Subpart F, Objectivity of Research. Each institution, domestic and foreign, that applies for or receives NIH research funding in the form of grants or cooperative agreements is subject to this regulation. This Financial Conflict of Interest ("FCOI") regulation applies to both prime and subrecipient institutions, domestic or foreign, and through implementation, to each Investigator who is planning to participate in, or is participating in, such research. Investigators, including subrecipient investigators, must disclose all financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).

Covered individuals must also disclose within 30 days of each occurrence (completion of the trip) any reimbursed or sponsored travel (i.e., that which is paid on behalf of the covered individual and not reimbursed to the covered individual so that the exact monetary value may not be readily available), related to the covered individual's University responsibilities.

Disclosure is not required if the travel is reimbursed or sponsored by the following:

- A federal, state or local government agency;
- An institute of higher education;
- An academic teaching hospital; or
- A research institute that is affiliated with an institution of higher education

For all applicable reimbursed or sponsored travel the following information must be provided:

- Purpose of the trip;
- Sponsor / organizer;
- Destination by country, state, town;
- Duration of the trip; and
- Estimate of the monetary value of the trip.

#### **Failure to disclose.**

When an SFI is identified but was not disclosed in a timely manner by the covered individual, or was not previously reviewed by the COI office during an ongoing PHS-funded research project, the Associate Vice Chancellor for Regulatory Compliance or designee will, within 60 days, review the SFI, determine whether it is related to PHS-funded research and determine whether a financial conflict of interest exists. If a financial conflict of interest exists the COIC Office shall:

1. Implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage the financial conflict of interest going forward;
2. When it has been determined that a financial conflict of interest was not previously identified or managed in a timely manner due to:
  - a. Failure of the investigator to disclose a significant financial interest that is determined by the COIC Office to constitute a financial conflict of interest;
  - b. Failure by the institution to review or manage such a financial conflict of interest; or
  - c. Failure by the investigator to comply with a financial conflict of interest management plan.

The COI Office will, within 120 days of its determination of noncompliance, complete a retrospective review of the investigator's activities and the PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, to determine if the financial conflict of interest led to a bias in the design, conduct or reporting of the research.

The COI Office will document the retrospective review to include:

1. Project number;
2. Project title;



3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
4. Name of the investigator with the FCOI;
5. Name of the entity with which the investigator has a financial conflict of interest;
6. Reasons for the retrospective review;
7. Detailed methodology used for the retrospective review including methodology of the review process, composition of the review panel, documents reviewed;
8. Findings of the review panel; and
9. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the COIC Office shall update the previously submitted FCOI report, specifying the actions taken to manage the conflict of interest going forward. If bias is found, the PHS Awarding Component will be promptly notified and a mitigation report will be submitted to the PHS Awarding Component promptly. The mitigation report will include the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias; including any qualitative and quantitative data to support any actual or future harm and analysis of whether the research project is salvageable. For non-PHS funded research, a similar remediation approach will be undertaken, and the appropriate sponsor will be notified of the review findings in accordance with the terms of University's agreement with that sponsor.

Thereafter, FCOI reports will be submitted annually. Depending on the nature of the financial conflict of interest, the COIC Office may decide that interim additional measures are necessary with regard to the investigator's participation in the funded research project between the date that the financial conflict of interest, or the investigator's noncompliance, is determined and the completion of the University's retrospective review.

### **3. Review Process**

#### **3.1. Annual Review of Conflict of Interest Disclosure Forms**

1. All covered individuals, as defined herein, are required to file an annual COI Disclosure Form.
2. If a covered individual has a spouse who is also required to submit a disclosure, it is expected that the outside income or relationship interest(s) which are disclosed will match. If outside income or relationships are disclosed by both spouses, and the disclosed amounts do not match, the COI Office will use the highest disclosed amount to process the disclosure form. For example, if one spouse discloses an interest in the amount of \$0-\$4,999, and their spouse discloses the same interest in the amount of \$5,000-\$9,999, it will be presumed that the interest disclosed in the amount of \$5,000-\$9,999 is correct, and the disclosure will be processed in accordance with that higher amount as outlined herein.
3. The COI Office is responsible for the collection and initial screening of all annual COI Disclosure Forms as required by University of Colorado Administrative Policy Statement 5012. The COI Office will receive quarterly reports from the CU Innovations Office detailing the intellectual property for which the University and/or faculty has licensed and receives compensation. The reports include licensing and patent information for

University faculty. If required, COI Disclosure Forms will be reconciled with OGC, IACUC and IRB databases to verify related grants, contracts or human subject protocols.

4. The COI staff will determine the review flow based on the review categories as detailed below. Any travel disclosure with an estimated value greater than \$10,000, will be reviewed as an updated disclosure. Any travel with an estimated value less than \$10,000 will be reviewed as part of the annual disclosure process.
5. If the COIC Committee determines after the initial review of a COI Disclosure Form that no conflict of interest exists, it will conclude its assessment.
6. The COIC Committee will make recommendations to the covered individual and the appropriate University Administrator as to whether the:
  - a. Activity poses no conflict, which will conclude the assessment;
  - b. Activity may have potential for conflict that can be managed; or
  - c. The activity has a potential for conflict that will not be allowed.
7. **Colorado Prevention Center.** The Colorado Prevention Center (“CPC”) is an academically led contract research organization and has an academic affiliation with the University. CPC staff includes faculty who also have academic appointments with and are compensated by the University. CPC maintains active contracts with industry sponsors for clinical trial services.

CPC will provide a list of all active industry relationships to the COI on a quarterly basis. All University faculty working at CPC will complete a COI Disclosure Form and will list themselves as scientific advisors to CPC. COI staff will review the disclosure of CPC in accordance with the process outlined herein.

### **3.2. Review Procedures**

Disclosures will be triaged based on the following:

1. Disclosures in which a new financial conflict of interest is identified receive expedited review by the COI Office. The disclosure is then reviewed by the COIC Committee.
2. Disclosures of those individuals involved in activities that resulted in management plan(s) for the previous disclosure period are given priority review by the COI Office.
3. Disclosures of researchers who are listed on federally funded sponsored research projects including grants, contracts, and cooperative agreements are reviewed COI Office.
4. All officers’ disclosures are reviewed by the COIC Committee.
5. The remaining disclosures are reviewed in the order that they were submitted and the actions taken with regard to the various levels of Disclosure are as follows:

- Disclosures in which the covered individual discloses no financial interest are acknowledged by an email from the COI Office.
- Disclosures with less than a significant financial interest are acknowledged by an email from the COI Office.
- Disclosures with a significant financial interest but no financial conflict of interest are reviewed and acknowledged by a letter from the COI Office.

### **3.3. Expedited Review**

The COIC committee may utilize an expedited review process for individuals involved in activities that resulted in management plan(s) for the previous disclosure period or for individuals who have no changes to their disclosures from the previous year. If monitoring mechanisms for an activity have previously been implemented and following appropriate review and approval as described herein, the expedited review process described in this paragraph will be followed unless:

1. A complaint has been issued against that individual in connection with the activity;
2. There is new information regarding the activity that may affect the decision or action of the COIC Committee; or
3. The standards by which the activity was judged have changed.

Should any one of the three above-mentioned circumstances take place, the forms must be fully reviewed utilizing the process outlined herein. In the absence of any of the above-mentioned circumstances, the COI Official or designee may administratively review the disclosure upon affirming:

1. That the activity is unchanged from the last time it was reviewed;
2. The monitoring mechanisms are still in place and are functioning effectively; and
3. That the activity continues to have the approval of the COI Official or designee.

## **4. Conflict of Interest and Commitment Committee.**

### **4.1. Purpose.**

The COIC Committee exists to protect the integrity of investigators and the University, and to maintain the public trust in University as a state institution that serves the citizens of the State of Colorado. Because serious financial and other conflicts of interest and commitments can harm the reputation of the University, as well as adversely affect its ability to fulfill its missions in education, patient care and research, these conflicts should be subject to the oversight and recommendations of a duly-constituted and broadly representative committee. The COIC Committee serves these functions. The Committee shall identify, manage and minimize actual and potential conflicts of interest and commitment where they exist. The Committee carries out this charge in a manner that is intended to foster, not hinder, research relationships.

#### **4.2. Committee Composition.**

The COIC Committee shall meet as necessary, normally on a monthly basis. There should be at least 8 committee members.

The COIC Committee shall consist of a broad cross section of the University community and may include:

1. COI Official;
2. COIC Co-Chairs;
3. Department Administrator;
4. IRB Director or designee (recused from voting on institutional conflicts of interest involving human subject research);
5. Clinical faculty member(s) who is a Principal Investigator of a federal grant or contract, a clinical drug trial or other clinical study involving human subjects in the study;
6. Basic science faculty member(s) who is a Principal Investigator of a federal grant or contract;
7. Faculty member(s) at large;
8. Affiliate member;
9. Community member(s).

Note: One member can serve more than one role.

#### **4.3. COIC Committee Membership Term**

1. COI Official shall be appointed for a term to be determined by the Chancellor.
2. Co-Chairs will be appointed by the Vice Chancellor for Research for an annual term (renewable).
3. Faculty members and department administrators shall be appointed by the COI Official for a three year term (renewable) in order to maintain continuity for the COIC Committee.
4. Community and affiliate members shall be appointed for a three year term (renewable) in order to maintain continuity for the COIC Committee.
5. The representatives from the IRB shall be permanent representatives on the COIC Committee, but may be removed from the COIC Committee at the request of their supervisor who will offer a different representative from the respective office.

#### **4.4. Co-Chair Roles and Responsibilities**

The Institutional Official (Vice Chancellor for Research) and the COI Official, in consultation and approval of the COIC Committee members, appoint two co-chairs of the COIC Committee for annual but renewable terms. Any change in appointment, including removal, requires written notification.

The Co-Chairs should be highly respected individuals from within the University, and they should be fully capable of managing the COIC Committee and the matters brought before it with fairness and impartiality. The COIC Committee should be perceived to be fair, impartial and

immune to pressure by University administration, the faculty, employees and officers whose relationships are brought before the COIC Committee.

The Co-Chairs advise the Institutional Official and the COI Official on committee member performance.

The performance of the COIC Committee Co-Chairs will be reviewed on an annual basis.

#### **4.5. Responsibilities of COIC Committee Members**

For each COIC Committee meeting, best efforts will be made to provide the agenda, disclosure and summary of connecting projects or relationships five (5) days in advance of the scheduled meeting. Members review the materials in advance of the meeting in order to participate fully in the deliberation. All copies of the review materials are to be treated as confidential materials and disposed of accordingly.

#### **4.6. Attendance Requirements**

All COIC Committee Members are expected to attend 75% of meetings held annually. If a committee member cannot attend a meeting then they should inform the COIC staff.

If the Committee Member will be absent for an extended period then the member should inform the COI Office in writing so that an appropriate replacement can be found.

#### **4.7. Training and Ongoing Education of COIC Committee Members**

New COIC Committee Members will meet or talk with the COIC staff for an informal orientation. The new member will be given a COIC binder that includes:

- A copy of this policy
- Relevant institutional policies
- Applicable federal regulations and guidance documents

New members are requested to attend an initial meeting in person to become orientated to the Committee process.

**Continuing Education.** To ensure that the decisions made by the COIC Committee are grounded in the current regulatory, policy or national recommendations, training will be provided on a regular basis. Educational activities include but are not limited to:

- Copies of appropriate publications or media items;
- Dissemination of new information including laws, regulations, policies or guidance

These materials will be provided to the members via e-mail or during COIC Committee meetings.

#### **4.8. Liability Coverage of COIC Committee Members**

The University maintains insurance coverage for employees or other persons who are authorized to act on behalf of the University as long as their acts or omissions were within the scope of their employment or authorized activity.

#### **4.9. Undue Influence**

If a Chair, Committee Member or COIC staff person feels that the COIC Committee has been unduly influenced by any party, that individual shall make a confidential report to the Vice Chancellor for Research or Chancellor depending on the circumstances. The University will conduct a thorough investigation and corrective action will be taken to prevent additional occurrences.

#### **4.10. Committee Administration**

1. The COI Office will be responsible for facilitating the meetings and recording the activities of the COIC Committee.
2. Meetings are limited to COIC Committee Members, invited staff and other invitees. Meetings are not open to the public.
3. A quorum consists of over half of all voting members. In general, an attempt will be made to ensure that there is a quorum present at all meetings. The COI Office may require that certain decisions be approved by a majority of all voting members, not just a majority of those attending a specific meeting.
4. Recusal should be required whenever any member has an actual or apparent conflict of interest with regard to any matter under review. A member is recused from discussion of a particular case under the following conditions:
  - a. The case involves a member of the same department;
  - b. The COI member has a personal interest because of inter-departmental relationships, such as collaboration with the faculty member whose case is under consideration; and/or
  - c. The COI member has a financial interest in the case under discussion.

Special exceptions to these guidelines may be made but only with prior approval of a majority of the voting members.

5. Documentation provided to the COIC Committee will include the Conflict of Interest Disclosure Form; Compelling Circumstances Questionnaire (if appropriate); a summary of connecting protocols, projects, technology or similar relationships; any other information provided by the individual whose relationships are being considered and any additional information requested by the COIC Committee.

### **5. Categories of Conflict of Interest.**

Activities and situations that could present conflict of interest or commitment can be divided into three categories:

1. Activities that ordinarily are permissible;
2. Activities that appear to present potential conflicts of interest or commitment; and
3. Activities that clearly present such serious problems as to be incompatible with University policies.

The separation into categories is imperfect and the following list of examples is not exhaustive.

1. Activities that ordinarily are permissible include:
  - a. Participation in scientific or professional association activities, editorial responsibilities or service on scientific review boards and panels;
  - b. Acceptance of honoraria for commissioned papers and for occasional lectures;
  - c. Performance of professionally related activities including but not limited to consulting, textbook authorship, involvement with professional societies, participation on review panels;
  - d. Service as a consultant to outside organizations, provided the arrangement does not unreasonably restrict publication of research results obtained within the University;
  - e. Service on boards and committees of public or private organizations when this service does not distract unduly from University obligations; and
  - f. Performance of duties that are specified under Regent-approved agreements such as the School of Medicine faculty practice plan.
2. Activities that appear to present potential conflicts of interest or commitment include:
  - a. Relationships that could or appear to enable an employee to influence the University's dealings with outside organizations in ways leading to personal gain or to improper advantage for anyone. For example, an employee could have a financial interest in an enterprise with which the University does business and be in a position to influence relevant business decisions on either side. Ordinarily, such problems may be resolved by full disclosure and by making appropriate arrangements that prohibit the employee from participating in the decisions.
  - b. Situations in which the time or creative energy an employee devotes to extramural activities, including those listed in the section above, appears to be substantial enough to compromise the amount or quality of his or her participation in the instructional, scholarly, and administrative work of the University itself.
  - c. Activities (e.g., research projects, conferences, teaching programs, remunerative consulting agreements, etc.) for which employees are personally remunerated that involve, or might reasonably be perceived to involve the University, its name, its employees, its laboratories, computers or other facilities and equipment.
  - d. Activities that violate, or might reasonably be perceived to violate, any of the principles governing research that is supported by funds administered through the University insofar as these principles are relevant to individual behavior.
3. Activities that present such serious problems as to be incompatible with University policies include:
  - a. Situations in which the individual assumes responsibilities for an outside organization that divert his or her attention from University duties or create other conflicts of loyalty.

- b. Using for personal profit unpublished information emanating from University research or other confidential University ; assisting an outside organization by giving it unreasonably exclusive access to such information (this section does not supersede Regent policy on classified research); or consulting under arrangements that impose obligations that conflict with University patent policy or with the University's obligations to research sponsors.
- c. Circumstances in which research that could, and ordinarily would, be carried on within the University is conducted elsewhere to the disadvantage of the University and its legitimate interests.

## **6. Review Standards**

### **6.1. Rebuttable Presumption Against Conflicts of Interest**

1. **Individual.** In order to assure that all potentially problematic circumstances are reviewed, an initial presumption that financially interested individual may not conduct the activity in question will be applied. This rule is not intended to be absolute; a financially interested individual may rebut the presumption by demonstrating facts that, in the opinion of the COIC Committee, constitute Compelling and/or Reasonable Circumstances. The individual would then be allowed to conduct the activity under conditions specified by the COIC Committee and, if applicable, approved by the responsible IRB.
2. **Institutional.** When reviewing circumstances that involve a potential institutional conflict of interest, the COIC Committee will apply a rebuttable presumption against conducting the activity in question. This rule is not intended to be absolute; the presumption may be rebutted by demonstrating facts that, in the opinion of the COIC Committee, constitute Compelling and/or Reasonable Circumstances. The project at the University would then be allowed to be conducted under conditions specified by the COIC Committee and, if applicable, approved by the responsible IRB.

### **6.2. Compelling Circumstances**

When Compelling Circumstances exist for human subject research project(s) involving greater than minimal risk, the project may be approved to proceed even when an individual and/or institutional significant financial interest exists. Whether the circumstances are deemed compelling depends, in each case, upon the nature of the science, the nature of the interest, how closely the interest is related to the research and the degree to which the interest may be affected by the research. When the financial interest is directly related to the research and may be substantially affected by it (e.g., an equity interest in a startup company that manufactures the investigational product), the risk is greatest and the bar must be high; however, even direct and potentially lucrative financial interests may be justified in some circumstances. The COIC Committee may approve the involvement of such an individual in the research, subject to conditions that ensure effective management of the conflict and credible oversight of the research.

In summary, when a financial conflict of interest exists, the individual or the project must demonstrate the following to the COIC Committee:



1. There is not a significant likelihood that subjects will be harmed by the involvement of the investigator or institution; and
2. All financial incentives for bias have been appropriately mitigated.

Further, the financially interested individual, or the project when the University has an institutional conflict of interest, should demonstrate the following to the COIC Committee:

1. The investigator and/or the institution are uniquely qualified to perform the research;
2. The research cannot be practically conducted without the investigator and/or the University; and
3. The significance of the research justifies the exception.

When the COIC Committee makes an exception and the research is allowed, some or all of the following safeguards should be implemented:

1. Auditing of the human research protection practices in place during the research;
2. Appointment of a disinterested observer to monitor the research;
3. Review of the research and data by a Data and Safety Monitoring Board; and/or
4. Placement of the funds which created the conflict of interest into an escrow account until the research is completed or creation of a divestiture plan prior to enrolling human subjects to the research study.

For example, when the individual holding such interests is uniquely qualified by virtue of expertise and experience and the research could not otherwise be conducted as safely or effectively without that individual, he/she should be permitted the opportunity to rebut the presumption against financial interests by demonstrating these facts to the satisfaction of the COIC Committee.

### **6.3. Reasonable Circumstances**

Conflicts of interest may occur in situations that do not involve human subject research or that involve human subject research of minimal risk. In these instances the rebuttable presumption continues to apply; however, the COIC Committee need only apply a Reasonable Circumstances standard in determining whether the activity may ensue. The COIC Committee may determine the specific Reasonable Circumstances. In general, the COIC Committee should determine the extent of the conflict to the University and the effect of the conflict upon the research/activity itself, the University, and the sponsor/external party.

### **6.4. Management Plans and Monitoring Mechanisms**

Strategies to address potential research conflicts are often individualized and depend on the specific issues raised. In all cases, in the interest of transparency, public disclosure of significant financial interests is fundamental. Management strategies are utilized to manage, mitigate or eliminate potential conflicts of interest. Resolution always begins with disclosure and sometimes involves a combination of conflict of interest and management strategies; therefore, the resolution should be the simplest effective means of managing the conflict.

The options for management may include but are not limited to the following disclosure plans and examples:

1. A statement demonstrating why the conflict is unlikely to affect the activity in question.
  - If the research project is funded by multiple sources, one should explain how any extra funds will expand the scope of the project.
2. A statement describing how the conflicted individual will be removed from the financial aspects of the research.
  - In research funded by a company in which the PI has a significant financial interest, a third party (e.g., the business manager/ administrator of the PI's department) will oversee the finances of the study.
3. A statement presenting a process to ensure that results are verifiable.
  - In research funded by a company with which the PI has a significant financial interest, a disinterested individual will review the procedures, data and/or results.
  - Reporting the potential conflict when results are presented and/or published.
4. Creation of an oversight committee to monitor the situation.
  - The committee can be composed of one or more faculty member or other professionals qualified to review the research. If the conflict is related to a research sponsor, no one on the committee should have a financial relationship with the sponsor.
5. Provision of special protections for students.
  - Creating a student advisory committee to which the student may bring any problems.
  - Declaring the student's precise role and function (e.g., working on only one project at a time).
  - Articulating student's Intellectual property rights and right to publication.

When an Individual is permitted to conduct human subject research, the COIC Committee should require the Individual to minimize the potential for conflict of interest by reducing or eliminating the interest or the individual's direct involvement in the research. If there are Reasonable and/or Compelling Circumstances that would allow the activity to continue, the COIC Committee is responsible for designing and implementing a management plan for the conflict as well as appropriate monitoring procedures and/or other conditions for the financially interested individual is involved in a conflicted activity.

The COI Office shall establish a procedure to mitigate or minimize potential conflicts of interest. At a minimum, the plan should include the following:

1. Disclosure of all potential conflicts of interest and conflicts of commitment, which include both financial interests and participation in the sponsor or licensee company as an employee, officer or director.
2. Identification of factors that may mitigate the likelihood of actual conflicts of interest, such as:
  - a. Whether a sponsor or licensee is publicly or privately held; this factor may affect the covered individual's status as a board member, officer or "key" employee;
  - b. A significant difference between the sponsor/licensee's and individual's research emphasis may reduce the likelihood of actual conflicts of interest.

3. Implementation of effective management strategies, such as the following, to minimize development of actual conflicts of interest and commitment:
  - a. Assign independent personnel to monitor the covered individual's research activities;
  - b. Require administrative review and approval of the covered individual's research project(s) that is/are subject to potential conflicts of interest or
  - c. Require modification of research plans or transfer portions of research to independent researchers, if necessary, to avoid actual conflicts of interest.
4. Careful review of the sponsorship and license terms. The COIC Committee should pay attention to any indications that the arrangement may not be an "arm's length" transaction. The following situations should be specifically reviewed:
  - a. Provision of an equity interest by an outside entity to an individual that provide disproportionate compensation (i.) relative to the standard share of royalties a faculty member might receive for technology licensed to an unrelated company, or (ii.) relative to the services provided;
  - b. Compensation should be fair market value for the services provided;
  - c. Licensing of inventions covering research that may cause the licensee to compete with the University for grant funding;
  - d. The present or near-term capacity to perform the essential functions outlined in the company's business plan;
  - e. Contracts given back to the University following development work, which could suggest that the technology was not licensed to a company in an arm's length transaction (exception: unique facilities).

#### **6.5. Special Instructions for Monitoring Students**

With respect to any monitored activity in which a student is involved, the following requirements shall be observed:

1. The COI Committee will determine if a monitor or monitoring panel needs to be established to oversee the role of a student in a particular study due to an individual or institutional COI. All monitors must meet regularly (at least annually) with any student of the faculty member who has an activity that is being monitored. Decisions as to which students should be included in these meetings should be left to the discretion of the monitor(s) and/or the appropriate dean or department chair. Monitors are urged to recognize that students who are not directly involved in a conflicted activity may still be affected by a faculty member's conflicted activity commitments. In addition, the COIC Committee should consider requesting monitors to participate as observers in the research advisory committees/thesis or dissertation committee of any student directly involved in a conflict of interest situation.
2. All students beginning studies with a faculty member who has an approved management plan for a conflict of interest situation must be informed: (a) that the conflicted activity exists and (b) that the student's concerns, if any, can be discussed with the dean, department chair or, if applicable, the COIC Committee, and/or the monitor or monitoring panel, as appropriate.

## **6.6 Special considerations for Managing Institutional Conflict of Interest**

The COIC committee is responsible for reviewing the annual financial disclosure of all officers for the University of Colorado Denver | Anschutz Medical Campus unless the office is directly under the Regent's officer policy. Business institutional conflicts of interest that may connect to research activity are usually reviewed at the same time as the individual conflict of interest and follow the same general policy as outlined in this document. The decision to accept restricted gifts is managed by the Chancellor in consultation with legal counsel.

## **6.7 External Gift Management and Institutional Integrity Policy-Anschutz Medical Campus**

The University of Colorado Anschutz Medical Campus has implemented the External Gift Management and Institutional Integrity policy ("Gift Policy"). The purpose of the policy is to maintain the public's trust by ensuring that the University's activities are neither compromised nor perceived to be biased by financial or other business considerations. This External Gift Policy Management and Institutional Integrity Policy (the "Policy") is designed to support faculty, senior leaders and the University by providing a structured process for the ethical review and management of gifts to be received by the University which are specifically directed to an individual faculty member's research or employment at the University. Additionally, the Gift Policy is intended to assess whether the person or entity providing the gift has previously conducted business with the University, including a past or current relationship, or has plans to develop such a relationship with the University.

Gifts to fund research will be evaluated in combination with other activities supported by the donor to ensure there is no potential to bias design, conduct or results of research. If the gift in combination with other external activities meet the threshold for a SFI then standard procedures for evaluating and managing COI will be followed.

## **6.8 Faculty Entrepreneurial Activity and SBIR/STTR Collaboration**

In accordance with University policy and procedure, all covered individuals are required to disclose all entrepreneurial/small business activities as part of the annual COI disclosure process; this includes but is not limited to faculty start-up companies. The COI Office will review small business/start-up activities in accordance with COI and other applicable institutional policies and procedures.

- Please refer to Attachments A and B of this policy for additional requirements which must be followed by University employees who wish to establish, or have established, a University Employee Owned Company (UEOC), and for SBIR/STTR program requirements.

## **7. Documentation**

### **7.1. Communication**

If the COIC Committee determines that an investigator's disclosure does not constitute a conflict of interest, the Committee will provide written notification of its decision and rationale to the investigator. Minutes from the COIC meeting will be taken by the COIC staff and reviewed and approved at the next COIC meeting.

## **7.2. Management plans**

The COIC Committee or administration will review all COI Disclosure Forms that indicate a financial relationship which meets the definition of a significant financial interest and determine if the SFI is related to the covered individual's University responsibilities, including PHS-funded research. The COIC Committee or administration will then determine if the SFI is a financial conflict of interest.

If there is a FCOI, then the COIC Committee or administration will determine if the FCOI can be managed and propose an appropriate management plan which will specify the actions that must be taken to manage such FCOI.

Such conditions may include:

1. Public disclosure of the financial conflict of interest when presenting or publishing
2. For research studies involving human subject 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
7. Severance of relationships that create financial conflicts.

All management plans will be responded to in writing, typically via email. Communications will be forwarded to the appropriate vice chancellor, dean or department chair. Within ten (10) business days, the covered individual should return a signed copy of the management plan affirming his/her agreement. If the covered individual has questions or concerns about the management plan, he/she should contact the COI Office within 10 business days.

The COIC Committee will notify the responsible IRB committee of any significant financial interests held by financially interested individuals who will conduct human subject research and of the COIC Committee's recommendations for managing the conflict of interest. Whenever possible, the IRB will not approve any initial or continuing review protocols prior to the approval of the conflict of interest management plan. When the COIC Committee has recommended a conflict of interest management plan and the plan has been accepted by the investigator, the investigator may be permitted to conduct human subject research.

All relevant conflicts of interest, including institutional conflicts of interest, should be disclosed to the research subjects in a form to be approved by the IRB of Record. The IRB has final decisions and IRB decisions on COI related to human subjects protocols are final. A copy of the final IRB approved management plan is given to the COI Office by the IRB Office to be maintained with their other documentation.

Management of identified conflicts of interest is a shared responsibility between the conflicted individuals, their supervisor, and the COI office. Time commitment is subject to approval as noted below on a per campus basis.

- For CU Denver Campus: Commitment of time to be allocated to the UEOC must be made in accordance with 1/6 rule. It is the responsibility of the University Employee's Department Head in consultation with the Dean of the applicable school/college to approve and oversee the commitment of time allocated. Approval must be documented in writing to the COI Office acknowledging the disclosed time allocation is acceptable.
- For Anschutz Medical Campus: It is the responsibility of the University Employee's direct supervisor to review the disclosed anticipated commitment allocation to determine if it is feasible for the University Employee to also be able to fulfil their other employment obligations to the University, based on their percentage of full-time employment. It is the responsibility of the University Employee's direct supervisor or designee to oversee the commitment of time as allocated. Approval must be documented in writing to the COI Office acknowledging the disclosed time allocation is acceptable prior to University Employee's effort being committed to the UEOC. Any University Employee who desires to commit time to a UEOC above the limits set forth in this Policy will be required to reduce their employment percentage with the University accordingly.

University Employees who desire to provide any type of services (not including Sponsored Projects) to a company in which they have an equity interest, must contract their effort via a consulting agreement through CU Medicine. If the work is in furtherance of a Sponsored Project, the UEOC must contract with the University via a Sponsored Project agreement.

### **7.3. Sponsored Project Grant Proposals**

OGC has institutional responsibility for reviewing grant proposals submitted by University faculty for extramural funding. As part of this duty, OGC reviews PHS grant proposals to confirm that key personnel have submitted a COI disclosure prior to submission to the PHS sponsoring agency. OGC utilizes an online grants management system to track COI disclosure status.

1. If key personnel listed on the proposal have not filed a COI disclosure, COI staff will contact the individual and request completion of the disclosure.
2. Key personnel who are not University employees but participating on the project as key personnel from other institutions are checked for PHS compliance through the Federal Demonstration Project ("FDP") FCOI Clearinghouse to determine if the individual's entity is a participating.
  - a. If the entity does not participate in the FDP Clearinghouse, OGC will require completion of the University Conflict of Interest Disclosure Form. The OGC COI form acts as an attestation that the non-University personnel will follow the University's COI policy or their own COI policy.
  - b. Personnel employed at institutions included on the FDP website are considered PHS/FCOI compliant.
3. If a proposal for extramural funding is awarded, a current and complete COI Disclosure will be verified. This process is further outlined below.
4. Collaborators at other institutions which are part of the FDP Clearinghouse will be considered compliant.

#### **7.4. Sponsored Project Awards**

If a proposal for extramural funding is awarded, OGC will verify that the PI and key personnel have a current COI on file Disclosure Form. In accordance with the PHS COI policy, both UCD University personnel and key personnel from other institutions who are following the University COI policy are required to have a current COI on file prior to expenditure of award funds.

#### **7.5. Subrecipient Awards**

OGC is responsible for sponsored projects subcontracting. OGC requires completion of a Subrecipient Commitment Form (“form”) prior to issuing a subaward to a subrecipient entity. The form requires potential subrecipients to provide their own institutional information about PHS COI compliance.

Upon award of a PHS award, and if applicable, a subcontract will be issued to the subrecipient entity. The subcontract includes an Institutional Conflict of Interest Assurance which must be completed by the subrecipient entity. This form will serve as attestation of compliance with the PHS COI policy.

Institutions and businesses in receipt of federal awards which subcontract to the University, including small businesses in receipt of SBIR/STTR awards, are required to flow down all terms and conditions of the prime grant to the University in accordance with the Office of Management and Budget, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*. Specific requirements for subcontracts to the University from small business in receipt of SBIR/STTR awards are further outlined in Attachment B and C to this policy.

#### **7.6. FCOI Reports**

If an investigator has an SFI which results in a conflict of interest and the investigator is the recipient of extramural funding from the PHS, the University is required to follow the PHS guidelines and may be required to provide the PHS Awarding Component with a report summarizing investigator’s SFI prior to spending.

If a financial conflict of interest is identified and eliminated prior to the expenditure of PHS-awarded funds, then an FCOI report does not need to be submitted.

For any significant financial interest that the COI Office identifies as conflicting subsequent to filing the initial FCOI report during an ongoing PHS-funded research project, the University will provide to PHS Awarding Component an FCOI report regarding the financial conflict of interest within 60 days.

These reports will include:

1. Project number
2. Project title
3. PD/PI or contact PD/PI if a multiple PD/PI model is used
4. Name of the investigator with the FCOI
5. Name of the entity with which the investigator has a financial conflict of interest
6. Nature of the financial interest

7. Value of the financial interest in increments (\$0-4,999; \$5,000-9,999; \$10,000-19,999; amounts between \$20,000-100,000 in 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)
8. A description of how the financial interest relates to the PHS-funded research and the basis for the determination that the financial interest conflicts with such research
9. A description of the key elements of the management plan including
  - Role and principle duties of the conflicted investigator in the research project
  - Conditions of the management plan
  - How the management plan is designed to safeguard objectivity in the research project
  - Confirmation of the investigator's agreement to the management plan
  - How the management plan will be monitored to ensure investigator compliance
  - Any other information as needed

A copy of the proposed FCOI report is provided by the COI Office to the Director of OGC or designee. The OGC Director or designee is responsible for reporting to the PHS Awarding Component in accordance with 42 CFR 50 Subpart F or the applicable contract.

#### **7.7. Annual FCOI reporting**

For any financial conflict of interest previously reported with regard to an ongoing PHS-funded research project, the University will provide to the PHS Awarding Component an annual FCOI summary that addresses the status of the financial conflict of interest and any change to the management plan. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The University will provide annual FCOI reports for the duration of the project period including extensions with or without funds in the time and manner specified by the PHS Awarding Component.

A copy of the annual FCOI report is provided by the COI Office to the OGC Director or designee. The OGC Director or designee is responsible for reporting to the PHS Awarding Component in accordance with 42 CFR 50 Subpart F or the applicable contract.

Note: The PHS COI requirement does not apply to Phase I SBIR and STTR programs. However, the requirement does apply to Phase II SBIR/STTR applications and awards.

#### **7.8. Non-PHS Funded Reporting**

The reporting and management of potential or actual conflict of interest relating to externally funded research shall comply with the sponsor's conflict of interest procedures and requirements. If a potential conflict of interest is apparent at the time of the application for funding, it shall be reported to the sponsor and/or university, as appropriate, at that time. The OGC director or designee will be responsible for forwarding the COI report to the funding agency if required by the sponsored project award terms and conditions.

#### **7.9. Appeals Process**

An investigator who wishes to appeal a decision of the COIC Committee may present their appeal in writing within 45 days of notification of a negative determination. The appeal should be directed to the Vice Chancellor of Research. If the Vice Chancellor approves the appeal it



will be forwarded to the Chancellor for final approval. The Chancellor will have final authority whether to permit the activity or to uphold the decision of the COIC Committee. If the Vice Chancellor upholds the decision of the COIC Committee the investigator has 45 days to appeal the decision directly to the Chancellor.

## **8. Non-Compliance**

### **8.1. Compliance Monitoring**

- 1. Office of Regulatory Compliance.** The Research QA and Education program has a monitoring program in conjunction with the COI Official and the COIC Committee to review approved activities and monitor compliance by the covered individuals with management plans. Reports of the monitoring activities will be provided to the Compliance Committee and the Vice Chancellor for Research.
- 2. Internal Audit.** Internal Audit may review the implementation of the University Conflict of Interest and Conflict of Commitment policy and procedures as needed. Through the use of traditional audit mechanisms, Internal Audit will also review the effectiveness of this Policy and the COIC Committee.

### **8.2. Relationship with University Human Research Protection Program (HRPP)**

The COIC Committee functions independently of, but in coordination with, other regulatory committees. The COIC Committee determines if a significant conflict of interest exists, determines whether or not the conflict can be managed and recommends a COI management plan when appropriate.

#### **When an FCOI involves Human Subject Research**

The proposed management plan is provided to the IRB of Record for review and approval. Otherwise, the plan is agreed upon by the conflicted individual in conjunction with the appropriate vice chancellor, dean or department chair.

#### **When a FCOI involves a reporting disclosure to NIH/Sponsor**

A copy of the agreed upon COI management plan or a summary thereof is sent to the Office of Grants and Contracts (when applicable). OGC will submit the appropriate documentation to the sponsoring agency.

### **8.3. Other components of the Human Research Protection Program**

The main components of the HRPP can have read only access to the COIC database as needed to meet business needs. This includes: IRB, OGC, IBC, RDRC, IACUC, Research Quality Assurance and Education Program. The COI Office has read only access to the IRB, OGC, and IACUC databases.

OGC includes a question on its sponsored projects internal routing form regarding Conflict of Interest. The question requires the PI to check a box indicating agreement with the requirement that all individuals performing work on the sponsored project are required to have a current disclosure on file in the COI Office.

Throughout the life of a research protocol, the IRB of Record may contact the COI Office about key personnel to determine if there is a potential conflict of interest. COMIRB use the Human

Subjects Module of the University Electronic Research Administration (“eRA”) module to track COI disclosure of key personnel. At minimum, the IRB of record will check for conflicts of interest when a potential conflict of interest is indicated (1) at the time of the initial protocol submission (2) at the time of a personnel change. The COI Office will determine whether an individual has a conflict of interest with the protocol and will report its determination to the IRB of Record. Upon identifying of a conflict of interest, the COI Office will follow the procedures outlined herein.

During the course of an ongoing research project, if an investigator or key personnel who is new to participating in the research project discloses a significant financial interest or if an existing investigator discloses a new significant financial interest, the disclosure shall be evaluated as outlined herein.

The Associate Vice Chancellor for Research meets regularly with the COIC manager and the other members of the COIC team as needed.

The Associate Vice Chancellor for Regulatory Compliance meets regularly with the Institutional Official to provide an update on any contentious issues or concerns raised by the COIC Committee.

#### **8.4. Relationship with Affiliate’s Human Research Protection Program.**

The COI Office will collect the annual disclosure for all faculty and designated employees. When the faculty member connects to one of the affiliated hospitals, the COI Office may disclose the information collected in the annual disclosure and any COI management plans that may be developed, as long as an appropriate confidentiality agreement is in place between the University and the affiliate. The management plans may be used by the affiliate to meet the requirements of a sub recipient award as outlined in the PHS policy.

#### **8.5. Compliance Responsibility.**

Faculty and staff are expected to comply fully and promptly with the policy outlined herein, including the disclosure requirements. It will be the responsibility of the appropriate vice chancellor, dean or department chair to ensure that COI Disclosure Forms are submitted from individuals on an annual basis and within 30 days of changes.

If an investigator fails to disclose in a timely manner one of his/her significant financial interests, the University must review the SFI, determine whether it is related to the PHS-funded research and determine whether a FCOI exists. If a FCOI exists, the University must submit a FCOI report within 60 days of identification. When a FCOI exists, the University must complete, within 120 days of determining noncompliance, a retrospective review of the investigator’s research activities to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct or reporting of the research. If bias is found, the University must promptly notify the PHS and submit a mitigation report to the PHS.

Any investigator who is determined not to be in compliance with this policy or a management plan may be required to undertake additional training as determined by the COI Official. Additional disciplinary action will be considered in consultation with the appropriate vice chancellor, dean or department chair.

## **8.6. Violations**

Instances of deliberate breach of the policy outlined herein include, but are not limited to: (a) failure to file or knowingly filing an incomplete, erroneous, or misleading disclosure; (b) violations of the guidelines; or (c) failure to comply with prescribed monitoring procedures. Such violations will be adjudicated in accordance with applicable disciplinary policies and procedures for each covered individual. Possible sanctions may include some or all of the following actions:

1. Termination of the activity that is a conflict of interest;
2. Divestiture of significant financial interests and/or
3. Disciplinary action against the employee up to and including termination

In the case of a violation of criminal or civil law, violators may be subject to civil or criminal penalties.

## **9. Public Access to Management Plans**

In accordance with PHS regulations, the University has a process through which members of the public can make a written request for a copy of a specific COI management plan. COI management plans may be requested by accessing a link on the COI website which will trigger an email to submit a written request. Requests for COI management plans will be responded to within five (5) business days. Other types of communication made to the University for access to COI management plans will be responded to within 5 business days of the request being received by the COI Office. The request must be specific enough that the COI Office can identify the appropriate plans that are being requested. The COI Office may engage other University administrative offices based on the nature of the request.

The response will include:

1. Investigator's name
2. Investigator's title;
3. Investigator's role with respect to the research project
4. Name of the entity with which the investigator has a financial conflict of interest;
5. Nature of the financial interest;
6. Value of the financial interest in increments (\$0-4,999; \$5,000–9,999; \$10,000-19,999; amounts between \$20,000-100,000 in 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).

## **10. Maintenance of Conflict Evaluation Forms and other Conflict of Interest Records**

Following final review and recommendation by the COIC Committee, the COI Office will maintain all COI Disclosure Forms and management plans. Records that relate to the report and evaluation of a disclosure, and management plan if applicable, shall be retained for at least six (6) years. For sponsored research, the retention period begins after a final report is submitted to the sponsor, or final action has been taken on any audit, litigation, or claim.

COI disclosures include information that may have a direct bearing on an individual's employment. Accordingly, the disclosures are considered sensitive and maintained in confidence in order to limit access to the information disclosed in the forms to individuals duly charged with the responsibility for review or for a University business purpose. However, the information (i.e., COI Disclosure Forms, management plans or monitoring procedures) may, to the extent required by law, be released in accordance with and as required by Colorado law, valid subpoena or lawful court order. Where permissible under the law, summary reports of the COIC Committee may be released to the public to promote research openness and integrity, particularly as it relates to required disclosures in informed consent documents.

## **11. Institutional Reports**

The COI Official will submit a final report to the Vice Chancellor for Research within sixty (60) days after the annual disclosure requirement period. During the collection period, ongoing reports will be presented by department and summarized at the school and vice chancellor level.

A report on potential institutional conflicts that have been reviewed by the COIC Committee will be submitted annually to the Vice Chancellor for Research and/or the Vice Chancellor for Health Affairs.

In accordance for Administrative Policy Statement 4013, *Disclosure of Interests*, information about Officer disclosures will be provided to the campus or University Controller if required.

## **12. Implementation and Policy/Procedure Breaches**

The Office of Regulatory Compliance is responsible for overseeing the implementation of the policy herein, including the process and mechanism for disclosure. The Associate Vice Chancellor for Regulatory Compliance in collaboration with the COIC Committee Co-Chairs will review all breaches of the evaluation and review process, including:

1. Failure to comply with the process (by refusal to respond, by responding with incomplete or knowingly inaccurate information, or otherwise);
2. Failure to remedy conflicts and
3. Failure to comply with a prescribed management plan.

The Associate Vice Chancellor for Regulatory Compliance will make recommendations to the Chancellor or designee on actions to be taken.

## **13. Interpretation**

Questions concerning the interpretation or applicability of this policy should be directed to the COI Office.

#### **14. Changes to COIC Documents**

The University COI policy herein can only be amended in compliance with procedures for changing institutional policy.

Changes to this document must be reviewed and approved by the COIC Committee, the COI Official and the Vice Chancellor for Research.

Other documents used by the COI Office and used by faculty will be reviewed and approved by the COIC Committee and the COI Official.

Other documents internal to the COI Office will be reviewed and approved by the COI Official.

**Attachment A: Requirements for Current University Employees who wish to establish, or have established, a University Employee Owned Company (UEOC).**

1. University Employee Start-Up Companies. Prior to the establishment of a UEOC to facilitate the private development of know-how, patents, and/or products developed while a University Employee, or which will seek to do business with the University, the University Employee must:
  - a. Notify the applicable Department Head/Chair, Dean of the University Employee's school or college (if applicable), or the Chancellor or their designee.
  - b. Work with the University COI Office to establish a baseline conflict of interest management plan based on the initial 3 year goals of the proposed company.
  
2. Investment in a UEOC.
  - a. Any personal investment by a University Employee in a UEOC must be declared per COI disclosure requirements;
  - b. Any Chair, Department Head or Dean who wants to invest in a company founded by a University Employee must discuss their desire to invest in a UEOC with their applicable Dean, or Chancellor or their designee, and secure appropriate approvals from said Dean or Chancellor prior to investing.
  - c. Any Department that desires to invest in a UEOC must obtain prior approval from the Dean of the applicable School or College or the Chancellor, as applicable.
  
3. Samples and/or Data.
  - a. University Employee acknowledges that Samples and/or Data collected or currently stored at the University are generally owned and/or controlled by the University except as limited by contract or data sharing requirements. Further, the University does not sell or make exclusively available Samples or Data to commercial entities, including start-up companies and UEOCs, unless the commercial entity enters into a collaborative research and/or commercialization relationship with the University.
  - b. Transfer of Samples and/or Data to a UEOC requires the University Employee to conduct an inventory of the Samples and/or Data concerned as well as copies of applicable study participant consent forms or Material Transfer Agreements ("MTAs"). The Office of Regulatory Compliance will review all applicable documentation to determine the current restrictions on the use of said Samples and/or Data.
  - c. Restrictions and /or limitations as to the use of such Samples and/or Data will be detailed in an MTA executed between the UEOC and University prior to transfer of any Samples and/or Data.
  - d. Prior written approval of the Department Head and Dean, as appropriate, is required before such an MTA transferring Samples and/or Data as described in this Policy can be executed.

**Attachment B: Requirements for UEOC that Apply for or Receive SBIR or STTR Funding from the Federal Government:**

1. PI Designation. The Small Business Concern "SBC" PI and the University PI ("Subcontractor PI") must be different individuals. If the SBC PI and University PI are immediate family members, then a COI management plan must be approved by the Office of Regulatory Compliance.
2. Required Subcontract Agreement. All work performed for, or in connection with, any SBC using University facilities, equipment, materials, employees, students, and/or other resources must be performed under a fully negotiated and executed agreement between the University and the SBC. The PI must work with the Office of Grants and Contracts on the agreement between the SBC and University. Such agreement must be in place before work on the University side can begin for the Sponsored Project and/or program.
3. Scope of Work. If a project is related to a SBIR or STTR award, the SBC's scope of work must represent a significant portion of the research and/or development activities for the entire award. For any project involving an SBC, there must be a clear distinction between the work done by the SBC and the work performed by the University.
4. Limitations on Subcontracts to the University. A University Employee who has an ownership interest in a SBC, regardless of the monetary value, must be managed in accordance with University COI policy. The PI must have a management plan approved by the Office of Regulatory Compliance before the subcontract will be executed.
5. SBC Requirements. The SBC must have evidence of functioning space in which research and/or development activities can and will take place. University facilities must not be the location for the immediate research and development activities of the SBC unless this work is conducted under a University-SBC subcontract.
6. Employment Limitations. No University student, staff member, visiting researcher or visiting scientist may perform work (either scientific or administrative) related to the University's portion of a SBC's SBIR or STTR award and concurrently serve as an employee or intern of that SBC. This limitation does not apply to faculty members, subject to applicable grant terms and conditions and regulations.
7. Prior Approval. Any University Employees or postdoctoral researchers that hold a management or officer position, a position as a member of the Board of Directors or of the Scientific Advisory Board, or undertake any responsibilities with a SBC must be managed with a COI management plan.
8. Misuse of Position. No University employee, including any faculty member or University staff member, may utilize their position at the University to influence or participate on behalf of a SBC in making business decisions or negotiating agreements between the SBC and the University.
9. Departmental Review and Approval. Proposals to conduct research at the University under a SBIR or STTR subaward must be reviewed and approved by the appropriate Department Chair, or designated representative, and the Department fiscal administrator, to ensure that the proposed project has scientific merit, constitutes a good use of University research space, is appropriately managed from a fiscal standpoint, and that the project will not compromise the University Employee's academic responsibilities.
10. Student and Postdoctoral Researcher Protections. University Employees may not require their graduate students or postdoctoral researchers to serve as the SBC PI.

Graduate students or postdoctoral researchers who wish to serve as the SBC PI must get written approval from the Vice Chancellor for Research. Additionally, undergraduate students and graduate students may not perform work for either the University or the SBC under an SBIR or STTR award when the University Employee has a financial interest in the SBC and the University Employee is the student's mentor.

11. Award Terms and Conditions. If the terms and conditions of a SBIR or STTR award are more restrictive than the University's policies, the award terms and conditions take precedence.
12. Intellectual Property. If a SBC applicant for a SBIR or STTR award might require a license from the University for Intellectual Property prior to commencing research under the SBIR or STTR award, the University requires that the SBC contact CU Innovations to inquire about the availability of such rights in advance of execution of the SBIR or STTR subcontract with the SBC.
13. University Employment Restrictions. Due to federal requirements relating to PI effort on SBIR funded grants, no University faculty may hold a greater than 0.49 FTE appointment at the University and concurrently serve as a SBC PI. In order to be a SBC PI, a University Employee must have an appointment below 50% and cannot receive benefits at the University.

Should any violation or potential violation of this Policy arise or be discovered at any time, it is the obligation of the University Employee who discovered or becomes aware of such violation or potential violation to immediately notify the Office of Regulatory Compliance and Finance Office so that appropriate remedial action, if necessary, can be taken. This Policy is applicable to all University Employees who participate in an SBIR or STTR collaboration.



### **Attachment C: Federal Requirements under SBIR and STTR programs**

1. The SBIR and STTR programs have regulations concerning financial conflicts of interest between award recipients and collaborators (subcontractors), in addition to effort allocation between the University and the SBC. Participation in these programs involving the University and a SBC can create a conflict of interest for University Employees, particularly if a University Employee has an equity interest in, works for, or has another form of relationship with the SBC.
2. Only an eligible SBC may submit an application for funding through the SBIR and STTR programs. The University may collaborate as a subcontractor with a SBC and receive funds through a sub award agreement with the SBC.
3. SBIR and STTR programs have different eligibility and participation requirements. Please reference each federal agency for their guidance <https://sbir.nih.gov/policy> (for NIH), <https://www.nsf.gov/pubs/2018/nsf18550/nsf18550.htm> (for NSF), and <https://www.acq.osd.mil/osbp/sbir/about/governing-laws-directives.shtml> (for DOD) for federal conditions associated with receipt and administration of these grants.
4. In general, SBIR program requirements of participating federal awarding agencies include:
  - a. The proposal must be submitted by an eligible SBC.
  - b. The primary employment (more than 50%) of the Principal Investigator (PI) must be with the SBC at the time of award and for the duration of the project. Primary employment with a SBC precludes full-time employment at another organization, including an academic appointment of 50% or more. Therefore, employees of the University with a .50 FTE or greater may not serve as the PI of a SBIR grant. The only mechanism by which a University Employee may serve as the PI of a S BIR grant is to take an unpaid leave of absence from the University or reduce their University appointment to less than 50%.
  - c. For projects with multiple PIs, at least one must meet the primary employment requirement. Deviations from this requirement may occur only with written approval from the federal awarding agency.
  - d. During Phase I, a minimum of two-thirds of total effort must be performed by the SBC.
  - e. During Phase II, a minimum of one-half of total effort must be performed by the SBC.
  - f. Collaboration with a research institution is optional.
5. In general, STTR program requirements of participating federal awarding agencies include:
  - a. The proposal must be submitted by an eligible SBC.
  - b. Primary employment for the PI is not stipulated under the STTR program; therefore, the PI may be primarily employed by either the SBC or the University at the time of award and for the duration of the project period. The PI's primary employment means the organization where the PI spends more than one half of their time.

This precludes full-time employment with both the University and an SBC at the same time.

- c. The PI must commit at least 10% of effort to the project. Combined with University activities, effort may not exceed 100%, which may require reduction in University appointment.
- d. SBCs are required to partner with research universities or other non-profit research institutions which have a formal collaborative and contractual relationship with the SBC.
- e. In both Phase I and Phase II, at least 40% of the work must be performed by the SBC and at least 30% of the work must be performed by the partnering research institution.

## Appendix I: Conflict of Interest Examples

The following activities represent actual conflicts of interest, are inconsistent with University policy and may not be undertaken.

1. A researcher uses his laboratory at the University to do product-testing research which is paid for by the company in which he is a 20% owner and founder. The research seeks to validate advertising claims made about a product sold by the company.
2. A clinician makes patient referrals to a diagnostic company in which she or her family member has a significant ownership interest.
3. An employee directs the purchase of supplies for the University or affiliated hospitals toward a business in which he or his family member has a significant financial interest.
4. An employee managing a design and construction project participates in the selection of an architectural firm in which her spouse is a partner.
5. A faculty member acts as the thesis or dissertation advisor to a graduate student for a research project, which was suggested by a faculty member. The faculty member expects the project to substantially enhance the value of a company in which the faculty member has a significant financial interest.
6. A researcher conducts clinical research on a product that she developed. She has licensed the product to an external organization in which she owns equity or has other direct relations including consulting.

The following examples represent conflicts of interest, but in most cases would be permitted to move forward after disclosure and an approved appropriate conflict of interest management plan.

1. A researcher conducts federally or foundation-sponsored non-clinical research on a product developed by a company for which he is a consultant.
2. A researcher who is a member of a company's scientific advisory board conducts non-clinical research sponsored by that company.
3. An employee manages a design and construction project involving an architectural firm in which his spouse is a partner, when the University employee did not participate in the selection of the firm for the project.
4. A researcher conducts federally or foundation-sponsored basic research on a University invention that has been licensed to a company for which he consults and on which he receives a share of University royalties.

## Appendix II: Best Practices Guidelines

**Participation in Business Negotiations.** No University employee having a significant financial interest in a commercial or non-profit organization outside of the University may participate in negotiating the terms and conditions of any agreement between the University and that organization.

**Participation in Administration of Agreements.** No University employee having a significant financial interest or a management position in a commercial or non-profit organization outside the University may have primary responsibility for administering an agreement between the University and that organization.

**Availability of Research Data.** All data and results arising from research in which an investigator has a significant financial interest are required to be disclosed under this policy and must be available for disinterested scientific review.

**Clinical Trial Investigators.** No one may participate as a principal investigator in a clinical trial sponsored by a start-up commercial or non-profit organization in which he or she has an equity interest, has an intellectual property interest, holds a management position or serves on the organization's Board of Directors.

**Outside Consulting Work.** Investigators receiving compensation from a commercial or non-profit organization outside the University must ensure that no services performed as part of outside consulting work duplicate any work they perform while participating in research. Prior approval of all outside consulting is required.

**Performance of University Obligations.** Investigators receiving compensation from a commercial or nonprofit organization outside the University must ensure that no services performed as part of outside consulting are inconsistent with their University obligations.

**Informed Consent.** No investigator having a significant financial interest may solely obtain informed consent in research involving human subjects.

**Disclosure of Interests.** All investigators having a significant financial interest must disclose the nature of the interest in connection with scholarly publication or presentation of the results of the research. Transparency is the key to managing conflicts of interest.

**Financial Interests in Competitors and Competitive Products.** For the purposes of this policy, investigators shall be considered as having a significant financial interest if they have any interest of economic or monetary value in a business that produces a competing product that could reasonably appear to affect or to be affected by the particular research or technology transfer transaction under consideration by UCD.

**Clinical Trials of University Technology.** No person shall participate in a clinical trial investigating technologies assigned to the University if that person has a substantial equity interest in the licensee or intellectual property interest in the technology. When the University has either a substantial equity interest in the licensee or an intellectual property interest in the technology, funding for the clinical trials will not be accepted without a full conflict of interest review and management plan being implemented.

**Data Production and Analysis.** Investigators having a significant financial interest shall not perform primary data analysis or production of data involving subjective scoring or similar methods of obtain data unless there is a clear and convincing indication that the design of the research and its analysis would provide no opportunity for bias.

**Protection of Students.** Particular attention shall be given to protecting students who could be adversely affected by the significant financial interest of an investigator or other University employee who has academic responsibility for the student.

**Oversight Arrangements.** In general, oversight committees or other oversight arrangements will be established in cases involving intellectual property interests, equity interests in start-up companies, student researchers and the potential for inappropriate use of state resources. Management plans should be written in lay terms, using language understandable to non-expert readers. Distancing oneself or creating a “firewall” from the interest in order to conduct the research or participate in an activity is a mechanism that may be accomplished through divestiture, constructing a divestiture plan, prohibiting buying or selling of the equity while the research is ongoing. In some instances the only realistic option may be to sever the relationship that created the potential conflict.

## Appendix III: References

### Federal Regulations

Public Health Service Regulations – 42 CFR Subpart F (50.601 – 50.607)

<https://www.gpo.gov/fdsys/pkg/CFR-2005-title42-vol1/content-detail.html>

Food and Drug Administration Regulations – 21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>

National Science Foundation Financial Disclosure Policy (NSF Grants Manual)

[https://www.nsf.gov/pubs/manuals/gpm05\\_131/gpm5.jsp#510](https://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510)

National Institute of Health Financial Disclosure Policy (NIH Grants Policy Statement)

<http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>

National Institute of Health Guidance Documents

<https://grants.nih.gov/grants/policy/coi/index.htm>

National Institutes of Health SBIR and STTR Guidance

<https://sbir.nih.gov/policy>

National Science Foundation

<https://www.nsf.gov/pubs/2018/nsf18550/nsf18550.htm>

Department of Defense

<https://www.acq.osd.mil/osbp/sbir/about/governing-laws-directives.shtml>

### CU Administrative Policy Statements

The University of Colorado System - Regents Laws, Article 3, Part E

<https://www.cu.edu/regents/laws-and-policies/regent-laws/article-3-officers-and-university-staff>

Policy 3B, Conflict of Interest-University Staff

<http://www.cu.edu/regents/policy-3b-conflict-interest-university-staff>

Policy 3C, Outside Consulting and Service on External Boards

<http://www.cu.edu/regents/policy-3c-outside-consulting-and-service-external-boards>

Policy 5E, Additional Remuneration for Consultative Services

<http://www.cu.edu/regents/policy-5e-additional-remuneration-consultative-services>

Fiscal Code of Ethics

<https://www.cu.edu/ope/aps/4016>

Disclosure of Interests

<https://www.cu.edu/ope/aps/4013>

Conflict of Interest and Commitment in Research and Teaching

<http://www.cu.edu/ope/aps/5012>

*Policy to Limit Conflicts of Interest between Health Care Professionals and Industry Representatives*

<http://www.ucdenver.edu/academics/colleges/medicalschooll/facultyAffairs/Documents/PharmSchoolInteractionsPolicyMay2016.pdf>

*External Gift Management and Institutional Integrity*, Policy No. 2044, applicable to the University of Colorado Anschutz Medical Campus

Note: Nepotism and Amorous Relationship policies that often have an element of conflict of interest have been purposefully excluded.

**Professional Association Policy and Guidelines** (i.e. “Best Practices”)

Association of American Medical Colleges

<https://www.aamc.org/initiatives/research/coi/>

Association of American Universities Report on Individual and Institutional Conflict of Interest

<https://www.aau.edu/node/9191>

Council on Governmental Relations Publications

<http://www.cogr.edu/ConflictofInterest>

Federation of American Societies for Experimental Biology COI Toolkit

<http://faseb.org/coi/Tools/List-of-Resources.aspx>

Guidance for Clinical Investigators, Industry, and FDA Staff-Financial Disclosures by Clinical Investigators

<https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm341008.pdf>