Procedures for Evaluating Conflicts of Interest (COI) and Commitment

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Appendix I Conflict of Interest Examples
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Procedures for Evaluating Conflicts of Interest (COI) and Commitment

These procedures supplement the Administrative Policy Statement at https://www.cu.edu/policies/aps/hr/5012.pdf. 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.

I. 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 of Colorado Denver (UCD) 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 the Colorado Multiple Institutional Review Boards (COMIRB).

A. 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 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.

B. 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 has 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, who are subject to separate guidelines and required to direct all outside professional activities through University Physicians Incorporated (UPI).

Conflicts of commitment that are not appropriate could occur, for example, in the following areas:
1. **Disproportionate Compensation.** If honoraria or consulting compensation to a faculty or staff member from outside entities, in the aggregate exceeds thresholds established from time to time by the Office of Regulatory Compliance or the COIC Committee, a potential for a conflict of commitment exists.

2. **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 1/6th rule [https://www.cu.edu/regents/Policies/Policy5E.htm](https://www.cu.edu/regents/Policies/Policy5E.htm).

3. **Conflict of Business or Mission.** Faculty and staff members may not engage in consulting or other external activities that compete or conflict with the University’s business activities or mission, and they must not divulge proprietary University business information.

4. **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: [https://www.cu.edu/policies/aps/academic/1013.html](https://www.cu.edu/policies/aps/academic/1013.html) and [https://www.cu.edu/policies/aps/academic/1014.html](https://www.cu.edu/policies/aps/academic/1014.html) and [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)

C. **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 or real estate trust, or any other legal entity organized for profit or charitable purposes. Business excludes UCD-related entities.

**Compelling Circumstances.** Those facts that convince the institution’s COIC Committee that a financially interested individual should be permitted to conduct human subjects 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 or serving as the principal investigator, co-investigator, and/or research coordinator enrolling research subjects (including obtaining subjects’ informed consent) or making decisions related to eligibility to participate in research, analyzing or reporting research data, or submitting manuscripts concerning the research for publication.

**Confidential or Privileged Information.** Information contained in documents so designated and medical, educational, personnel, or security records of individuals; anticipated material requirements or price action knowledge of possible new sites for University-sponsored operations; or 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 (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. Separate policies apply to faculty in the School of Medicine, who are subject to separate guidelines and required to direct all outside professional activities through University Physicians Incorporated (UPI).

**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 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.

**Consulting.** A relationship with an individual or a Business 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 service 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.

- (Does not include Instructor, Lecturer, Adjunct Professor, Retiree, Clinical Faculty unless conducting research).

- All faculty (Assistant professor or Higher).
- The Project Director/ Principal Investigator 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 obtains informed consents, determines eligibility, reviews data or conducts data analysis,(i.e. PI and Co-PI anyone listed on the IRB application form, IACUC Protocol and OGC Grant) 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, DSMB Members and/or other research review committees).
- Staff who negotiate or execute research agreements on behalf of UCD Area/Program Administrators, Staff of Grants and Contracts.
- University of Colorado Denver campus officials (Except Chancellor, Executive VC/VP for Health and Legal Counsel)
- (Does not include Instructor, Lecturer, Adjunct Professor, Retiree, Clinical Faculty unless 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. A faculty member or UCD employee’s spouse/domestic partner, and dependent children are considered Family Members.

FCOI Report means UCD’s report of a financial interest to a PHS Awarding Component, to a lead institution if required under the terms of the sub-recipient agreement or sponsor if required under the contract.

Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research or their 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 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. contract research organization, or 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 University General Counsel. (Private equity or venture capital firms that evaluate new technologies for their own benefit are not considered Financial Investment Firms. Consulting for them involves the institutional pre-approval process that is required when consulting for entities other than Financial Investment Firms). ?Add – business interest conflict.

**Honoraria**

- **For Schools without a specific definition for Honoraria, the following definition will be used:**
  Honoraria include one-time payment for presentations, lectures, articles, visiting professorships, article reviews, editing services, expert witness testimony by accomplished faculty who have achieved a level of expertise sought by others outside the University. If there is a contract or other formal agreement, or if there is an established reward, those payments are not considered honoraria.

- **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 need not 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. Includes but not limited to speakers’ bureaus, CE (Continuing Education) and other presentations, article reviews, editing services, expert witness testimony. If there is a contract or other formal agreement, or if there is 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 C.F.R. 46 and 21 C.F.R. 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 prohibits fraudulent activities of any kind in connection with the offer, purchase, or sale of securities. These provisions are the basis for many 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. “Tipping” other traders of such non-public information who then trade a security affected by the tip is also illegal, as is acting on an illegal tip.

**Institutional Conflicts of Interest.** The term institutional conflicts of interest refers to 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 university as a body corporate or by a university or campus official acting within his/her authority on behalf of the university or campus, that could bring financial gain to the university, campus, any of its units, and the individuals covered by this policy.

Institutional financial conflict of interest includes:
- Licensing, technology transfer, and patents
- Investments
- Gifts
- Other financial interests

**Institutional Responsibilities:** An investigator’s professional responsibilities conducted on behalf of the Institution, and include: research, research consultation, teaching, professional practice, purchasing, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**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. Please see Administrative Policy Statement for Intellectual Property Policy on Discoveries and Patents for Their Protection and Commercialization at [https://www.cu.edu/policies/aps/academic/1013.html](https://www.cu.edu/policies/aps/academic/1013.html)

**Investigator** includes 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** includes the Project Director/Principal Investigator and any other person who is responsible for the design, conduct and reporting of basic, animal or clinical research, this includes PRAs, or anyone who obtains informed consents, or those who determine eligibility, or those who review data or conduct data analysis.

**Manage** means 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.** Officers of the Administration are those 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.

All Officers must disclose annually the following:
- Outside offices, directorships, employment
- Outside financial interests
- Immediate family members’ professional services
- Other interests related to the University
- Conflicts of interest

**Outside Income.** Outside Income includes 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 UCD or its affiliates;
- Income from seminars, lectures, or teaching engagements sponsored by public entities (ex. Denver Public Schools, income from review boards, and NIH peer review boards);
- Income from service on advisory committees or review panels for public entities (ex. 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.** To be part of the described activity in any capacity, including but not limited to, designing or directing research, 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 or 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.
**PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

**PHS awarding Component** means the organizational unit of the PHS that is subject to 42 CFR 50 Subpart F – Promoting Objectivity in Research.

**Research** means 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 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 institutional officials and to the institutional COIC Committee, or the transmission of such information within the institutional channels (e.g., from the COIC Committee to COMIRB).

**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 UCD activities but having significant financial interest. Reasonable circumstances might include the extent of the conflict to the institution and the potential effect of the conflict upon the research or activity itself, the institution, and the sponsor or external party.

**Reasonable Research Costs**. Payments to the University to the 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 University are not considered Significant Financial Interests.

**Royalties**. Royalty income (or the written contractual right to receive future royalties) 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 an Advisory Committee is not “fiduciary service.”

**Significant Financial Interest (SFI)** – means 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, including those 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 \textit{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 \textit{publicly} traded entity.
- Equity interests, including stock options, of \textit{any amount} in a \textit{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.

\textbf{What is NOT considered a “significant financial interest”?}

- Salary, royalties, or other compensation from UCD or its affiliates if the investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution 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 (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.

\textbf{Small Business Innovation Research (SBIR) includes the Small Business Technology Transfer (STTR) Program}

\textbf{Speakers Bureau –} Under SOM policy, Industry Conflict of Interest Policy last revised January, 2014, activity on speaker’s bureaus is limited and under the May 2011 resolution effective June 1, 2011, 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** – means research, training, and instructional projects; or involving funds, materials, or other compensation from outside sources under agreements that contain any of the following:

a. The agreement binds UCD to a line of scholarly or scientific inquiry specified in a substantial level of detail. Such specificity may be indicated by a plan, by the stipulation of requirements for orderly testing or validation of particular approaches or by the designation of performance targets.

b. A line item budget or modular budget is involved. A line-item budget details the expenses by activity, function, or project period. The designation or overhead (direct and indirect costs) qualifies a budget as “line item.”

c. Financial and/or programmatic reports are required.

d. The award is subject to audit.

e. The agreement provides for the disposition of either tangible (for example, new equipment, records, technical reports, theses, or dissertations) or intangible (for example, rights in data, copyrights, or inventions) properties which may resume the activity.

**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). To actually 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.

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

### II. Conflict of Interest and Commitment Office

The Conflict of Interest and Commitment Office exists to implement and enforce the UCD policies and procedures concerning conflict of interest and commitment as outlined in this document. This includes creating and maintaining an up-to-date written and enforced policy that complies with the regulations, ensuring that the UCD policies and procedures document is posted on the UCD website, collecting the annual conflict of interest disclosures, normally September through November, establishing the interconnections across projects, protocols and technology within the institution and administering or facilitating the review process, write the COIC Committee minutes and maintain the documentation and coordinating training.
The Office staff consists of a COIC Manager who reports to the COI Official who is also the Assistant Vice Chancellor for Regulatory Compliance. Additional administrative support is provided by the Administrative Core within the Regulatory Compliance Office.

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

The performance of all staff within the COIC Office will be reviewed at least annually in accordance with state requirements.

**A. Education and Training.**

**Information.** Letters, email notifications and articles in UCD 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. The Conflict of Interest and Conflict of Commitment Policy is made publicly available at: [https://www.cu.edu/policies/aps/hr/5012.html](https://www.cu.edu/policies/aps/hr/5012.html)

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 UCD revises its FCOI policy.

**Training**

All covered personnel are required to complete training within 60 days of joining the institution; prior to engaging in any funded research and at least annually with the annual financial disclosure. [Training is a mandatory portion of the COI disclosure form and has to be taken before a new or revised disclosure can be submitted.]

Training will include information on Institutional COI policy; investigators disclosure responsibilities and federal regulations relating to COI.

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

The required training materials will be linked to the disclosure form. So that training will be a mandatory part of each disclosure submitted to the COIC office and therefore, mandatory training will occur at least annually.

UCD is committed to communicating our standards for ethical conduct and UCD policies to all employees. UCD provides education and training to develop awareness and stress compliance with the Conflict of Interest and Conflict of Commitment Policy through individual guided study. Materials and resources are also available at:
B. Disclosure Requirements

All personnel who meet the definition of a covered individual must complete a UCD financial disclosure form:

- Within 60 days of being hired;
- No later than at the time of application for research funding (i.e. cannot submit a grant if a current disclosure is not on file with the COIC office);
- Annually between September and November or as requested by the COI Official;
- Within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance);
- Within 30 days of the occurrence of any trip for which there is reimbursement or sponsored travel.

What has to be disclosed?

UCD has a zero threshold for disclosure of financial interests of the covered individual and/or spouse/domestic partner and/or dependent children that reasonably appear to relate to the covered individual’s institutional responsibilities.

Investigators must also disclose within 30 days of each occurrence (completion of the trip) of any reimbursed or sponsored travel (i.e. that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the Investigator’s institutional 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:

- the purpose of the trip,
- the sponsor / organizer,
- the destination by country, state, town,
- the duration of the trip, and
- an estimate of the monetary value of the trip.

Failure to disclose

When the institution identifies a SFI that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed by the institution during an ongoing PHS-funded research project, the Assistant Vice Chancellor for Regulatory Compliance or designee will, within 60 days, review the SFI, determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

1. Implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
2. Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the investigator to disclose a significant financial interest that is determined by the institution to constitute a financial conflict of interest; failure by the institution to review or manage such a financial conflict of interest; or failure by the investigator to comply with a financial conflict of interest management plan, the institution will, within 120 days of the institution’s determination or 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, was biased in the design, conduct or reporting of the research.

The COIC 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 institution shall update the previously submitted FCOI report, specifying the actions taken to manage the conflict of interest going forward. If bias is found, the institution will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. 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 institution’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; 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 the institution’s agreement with that sponsor.

Thereafter, UCD will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, UCD may decide that interim additional measures are necessary with regard to the investigation’s participation in the funded research project between the date that the financial conflict of interest or the investigators noncompliance is determined and the completion of the institution’s retrospective review.

III Review Process
   A. Annual Review of Conflict of Interest Disclosure Forms.
1. Annual disclosure is required of all Covered Individuals of the University of Colorado Denver with the UCD COIC Office.

2. The COIC Office is responsible for the collection and initial screening of all Annual Conflict of Interest Disclosure Forms in accordance with CU Policy on Conflict of Interest and Commitment and in accordance with the policies and procedures set herein. The COIC Office will receive and review monthly reports from the Technology Transfer Office detailing the intellectual property for which the institution and/or faculty has licensed and receives compensation. The COIC Manager will also correlate financial disclosures with the Office of Grants and Contracts database, IACUC and the COMIRB database to verify related grants, contracts or human subject protocols.

3. The COIC Manager will determine the review flow based on the review categories as detailed below. Any travel disclosure with an estimated value over $10,000, will be reviewed as an updated disclosure. Any travel with an estimated under $10,000 will be reviewed as part of the annual disclosure process.

4. If the Committee determines after the initial review of disclosure that no conflict of interest exists, it will conclude its assessment.

5. The COIC Committee will make recommendations to the individual and the appropriate UCD Administrator as to whether the:
   a. activity poses no conflict and can conclude its assessment,
   b. may have potential for conflict that can be managed or,
   c. potential for conflict that will not be allowed.

B. Review Procedures.

The COIC Manager will triage review of disclosures based on the following:

**Category 1 Review** - Initial Review with no financial interest receives acknowledgement e-mail from COIC Office

**Category 2 Review** – Initial Review with less than a significant financial interest receives acknowledgement e-mail from COIC Office, with or without UC Denver related activity.

**Category 3 Review** – Initial Review with no funded research or human subject research with a significant financial interest for review by COIC Office, receives a SFÍI letter.

**Category 4 Review** – Initial Review for investigators with funded research or human subject research with a significant financial interest for review by COIC Committee.
Category 5 Review – Initial Review of UC Denver officers who have a financial interest for review by COIC Committee.

Category 6 Review – Continuing Review – Disclosure and summaries are the same as previously submitted for administrative review by the COIC Office.

Category 7 Review – Continuing Review – Positive disclosure has become negative disclosure for administrative review by the COIC Office.

Category 8 Review – Continuing Review - Disclosure or summary has changed and UC Denver activity and less than a significant financial interest or UC Denver officers that have not changed for review by COIC Office.

Category 9 Review – Continuing Review – Disclosure or summary has changed and UC Denver activity with a significant financial interest for review by the Committee.

Category 10 Review – Any of the above categories which are complex or unusual financial interest, can be sent to COI Committee.

C. Expedited Review. (Categories 6, 7 and 8)

Individuals involved in activities resulting in management plans for the previous year or individuals who have no changes to their disclosures from the previous year may, under certain circumstances, utilize the expedited review process. If monitoring mechanisms for an activity have previously been implemented following appropriate review and approval as described by the Policy, the Financially Interested Individual may use the Expedited Review Process described in this paragraph 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 in this policy. 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 his/her approval.
IV. **Conflict of Interest and Commitment Committee.**

**A. Purpose.** The COIC Committee exists to protect the integrity of investigators, UCD, and maintain the public trust in UCD 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 UCD, 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. UCD’s 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.

**B. Committee Composition.** The COIC Committee shall meet as necessary (normally at least monthly). There should be at least 8 committee members.

The COIC Committee shall consist of a broad cross section of the UCD community and can include:

1. COI Official.
2. COIC Co-Chairs
3. Department Administrator.
4. Director (or designee), COMIRB (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 or of 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.

**C. 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.

D. Co-Chair Roles and Responsibilities. The UCD Institutional Official (Vice Chancellor for Research), in consultation and approval of the Committee members, and the COI Official appoints two co-chairs of the 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, fully capable of managing the 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 the institution’s administration, the faculty, employees and officers whose relationships are brought before the Committee.

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

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

E. Responsibilities of COIC Committee Members. The agenda, disclosure, summary of connecting projects or relationships is provided at least 5 days in advance of the scheduled COIC 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.

F. 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 Manager.

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

G. Training and Ongoing Education of COIC Committee Members. New COIC Committee Members will meet or talk with the COIC Manager for an informal orientation. The new member will be given a COIC binder that includes:

- Relevant institutional policies
- UCD COIC Procedure document
- 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 proved to the members via e-mail or during the Committee meetings.

**H. Liability Coverage of COIC Committee Members.** The University’s insurance coverage applies to employees and any other person authorized to act on behalf of the University for acts or omissions within the scope of their employment or authorized activity.

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

**J. Committee Administration.**

1. The COIC Office will be responsible for facilitating the meetings and recording the activities of the COIC Committee.

2. Meetings are limited to COI members, invited staff, and other invitees, and 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 COIC 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

   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 financial conflict of interest disclosure form, compelling circumstances (if appropriate), 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 Committee.

V. **Categories of Conflict of Interest.**

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

A. Activities that ordinarily are permissible;

B. Activities that appear to present potential conflicts of interest or commitment;

C. 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.

A. **Activities that ordinarily are permissible include:**

1. Participation in scientific or professional association activities, editorial responsibilities, or service on scientific review boards and panels;

2. Acceptance of honoraria for commissioned papers and occasional lectures;

3. Performance of professionally related activities such as consulting, textbook authorship, involvement with professional societies, and participation on review panels, etc.;

4. Service as a consultant to outside organizations, provided the arrangement does not unreasonably restrict publication of research results obtained within the University;

5. Service on boards and committees of organizations, public or private, that does not distract unduly from University obligations; and

6. Performance of duties that are specified under Regent approved agreements such as the School of Medicine faculty practice plan.

B. Activities that appear to present potential conflicts of interest or commitment include:
1. Relationships that might enable an employee to influence the University's dealings with an outside organization 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. Ordinarily, such problems may be resolved by full disclosure as well as making appropriate arrangements that clearly exclude that employee from participating in the decisions.

2. Situations in which the time or creative energy an employee devotes to extramural activities, including those listed in the section above, appears substantial enough to compromise the amount or quality of his or her participation in the instructional, scholarly, and administrative work of the University itself.

3. Activities (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.

4. Activities that violate or might reasonably be perceived to violate any of the principles governing research supported by funds administered through the University insofar as these principles are relevant to individual behavior.

C. Activities that present such serious problems as to be incompatible with University policies include:

1. 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.

2. Use for personal profit of unpublished information emanating from University research or other confidential University sources, or 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.

3. 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.

VI. Review Standards.

A. Rebuttable Presumption Against Conflicts of Interest.
1. **Individual.** In order to assure that all potentially problematic circumstances are reviewed, UCD will presume that a financially interested individual may not conduct the activity in question. 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 UCD would then be allowed to be conducted under conditions specified by the COIC Committee and, if applicable, approved by the responsible IRB.

**B. Compelling Circumstances.** In the event of Compelling Circumstances, an individual holding Significant Financial Interest or UCD having an Institutional Conflict of Interest in human subjects research involving greater than minimal risk may be permitted to conduct the research. Whether the circumstances are deemed compelling will depend 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 might 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 UCD has an institutional conflict of interest, 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;

2. All financial incentives for bias have been appropriately mitigated.

Further, the financially interested individual or the project when UCD 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 research and/or the institution.

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 shall be implemented:

1. Auditing of the human research protection practices in place during the research.
2. A disinterested observer must monitor the research.
3. A Data and Safety Monitoring Board must review the research and data.
4. Funds creating the conflict of interest must be placed into escrow until the research is completed or a divestiture plan must be created 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.

C. 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 Committee should determine the extent of the conflict to the institution and the effect of the conflict upon the research or activity itself, the institution, and the sponsor or external party.

D. 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, it should strive for the simplest effective means of managing the conflict.

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

1. A statement demonstrating why the conflict is unlikely to affect the activity in question.
   - If the research project is funded by multiple sources, explain that 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 (perhaps 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 (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, as a first principle, 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 to be imposed when a Financially Interested Individual is involved in a conflicted activity.

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

1. Disclose all potential Conflicts of Interest and Conflicts of Commitment, both financial interests and participation in the sponsor or licensee company as an employee, officer or director.

2. Identify factors such as the following that may mitigate the likelihood of actual conflicts of interest.
a. Whether a sponsor or licensee is publicly or privately held may affect the covered individual’s status as a board member, officer, or “key” employee.

b. A significant difference between the research emphasis of the sponsor or licensee and that of the individual may reduce the likelihood of actual conflicts of interest.

3. Implement 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.

c. Require modification of research plans or transfer portions of research to independent researchers, if necessary, to avoid actual Conflicts of Interest.

4. Carefully review sponsorship and license terms. Be aware of any indications that the arrangement may not be an “arm’s length” transaction. Specifically investigate:

a. Grants of an equity interest to an individual that provide disproportionate compensation (a) relative to the standard share of royalties a faculty member might receive for technology licensed to an unrelated company, or (b) 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 institution for grant funding.

d. The present or near-term capacity to perform the essential functions outlined in the company’s business plan.

e. Contracts-back to the institution of development work, which suggests that the technology could not have been licensed to a company in an arm’s length transaction (exception: unique facilities).

E. Special Instructions for Monitoring Students. With respect to any monitored activity in which a student is involved, the following requirements shall be observed:

1. 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 Deans and Department Chairs. 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 Department Chair, Dean or, if applicable, the COIC Committee, and/or the monitor or monitoring panel, as appropriate.

VII Documentation

A. 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 manager and reviewed and approved at the next COIC meeting.

B. Management plans
The COIC Committee or administration will review all disclosures that disclose a financial relationship that meets the definition of a significant financial interest and determine if the SFI is related to their institutional 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 can 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 and communications forwarded to the appropriate supervisor, dean or department head. Within 10 days the individual should return a signed copy of the management plan affirming their agreement or contact the COIC Office if there are questions or concerns.
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 prior to the approval of the conflict of interest management plan. When the 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 Institutional Conflicts should be disclosed to the research subjects in a form to be approved by the responsible IRB. The IRB has final decisions and IRB decisions on COI are final. A copy of the final IRB approved management plan is given to the COIC Office by the IRB Office to be maintained with their other documentation.

C. Subrecipient Awards and Investigators
The UCD Office of Grants and Contracts is responsible for ensuring that part of the written agreement with the sub-recipient is to ensure that the conflict of interest policy of the sub-recipient Institution will apply to the sub-recipient investigators unless an agreement is made in conjunction with the COIC Office that UCD’s COI policy will apply.

UCD Office of Grants and Contracts policy will outline the reporting requirements to UCD prior to the expenditure of any funds to the sub-recipient.

D. FCOI Reports
Prior to the expenditure of any funds under a PHS-funded project, UCD must provide the PHS Awarding Component an FCOI report regarding any investigator’s SFI found by UCD to be conflicting.

If UCD identifies a financial conflict of interest and eliminates it 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 COIC Office identifies as conflicting subsequent to UCD’s initial FCOI report during an ongoing PHS-funded research project, UCD will provide to PHS Awarding Component within 60 days an FCOI report regarding the financial conflict of interest and ensure that the

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 – 9,9999; $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;
   • And other information as needed

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

E. Annual FCOI reporting
For any financial conflict of interest previously reported with regard to an ongoing PHS-
funded research project, UCD will provide to the PHS Awarding Component an annual
FCOI report 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. UCD 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 COIC Office to the Director of the
applicable Grants and Contracts office. The Director of the Grants and Contracts Office
is responsible for reporting to the PHS Awarding Component in accordance with 42 CFR
50 Subpart F or the applicable contract.

Note: SBIR and STTR programs are not considered PHS research under 42 CFR 50
Subpart F.

F. Non-PHS Funded Reporting
Similar reports as those detailed above will be provided by the COIC Office to the
Director of the applicable Grants and Contracts office who will be responsible for
forwarding to the applicable funding agency or sponsor in accordance with the relevant
grant or contract with UCD or the affiliate hospital for the duration of the project.

G. 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.

VIII. Non-Compliance

A. 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 UCD Compliance Committee and the Vice Chancellor for Research.

2. **Internal Audit.** Internal Audit may review the design of the 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 the Policy and the COIC Committee.

B. **Relationship with UCD HRPP.** The COIC Committee functions independently of, but in coordination with, other institutional 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 faculty or employee 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 is also sent to the Office of Grants and Contracts (when applicable).

**Other components of the UCH HRPP**
All the main components of the UCD HRPP have read only access to the COIC database. This includes: COMIRB, Grants and Contracts Office, IBC, RDRC, IACUC, Research Quality Assurance and Education Program. The COIC Office has read only access to COMIRB, OGC, IBC, RDRC, IACUC and Research Quality Assurance and Education Program.

UCD Grants and Contracts Office in policy 4-5 outline UCD policy to ensure that a management plan has been developed by the UCD COIC Office and a copy submitted to the PHS Awarding Component prior to any expenditure on the applicable award or subcontract.
Whenever in the course of an ongoing research project an investigator who is new to participating in the research project discloses a significant financial interest or an existing investigator disclose a new significant financial interest to the UCD COIC Office, The Vice Chancellor for Research meets monthly with the Assistant Vice Chancellor for Regulatory Compliance and the Directors that report directly to him.

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

**C. Relationship with Affiliate's HRPP.** The UCD COIC Office will collect the annual disclosure for all faculty and designated employees. When the faculty member connects to one of the affiliate hospitals, the COIC 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 UCD 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.

**D. Compliance Responsibility.**

UCD expects individuals to comply fully and promptly with the policy, including the requirements of disclosure. It will be the responsibility of the appropriate department chair, vice chancellor, or dean to ensure that Conflict of Interest and Commitment 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 their Significant Financial Interests, then UCD must review the SFI, determine whether it is related to the NIH-funded research, determine whether an FCOI exists, and if so, submit an FCOI report within 60 days of identification; complete., within 120 days of determining noncompliance, a retrospective review of the Investigator’s research activities to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct or reporting of the research; and if so, promptly notify the NIH and submit a mitigation report to the NIH.

Any investigator who is determined not to be in compliance with this policy or management plan will be required to undertake additional training to be determined by the COI Official and additional disciplinary action will be considered in consultation with the appropriate Vice Chancellor, Dean or Department Head.

**E. Violations.**

Instances of deliberate breach of policy include, but are not limited to: (a) failure to file or knowingly filing an incomplete, erroneous, or misleading disclosure form, (b) violations of the guidelines, or (c) failure to comply with prescribed monitoring procedures, 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

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.

IX. Public Access to Management Plans

UCD has a web portal through which members of the public can make a written request to obtain a copy of specific FCOI management plans. Requests made via the web portal will be responded to within 5 days. Other types of communication made to UCD for access to FCOI management plans will be responded to within 5 days of the request being received by the COIC Office administration. The request must be specific enough that the COIC administration can identify the appropriate plans that are being requested.

The response will include:

1. Investigator’s name
2. Investigators 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.

X. Maintenance of Conflict Evaluation Forms and other Conflict of Interest Records

Following final review and recommendation by the COIC Committee, the COIC Office will maintain all COI forms and management plans. All COI forms and management plans are official records and will be maintained for at least 3 years following the closure of any research projects connected to the FCOI. The forms contain information that may have a direct bearing on an individual’s employment. As such, the forms will be considered sensitive and maintained in confidence so as to restrict the information disclosed in the forms to individuals duly charged with the responsibility for review or a UCD business purpose. However, the information (i.e., COI 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.

XI. 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 to the Vice Chancellor for Research and/or the Vice Chancellor for Health Affairs annually.

XII. Implementation and Policy/Procedure Breaches.

The Office of Regulatory Compliance is responsible for overseeing the implementation of the COI policy and procedures herein, including the process and mechanism for disclosure. The Assistant 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 monitoring plan.

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

XIII. Interpretation.

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

XIV. Changes to COIC Documents.

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

The COIC procedures document must be reviewed and approved by the COIC Committee, the COI Official and the Vice Chancellor for Research.

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

Other documents internal to the COIC Office will be reviewed and approved by the COI Official.
Appendix I -
Conflict of Interest Examples

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

1. A researcher uses his laboratory at UCD to do product-testing research, paid for by the company in which he is a 20% owner and founder, which seeks to validate advertising claims made about a product sold by that 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, suggested by a faculty member, that the faculty member expects to substantially enhance the value of a company in which the faculty has a significant interest.

6. A researcher conducts clinical research on a product developed by her and licensed 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 UCD 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 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 or 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. Investigators shall be considered as having a financial interest for the purposes of this policy 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.

Clinical Trials of University Technology – No person shall participate in a clinical trial involving technologies licensed 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 or 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 C.F.R. Subpart F (50.601 – 50.607)
   http://www.access.gpo.gov/nara/cfr/waisidx_05/42cfr50_05.html

Food and Drug Administration Regulations – 21 C.F.R. Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860
   http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200521

Federal Policy and Guidelines

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

National Institute of Health Guidance Documents

Office for Human Research Protections Guidance Document
   http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Food and Drug Administration Guidance Documents
   http://www.fda.gov/opacom/morechoices/industry/guidedc.htm

U.S. General Accounting Office Report to Senator Frist on Conflict of Interest in Biomedical Research
   http://www.aau.edu/Search/AdvancedSearch.aspx?id=1124

CU Administrative Policy Statements

The University of Colorado System - Regents LawsArticle 3, Part E
   https://www.cu.edu/regents/Laws/article-03.html

Regents Policies, Policy 2A
   http://www.cu.edu/regents/Policies/Policy2A.htm

Policy 3B
   http://www.cu.edu/regents/Policies/Policy3B.htm

Policy 3C
   http://www.cu.edu/regents/Policies/Policy3C.htm

Policy 5E
   http://www.cu.edu/regents/Policies/Policy5E.htm
Conflict of Interest and Commitment Policy
https://www.cu.edu/policies/aps/hr/5012.html

UC Denver SOM Policy: to limit conflicts of interest between Health care professionals and industry representatives, May 27, 2008 and additional resolution regarding speakers bureaus effective June 1, 2011
http://www.ucdenver.edu/academics/colleges/medicalschool/facultyAffairs/Rule
sPolicies/Pages/RulesPolicies.aspx

Fiscal Code of Ethics
https://www.cu.edu/policies/aps/finance/4016.html

Officer Disclosure of Interests
https://www.cu.edu/policies/aps/finance/4013.html

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/coi/

Association of American Universities Report on Individual and Institutional Conflict of Interest
http://www.aau.edu/research/COI.01.pdf

Council on Governmental Relations Publications
http://www.cogr.edu/Pubs_Conflicts.cfm

Federation of American Societies for Experimental Biology
http://opa.faseb.org/pdf/FASEB_COI_paper_7x06.pdf