UNIVERSITY OF COLORADO DENVER

PROCEDURES FOR EVALUATING CONFLICTS OF INTEREST AND COMMITMENT

COIC Procedures – Final
January 9, 2009
Procedures for Evaluating Conflicts of Interest (COI) and Commitment

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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/Academic/Conflict-of-Interest.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 of the University of Colorado Denver (UC Denver) shall appoint such an official for each COI Committee. The COI Official will report to the Chancellor regarding all COI activities. The COI Official will serve as the chair of the COI Committee and also as a liaison to the Colorado Multiple Institutional Review Boards (COMIRB) and Downtown Denver Campus' IRB.

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 have the appearance of adversely affecting, an employee's commitment to his/her University duties or responsibilities. Such activities are encouraged insofar as they are conducted in accordance with University policy (including the one-sixth rule), promote professional development of faculty and student employees, and enrich their contributions to the institution, to their profession and to the community. Consulting relationships, for example, may serve to create conduits for the exchange of information and technologies that enhance the University environment and permit faculty to test the soundness of their ideas (Regent action 6/12/48). Separate policies apply to faculty in the School of Medicine, 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 COI Committee, a potential for a conflict of commitment exists.

2. **Conflict of Time.** When the commitments for external activities – 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.

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 UC Denver-related entities.

**Compelling Circumstances.** Those facts that convince the institution’s Conflict of Interest Committee that a financially interested individual should be permitted to conduct human subject research involving greater than minimal risk. When considering a request by a financially interested individual to conduct research, the circumstances that the COI 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, 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.

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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 Member 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.

- Faculty
- Individuals who are responsible for the design, conduct and reporting of basic or clinical research, this includes PRAs, (or anyone who obtains informed consent, those who determine eligibility, those who review data or conduct data analysis)
- 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 UC Denver. Area, Staff of Grants and Contracts.

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. Means a faculty members or UC Denver employees, spouse/domestic partner, and/or dependent children.

Financial Interest Related to the Research. Means a financial interest in the sponsor, product or service being tested, or competitor of the sponsor or product or service being tested.

Financially Interested Company. Means 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. Means 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. Means 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 COI Committee and a contract review by the University General Counsel. (Private equity or venture capitol 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).

Honoraria. For Schools without a specific definition for Honoraria, the following definition will be used: Means 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 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.

School 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 Subjects Research. Means 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. part 46 and 21 C.F.R. Part 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. Means 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 nonpublic 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 Review Board. Means 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. Means 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/Academic/IP-Discoveries.pdf
**Non-Human Subjects Research.** Means basic research, animal research, or other research that is not Human Subjects Research.

**Outside Income.** Means 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).

**Participate.** Means 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.

**Reporting.** Means the provision of information about significant financial interests by a covered individual to responsible institutional officials and to the institutional COI Committee, or the transmission of such information within the institutional channels (e.g., from the COI Committee to COMIRB).

**Reasonable Circumstances.** Means the circumstances that a reasonable prudent layperson would expect a covered individual to maintain given the need to accomplish a specific task related to UC Denver 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.** Means 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.** Means 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.** Means 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.** Means anything of monetary value, including, but not limited to:

- Salary or payment for services, Consulting fees, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts, or other emoluments, or “in kind” compensation from a financially interested company (or entitlement to the same), whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose **not** directly related to the reasonable costs of conducting research or activity (as
specified in the research agreement) that in the aggregate have in the prior calendar year exceeded the de minimus amount of a value equal to or greater than $10,000, or are expected to exceed that amount in the next twelve months.

- Equity interests, including stock options, of any amount (or entitlement to the same) in a non-publicly-traded (privately held) financially interested company.
- Equity interests, including stock options (or entitlement to the same) in a publicly traded financially interested company of either a value equal to or greater than $10,000 or 5% equity ownership which ever is less.
- 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.
- Compensation from a financially interested company (or entitlement to interests (e.g. stocks, stock options, or other ownership interests); and intellectual property rights (e.g. patents, copyrights, and royalties from such rights) that in the aggregate have in the prior calendar year exceeded the de minimus amount of a value equal to or greater than $10,000, or are expected to exceed that amount in the next twelve months.
- Membership on a Board of Director's.
- Proprietary interest related to the research of any value.
- No arrangement has been entered into where the amount of compensation or the value of the ownership interests will be affected by the outcome of the research.

**What is NOT considered a “significant financial interest”?**

- Salary, royalties, or other compensation from UC Denver;
- Income from seminars, lectures, or teaching engagements sponsored by public entities (Denver Public Schools, income from review boards, and NIH peer review boards);
- Income from service on an advisory committee or review panel for public entities (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.

**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 UC Denver 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.** Means a security that represents part ownership, or equity, in a corporation. Each share of stock is a proportional stake in the corporation's assets and profits, some of which could be paid out as dividends.

**Stock Options.** Means 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.** Means any process, method, product, compound, drug, device, or any diagnostic, medical, or surgical procedure developed using UC Denver facilities, equipment or funds, whether intended for commercial use or not.

## II. Conflict of Interest Committee.

**A. Purpose.** The COI Committees exist to protect the integrity of investigators, UC Denver, and maintain the public trust in UC Denver 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 UC Denver, 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 duly-constituted and broadly representative committee. UC Denver’s COI Committees serve 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 COI Committee shall be appointed by the UC Denver Chancellor and meet as necessary. The COI Committees shall consist as follows:

**C. COI Committee**

1. COI Official.
2. Department Administrator.
3. Director, COMIRB or their designee (recused from voting on institutional conflicts of interest involving human subjects research).
4. Clinical faculty member 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.
5. Basic Science faculty member who is a principal investigator of a federal grant or contract.
6. Faculty members at large.

7. Affiliate Member.

9. Community member(s).

**D. Committee Membership Term.**

1. Officials shall be appointed for a term to be determined by the Chancellor.

2. Faculty members and department administrators shall be appointed for two-year staggered terms in order to maintain continuity for the COI Committee.

3. Community and affiliate members shall be appointed for two years and may serve additional terms if the person and the Chancellor so desire.

4. The representatives from the IRB shall be permanent representatives on the COI Committee, but may be removed from the COI Committee at the request of their supervisor who will offer a different representative from the respective office.

**III. Review Process.**

**A. Annual Review of Conflict of Interest Disclosure Forms.**

1. Annual disclosure is required of all Covered Individuals and staff of the University with the Office of Regulatory Compliance.

2. The Office of Regulatory Compliance is responsible for the collection and initial screening of all Annual Conflict of Interest Evaluation Forms in accordance with CU Policy on Conflict of Interest and Commitment in accordance with the policies and procedures set herein.

3. The Office of Regulatory Compliance will communicate directly with the investigator regarding Category I disclosures. The Office of Regulatory Compliance will refer all other categories of disclosure forms that indicate a possible conflict of interest to the Conflict of Interest Committee for review and determination.

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

5. The COI Committee will make recommendations to the individual and the appropriate UC Denver 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. Committee Administration.**

1. The Office of Regulatory Compliance will be responsible for facilitating the meetings
and recording the activities of the COI 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 Office of Regulatory Compliance 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.

C. Communication. If the Conflict of Interest 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. Notice will also be sent to the appropriate Dean and the IRB.

All disclosures will be responded to in writing and communications forwarded to the appropriate Supervising manager as needed. The COI Committee will notify the responsible IRB committee of any Significant Financial Interests held by Financially Interested Individuals who will conduct human subject’s research and of the COI Committee’s recommendations for managing the conflict of interest. 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’s research. The Committee will notify the IRB when a disclosure statement must be included in the informed consent document. 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.

IV. Review Standards.

A. Rebuttable Presumption Against Conflicts of Interest.

1. Individual. In order to assure that all potentially problematic circumstances are reviewed, UC Denver 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 COI
Committee, constitute compelling and/or reasonable circumstances. The individual would then be allowed to conduct the activity under conditions specified by the COI Committee and, if applicable, approved by the responsible IRB.

2. Institutional. When reviewing circumstances that involve a potential institutional conflict of interest, the COI 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 COI Committee, constitute compelling and/or reasonable circumstances. The project at UC Denver would then be allowed to be conducted under conditions specified by the COI 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 UC Denver 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 COI 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 UC Denver has an institutional conflict of interest, the individual or the project must demonstrate the following to the COI 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 UC Denver has an Institutional Conflict of Interest should demonstrate the following to the COI 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 COI 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 COI 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 COI Committee need only apply a reasonable circumstances standard in determining whether the activity may ensue. The COI 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) 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’s research, as a first principle, the COI 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 COI 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. (See Appendix VI) UC Denver 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.

c. 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 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 COI 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 COI Committee, and/or the monitor or monitoring panel, as appropriate.

F. **Appeals Process.** An investigator who wishes to appeal a decision of the COI 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 COI Committee. If the Vice Chancellor upholds the decision of the COI Committee the investigator has 45 days to appeal the decision directly to the Chancellor.

G. **Expedited Review.** 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 COI 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.

V. **Categories of Conflict of Interest.** Activities and situations that could present conflicts 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 Regental approved agreements such as the School of Medicine faculty practice plan.

B. **Activities that appear to present potential conflicts of interest or commitment include:** 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 Regental 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. **Education and Training.**

**A. Information.** Letters, email notifications and articles in UC Denver 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/policiesAcademic/Conflict-of-Interest.pdf.

Individuals must acknowledge their understanding of this policy as part of submitting the Annual Conflicts of Interest Disclosure Form. The form is returned to the Office of Regulatory Compliance.

**B. Training.** UC Denver is committed to communicating our standards for ethical conduct and UC Denver policies to all employees. UC Denver provides education and training to develop awareness and stress compliance with the Conflict of Interest and Conflict of Commitment Policy. The Conflict of Interest training course that is offered online, in didactic sessions, or through individual study guide. Materials and resources are also available at
www.uchsc.edu/regcomp/coi

VII. Compliance Monitoring.

A. Office of Regulatory Compliance. The Office of Regulatory Compliance will establish a monitoring program in conjunction with the COI official and the COI Committee that will review approved activities and monitor compliance by the Covered Individuals with management plans. The Office of Regulatory Compliance will also work with the COI Committee to establish a self-evaluation tool of the Committee. Reports of the monitoring activities will be provided to the UC Denver Compliance Committee and the Chancellor.

B. 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 COI Committee.

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

Following final review and recommendation by the COI Committee, the Office of Regulatory Compliance will maintain all COI forms and management plans. All COI forms and management plans are official records and will be maintained according to an appropriate retention schedule. 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 an UC Denver business purpose. However, the information (i.e., COI forms, management plans or monitoring procedures) may be released in accordance with and as required by Colorado law or lawful court order. Where possible, summary reports of the COI Committee may be released to the public to promote research openness and integrity, particularly as it relates to required disclosures in informed consent documents.

IX. Reports.

The COI Official will submit a report to the Chancellor within sixty (60) days of the annual disclosure requirements. Ongoing reports will be presented by department and summarized at the School and Vice Chancellor level. Copies of the reports will be sent to the various Deans and Vice Chancellors. Final determinations regarding any other conflicts and disclosures that are submitted/disclosed during the fiscal year must be submitted to the Chancellor on a rolling quarterly basis. The report shall include the following information:

1. the total number of disclosure forms received from individuals in that unit (including percentage of timely completion);
2. the number of individuals disclosing conflicted activities;
3. the number of activities that were approved and denied;
4. the number of activities for which measures for managing conflicts have been established; and
5.  the activities by category of review.

The report shall be presented by department or other academic service area or administrative area and summarized at the School or Vice Chancellor level.

X. **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 COI Official and the Assistant Vice Chancellor for Regulatory Compliance 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 Office of Regulatory Compliance will make recommendations to the Chancellor or designee on actions to be taken.

XI. **Compliance Responsibility.**

UC Denver 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.

XII. **Prohibited Activities**

**UC Denver does not permit arrangements to be entered into where:** the value of the ownership interest, stock options, or other interest in a financially related company of any value may be affected by the outcome of the research, or the amount of the compensation will be affected by the outcome of the research.

XIII. **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.

XIV. Interpretation.

Questions concerning the interpretation or applicability of this policy should be directed to the UC Denver Office of Regulatory Compliance.
Appendix I

Conflict of Interest Examples

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

1. A researcher uses his laboratory at UC Denver 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 UC Denver 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 Trail 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 participate in the informed consent process 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 Trails of University Technology – No person shall participate in a clinical trail 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


Federal Policy and Guidelines


National Institute of Health Guidance Documents

Office for Human Research Protections Guidance Document
http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf

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/research/GAO.pdf

The University of Colorado System - Regents Laws Article 3, Part E
http://www.cu.edu/regents/Laws/Article3E.htm

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

Policy 6A
http://www.cu.edu/regents/Policies/Policy6A.htm
CU Administrative Policy Statements
Conflict of Interest Policy (Current)
   http://www.cusys.edu/policies/Academic/coninterest.html

Conflict of Interest and Commitment Policy (Draft)
   INSERT WEBSITE


Officer Disclosure of Interests _
   http://www.cusys.edu/policies/Fiscal/Officer-Disclosure.pdf

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

Campus Procedures – in development

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

Association of American Medical Colleges,
   Protecting Subjects, Preserving Trust, Promoting Progress: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research __
   http://www.aamc.org/research/coi/firstreport.pdf

   Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution’s Financial Interests in Human Subjects Research __

   Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research,”
   http://www.aamc.org/jointcoireport

U.S. Medical School Policies on Individual Financial Conflicts of Interest: Results of an AAMC Survey __


Council on Governmental Relations Publications _
   http://www.cogr.edu/files/publications_Conflicts.cfm

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