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Research Conflict of Commitment and Conflict of Interest

PURPOSE

The purpose of this policy is to provide guidelines for Individuals for establishing principled outside financial relationships with industry and other organizations and to establish rules for interactions with Industry, medical service representatives and other vendors throughout Denver Health and Hospital Authority (Institution) while remaining in compliance with disclosure, management and approvals. The Institution supports principled relationships with industry and other organizations in which its faculty and staff collaborate. The Institution has adopted the following policy to protect the integrity of research, the objectivity of education, the safety of human subjects in research, the quality of patient care, the reputations of faculty and staff, and their professional commitment to the Institution - all of which promote the public's trust in the Institution and the healthcare profession.

SCOPE

Denver Health and Hospital Authority (DHHA) – All locations and departments

DEFINITIONS

- A. *Individual:* a faculty member, employee, student, trainee or volunteer who owes a primary duty of loyalty and support to the Institution, including part-time appointments. Individual includes spouse and dependent children when considering financial or fiduciary interests.
- B. *Institution:* Denver Health and Hospital Authority aka Denver Health, DHHA, and its controlled affiliates.
- C. *Industry:* Biomedical, pharmaceutical and medical device companies and companies that make other products used in the treatment of patients or the provision of medical care and/or vendors of the Institution.
- D. *Income:* The amount of money received during a period of time in exchange for labor or services, from the sale of goods or property, or as a profit from financial investments.
- E. *Entity:* A for-profit or not-for-profit organization for which an Individual spends considerable time and/or receives income.

- F. *Equity*: The ownership interest of shareholders in a for-profit corporation, partnership, or similar organization, as determined through reference to public prices or other resources of fair market value.
- G. *Conflict of Commitment*: A situation in which an Individual's Outside Interests may appear to interfere with the Individual's ability to fulfill his or her commitment to the Institution; or an Individual's responsibilities, financial interest or opportunity for personal benefit in connection with an Outside Interest may appear to interfere with the Individual's professional judgment in exercising any Institutional duty or responsibility. Any relationship with an outside entity that requires frequent and/or prolonged hours of effort spent outside Denver Health may present a conflict of commitment, *regardless of amount of income received or the, number of days, time of day or day of the week devoted to the sea activities*.
- H. *Conflict of Interest*: In professional and scientific endeavors refers to a situation in which financial or other personal considerations may compromise, or have the appearance of compromising, an Individual's professional judgment in conducting or reporting research, patient care, or carrying out or directing other types of institutional programs. The bias that may result from such conflicts could impact not only the collection, analysis, interpretation and reporting of data, but also on the hiring of staff, procurement of materials, or other activities influencing the course of the institution's objectives.
- I. *Industry-Sponsored Travel*: Individuals must disclose on the **Travel Authorization** the occurrence of any reimbursed or industry-sponsored travel (i.e., that which is paid on behalf of the Individual and not reimbursed to the Individual so that the exact monetary value may not be readily available), related to the Individual's institutional responsibilities. However, the disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:
1. A federal, state, or local government agency
 2. An Institution of higher education as defined at 20 U.S.C. 1001(a)
 3. An academic teaching hospital
 4. A medical center
 5. A research institute that is affiliated with an Institution of higher education.
- J. *Travel Authorization*: A form that serves as the disclosure for all travel including pre-paid Industry-Sponsored Travel and must be completed in its entirety prior to any professional travel. Reimbursed or Industry-Sponsored travel information will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of travel. The Director of SPARO, in conjunction with the Director of Compliance and Internal Audit will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest (FCOI) with PHS-funded research. These determinations will be shared with the Assistant Vice Chancellor for Regulatory Compliance at UCD.
- K. *Conflict of Interest Committee (COIC)*: A Committee of UCD faculty and administrators responsible for ensuring that individual conflicts of interest in research are identified, managed, or eliminated, in accordance with federal regulations and in the best interests of research subjects, trainees, researchers and the Institution. Denver Health entered into an agreement with University of Colorado, Denver for their COIC to perform this service for Denver Health and to provide management plans, when required by the PHS.
- L. *Outside Employment*: Services provided for entities outside the Institution for which an Individual spends considerable time and/or receives income. All Outside Employment requires prior approval and includes, but is not limited to, consulting, scientific advisory board memberships, clinical trial review panels, developing educational materials, teaching, laboratory testing, expert legal testimony, paid court

appearances, and legal expert witness consultation activities. Other activities considered Outside Employment that require prior approval are fiduciary and management roles in organizations outside the Institution, including board member appointments, and serving as an officer, manager, or medical director of a for-profit company, non-profit organization or charitable foundation. If a Denver Health employee chooses to take PTO and consult with an outside entity, they can be paid directly. If the work is done on Denver Health time, the Denver Health employee needs to sign over the honorarium to Denver Health to be deposited into an academic enrichment fund.

- M. *Outside Interest*: A personal professional relationship with any domestic or foreign, public or private, entity (excluding a Federal agency) with which an Individual (and spouse, domestic partner, or dependent children) has a financial interest or regular time commitment.
- N. *Financial Interest*: Anything of monetary value, whether or not the value is readily ascertainable; including income for services, ownership, equity interest, and fiduciary or management relationships, whether paid or unpaid.
- O. *Significant Financial Interest (SFI)*: A financial interest consisting of one or more of the following interests of an Individual (and those of the Individual's spouse, domestic partner, or dependent children):
1. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any income received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
 2. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any income received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 3. Significant Financial Interest EXCLUSIONS:
 - a. Salary, or other income paid by the Institution to the Individual if the Individual is currently employed or otherwise appointed by the Institution
 - b. Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights
 - c. Any ownership interest in the Institution held by the Individual, if the Institution is a commercial or for-profit organization.
 - d. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Individual does not directly control the investment decisions made in these vehicles.
 - e. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
 - f. Income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- P. *Investigator*: The project director or principal Investigator and any other person, regardless of title or position, who the Institution deems is responsible for the design, conduct, or reporting of research funded

by PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Q. *Financial Conflict of Interest (FCOI)*: a situation in which the Institution, through its designated official(s), reasonably determines that an Investigator's SFI is related to a PHS-funded research project and could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

R. *Sub recipient*: A party that receives a subaward from a recipient or another sub recipient under a Federal financial assistance award and is accountable to the recipient or sub recipient for the use of the Federal funds provided by the subaward.

POLICY

A. Individuals are required to disclose to the Institution any outside interests, including time commitments and financial relationships, with Industry or other outside organizations, including outside interests of immediate family members that are related to the Individual's Institutional duties. The Department of Sponsored Programs and Research (SPARO) will work in conjunction with the Office of Integrity and the University of Colorado, Denver (UCD) Office of Regulatory Compliance to assist faculty and staff in managing any associated conflicts of interest or commitment which might arise in permissible personal outside financial relationships, and eliminating those that cannot be effectively managed.

B. This policy applies to all Denver Health providers, DHHA employees, students, trainees or volunteers.

PROCEDURES

A. Conflict of Interest and Disclosure:

Faculty and staff members of DHHA, in recognizing that their primary professional responsibility is to the Institution will devote their energies to external activities in congruence with the Institution's mission and will conform to each section of this Policy. Providers, staff and/or credentialed staff must disclose any outside commitments annually through electronic procedures established by the Office of Integrity. Conflict of commitment and disclosure policies as well as Employee Principals and Practices are Conflict with Operational Objectives -Management Employees (4-137); Conflicts of Interest (4-112) and Employment at other Organizations (4-125) and Conflicts of Interest Policy for Medical Staff.

1. Use of the Institution's Resources:

- a. Denver Health and Hospital Authority governs an Individual's participation in any agreement under which an outside entity will profit from the resources (including information) of the Institution as well as from the Individual's personal involvement. Examples include but are not limited to start-up companies, inventions and patent ownership, data ownership, authorship and copyright ownership.
- b. Because consulting arrangements and publication of books involve an Individual's personal effort, contracts for publications and payment of related royalties are not subject to sharing of income with the Institution, although they still must be reported and approved prior to any activity.
- c. The Individual must report to the Institution if the Institution will investing its resources and sharing in the risks of a venture or in any other way subsidizing the activity, whether or not sharing in any revenues generated by the activity.

B. Sharing of Intellectual or Tangible Property:

Individuals must disclose any relationship they are considering or are engaged in with an outside entity when the entity anticipates providing financial or other support for the Individual's work, or when the entity

anticipates utilization of intellectual property (e.g., inventions, know-how) or tangible property (e.g., research materials) or original works of authorship (e.g., computer software but not textbooks) of that Individual's academic work or the work of a subordinate Individual in compliance with P-21.160 Intellectual Property Policy.

C. Submission of Research Proposals

Individuals acting as Investigators or otherwise conducting Industry-sponsored research, must comply with all institutional and federal requirements regarding management of conflicts of commitment and conflicts of interest as specified in Institutional policies and/or PHS regulation 42 CFR, Part 50, Subpart F and 45 CFR, Part 94.

- Conflict of Interest and Disclosure:

A. The Institution requires that providers, staff and/or credentialed staff disclose annually all outside interests, both research and non-research related, each year through the online disclosure process that is conducted by the Office of Integrity at Denver Health.

In addition, annual disclosures are required by all persons working on research projects through UCD's InfoEd portal. Upon disclosing outside interests, UCD's Office of Regulatory Compliance will identify financial interests and report to the COIC, which will set forth plans to manage identified SFIs. Sponsor specific disclosure is required for non-grant-funded, industry-sponsored travel. Individuals must update his/her disclosure within 30 days of a substantial change in external activities.

1. Disclosure of sponsor specific interests is required with submission of grants, contracts, and regulatory protocols and through requisitions to Institutional purchasing committees.
2. Conflicts of interest in clinical research require disclosure of financial relationships with Industry to the human subjects enrolled in the project.
3. Public disclosure of outside interests is required for all publications (including news releases), presentations (including posters) and approved media contact related to an Individual's relationship with the sponsor of his/her research or in the ownership of a related entity or intellectual property, such as new or experimental drugs, devices or therapies.
4. Prior to professional travel, the Individual will disclose the Sponsor's name, the destination, purpose and duration of travel by fully completing the Travel Authorization Request.
5. Clinicians with past and/or present financial relationships with Industry (e.g., consulting and speaking agreements, research contracts) must disclose relationships to patients when such a relationship might appear to be a conflict of interest.
6. Disclosure of financial interests will be made by all Institutional Review Board (IRB) members, and by all Institutional purchasing and formulary committee members. Committee members with a financial interest in a sponsor or vendor will recuse themselves from voting on decisions involving the entity in which they have an interest.

B. Financial Conflict of Interest (FCOI) in Research:

On behalf of the COIC, the Office of Regulatory Compliance evaluates all disclosures of financial interest, including a review of related research projects to determine if a FCOI exists for PHS-funded research or if an SFI may be a potential conflict of interest on all other sponsored research. If the Office of Regulatory Compliance determines that a FCOI exists on PHS-funded research, the COIC reviews the design, conduct, and reporting of the research to determine and implement the appropriate management and reporting in accordance with PHS regulations 42 CFR, Part 50,

Subpart F and 45 CFR, Part 94, and state regulations, to protect the credibility and integrity of the Institution's faculty and staff. If the Office of Regulatory Compliance determines that a significant financial interest exists for other sponsored research, it reviews the design, conduct and reporting to determine and implement the appropriate management and reporting for potential conflicts of interest.

C. Human Subject Research:

If a potential conflict of interest is identified in research involving human subjects, the IRB and COIC at UCD will conduct their respective reviews in parallel, and the IRB will withhold final approval pending the completion of the COIC review, resolution of the issues and recommendations for management. The management plan will be provided to the Director of SPARO for submission to PHS.

D. DHHA Compliance with PHS regulation 42 CFR, Part 50, Subpart F and 45 CFR, Part 94 in PHS-funded research. Prior to the expenditure of funds and within 60 days of any subsequently identified FCOI on PHS-funded research:

1. The Institution shall adhere to its publicly available policy and provide reports regarding identified FCOI to the PHS Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this regulation.
2. The Institution will ensure that each Investigator is informed of its policy on FCOI, the Investigator's responsibilities regarding disclosure of SFI's, and of these regulations. Each Investigator must complete training regarding FCOI requirements prior to engaging in research related to any PHS-funded contract and at least every four years, and immediately when any of the following circumstances apply:
 - a. The Institution revises its FCOI policies or procedures in any manner that affects the requirements of Investigators.
 - b. An Investigator is new to the Institution.
 - c. The Institution finds that an Investigator is not in compliance with the Institution's FCOI policy or management plan.
3. If an Investigator carries out PHS-funded research through a subrecipient (e.g., subcontractors, or consortium members), the Institution will take reasonable steps to ensure subrecipient Investigator compliance through:
 - a. A written agreement with the subrecipient that establishes whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.
 - b. The Director of SPARO will provide FCOI reports to the PHS Awarding Component regarding all FCOI of all subrecipient Investigators consistent with this regulation.
4. If an Investigator's SFI is related to PHS-funded research:
 - a. The COIC determines if the SFI could be affected by the PHS-funded research, or is in an entity whose financial interest could be affected by the research.
 - b. The COIC determines if a FCOI exists when the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
5. Management of an identified FCOI initiates development and implementation of a management plan by the COIC and, if necessary, a retrospective review and mitigation report pursuant to § 94.5(a).

6. The Institution provides initial and ongoing FCOI reports to the PHS awarding component as required pursuant to § 94.5(b).
 7. The Institution maintains records relating to all Investigator disclosures of financial interests, the COIC's review of, and response to, such disclosures, and all actions under Institutional policies or retrospective review, if applicable, for at least three years from the date of the final expenditure of funds.
 8. The Institution maintains enforcement mechanisms and provides sanctions and other administrative actions to ensure Investigator compliance as appropriate.
 - a. The Institution ensures public accessibility, via written response to any requestor within five business days of a request, for information concerning any SFI disclosed to the Institution that meets the following three criteria:
 - b. The SFI was disclosed and is still held by Investigator
 - c. The Institution determines that the SFI is related to the PHS-funded research
 - d. The Institution determines that the SFI is a FCOI
 9. The information available via written response to any requestor within five business days of a request shall include, at a minimum, the following:
 - a. Investigator's name,
 - b. Investigator's title and role with respect to the research project,
 - c. Name of the entity in which the SFI is held,
 - d. Nature of the SFI, and
 - e. Approximate dollar value of the SFI, 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.
- Other External Professional Relationships Requiring Prior Approval:
 - A. Receiving Travel Funds from an Industry Sponsor (Travel Authorization): Individuals may accept travel funds or reimbursement from industry in the following circumstances:
 1. For reimbursement for travel to provide contractual services, such as approved consulting.
 2. Participate in meetings directly related to ongoing sponsored research.
 3. To view capital equipment in situ if the equipment is being considered for purchase by DHHA; must submit request for prior approval by his/her Director of Service through DHHA's Travel Authorization Site.
 4. To participate in initial and ongoing education necessary to operate or use products and devices which require specialized expertise and are currently being used at the Institution; must submit request for prior approval by his/her Director of Service through DHHA's Travel Authorization Site.
 5. Students and trainees may accept travel funds from scientific societies whether or not Industry is the source of the funds, provided that the society controls the selection of the recipient of travel support.
 - B. Receiving Licenses, Royalties and Equity Individuals must disclose their proposed outside relationships with industry and other entities in which they expect to receive royalties or equity under

which they or DHHA is expected to license DHHA-owned technology or copyrights, as defined in the UCD Tech Transfer Policy. These relationships must be reported in advance to the appropriate Director of Service for review and approval prior to agreeing to, engaging in, or accepting income for the activities.

- C. Engaging in a Faculty Start-up Company Individuals must disclose their proposed outside professional relationships with their own and other DHHA start-up companies in which they have or expect to have a financial interest or under which they or DHHA is expected to license DHHA -owned technology or copyrights, as defined in the UCD Tech Transfer Policy. These relationships must be reported in advance to the appropriate Director of Service for review and approval prior to agreeing to, engaging in, or accepting income for the activities.
 - D. In-Kind Gifts to the Institution: Gifts and loans to the Institution of equipment, devices, supplies and similar items from Industry for use in education, research or clinical care must be consistent with institutional guidelines and procedures and will have no expectation of return benefit, or “quid pro quo”. The Denver Health Foundation will document and process all gift transactions.
- Sanctions for Breach of Policy:
 - A. Individuals have an obligation to comply with the Conflict of Commitment and Conflict of Interest Policy.
 - 1. Examples of conduct that violate this policy include:
 - a. Failure to submit required conflict of interest disclosure statements
 - b. Intentional deception or dishonesty in disclosures,
 - c. Repeated omission of industry relationships in disclosures, or
 - d. Failure to comply with management plan requirements.
 - 2. These examples are not intended to be exhaustive. Reports of suspected violations may be made to any of the Individuals listed below, or anonymously through the DHHA compliance hotline. Suspected violations will be investigated by the Research Compliance Analyst and referred to the following for sanctioning as appropriate:
 - a. Students: Department of Education
 - b. Graduate Students: Department of Education
 - c. Postdoctoral: Department of Education
 - d. Staff: Human Resources v. Nurses: Chief Nursing Officer
 - e. Physicians: Chief Medical Officer
 - f. House Staff: Chief Medical Officer
 - B. Possible penalties may include:
 - 1. Reimbursement to the Institution for misused resources
 - 2. Formal reprimand for placement in employee or student file
 - 3. Ineligibility to participate in grant applications or on committees
 - 4. Dismissal from an educational or training program.
 - 5. Termination of employment.
 - C. If the failure of a research investigator to comply with this policy has, or appears to have, biased the

design, conduct, or reporting of PHS-funded research, in accordance with 42 CFR Part 50 Subpart F, Section 50.606 (a) and 45 CFR, Part 94, the Institution must promptly notify the PHS Awarding Component of the findings and corrective action taken or to be taken. The PHS Awarding Component will consider the situation and may take appropriate action or refer the matter to the Institution for further action, such as determining how to maintain appropriate objectivity in the funded project.

- D. Allegations of research misconduct are addressed by a separate policy entitled P-21.270 Responding to Allegations of Research Misconduct. If, in the course of investigating allegations of research misconduct, evidence of violations of the Conflict of Commitment and Conflict of Interest Policy is discovered, the SPARO Research and Compliance Analyst conducting the research misconduct investigation may consult with the University of Colorado Denver's Conflict of Interest Office to determine the need for any additional course of action.

EXTERNAL REFERENCES

A. Governing Law of Regulations/Guidelines:

1. Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94) <http://grants.nih.gov/grants/policy/coi/>
2. Bayh-Dole Act (1980), 37 CFR 401.1-16 <http://www.gpo.gov/fdsys/pkg/CFR-2002-title37-vol1/content-detail.htm>
3. Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) <http://oig.hhs.gov/fraud/enforcement/cmp/index.asp>
4. "Stark Law" Section 1877 of the Social Security Act 42 U.S.C. 1395nn, <https://www.cms.gov/PhysicianSelfReferral/>
5. Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of CME: Standards to Ensure the Independence of CME Activities
6. PhRMA: <http://www.phrma.org/>
7. AdvaMed: <http://www.advamed.org/MemberPortal/>

RELATED DHHA DOCUMENTS

- A. [Intellectual Property](#)
- B. [Responding to Allegations of Research Misconduct](#)
- C. [Code of Conduct](#)
- D. [Conflicts of Interest](#)
- E. [Employment at Other Organizations](#)
- F. [Continuing Education](#)
- G. [Employee Travel](#)

Attachments:

[Image 01](#)