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Owner Norma Stiglich:
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Conflicts of Interest

COPY

Policy

PURPOSE

To identify and manage potential conflicts of interest that may affect decisions and influence operations at Denver Health (DH). The purpose of this policy is to protect patient safety, quality of patient care, integrity of research, objectivity of education and training, and the reputations and professional commitments of faculty and staff.

SCOPE

This policy applies enterprise-wide to Denver Health Employees, Board Members ("Directors"), Affiliates, Contractors and Agents for all DH entities.

DEFINITIONS

Affiliate: Staff from organizations with affiliation agreements with Denver Health (DH).

Conflict of Interest: Outside relationships, financial interests, or circumstances that create an actual or perceived conflict of interest in a person's ability and obligation to act in the best interests of DH and its patients. A Key Person's responsibilities could be affected or appear to be affected if the Outside Activity:

- A. Influences the way the individual performs his or her DH responsibilities, or influence the individual's conduct or decisions.
- B. Impairs the individual's judgment in performing his or her DH responsibilities.
- C. Induces the individual to disclose confidential or proprietary information acquired through the performance of DH responsibilities.
- D. Influences DH contracting and procurement activities in ways that financially benefit the individual or their Immediate Family Members.

Contractor: Individuals paid by DH in accordance with contractor agreements, either with the individual or with a business or company. These individuals are not employees of DH and may be self-employed and are not eligible for employee benefits provided by DH.

Financial Interest: A compensation arrangement or ownership interest that provides monetary value, whether or not the value is readily ascertainable (for example, leases, equity, incentive plans, outside employment, honoraria, sponsored travel, consulting, paid board memberships, publications, etc.).

Immediate Family Members: Includes husband or wife; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law.

Institutional Animal Care and Use Committee (IACUC): Responsible for the oversight and evaluation of an institution's animal care and use program, procedures and facilities.

Institutional Review Board (IRB): Any board, committee, or other group formally designated by an institution to review, approve the initiation of, and conduct periodic review of research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of human subjects. COMIRB is the designated IRB for DH.

Investigator: The Principal Investigator/Project Director, Co-Principal Investigator(s), and any other persons ("Research Personnel") who are responsible for the design, conduct, or reporting of research, educational or service activities funded--or proposed for funding--by an external sponsor. This includes sub-recipients of funds.

Key Personnel/ Key Person:

- A. DH personnel who hold a .5 FTE or higher in the following departments: Enterprise Compliance Services (ECS), Sponsored Programs and Research Office (SPARO), Finance, Office of General Counsel, Risk Management, and Purchasing. (Administrative support or clerical staff may be excluded at the discretion of management.)
- B. DH personnel who hold a .5 FTE or higher and serve as managers, supervisors, or executive staff.
- C. Denver Health Board Members.
- D. DH medical staff members who hold a .5 FTE or higher.
- E. DH personnel serving on key committees that make compliance, financial, purchasing, or pharmacy and therapeutic decisions.
- F. DH personnel who are known to select or place orders with vendors (other than persons

involved with only *de minimis* purchases such as administrative assistants who order small quantities of office supplies).

- G. Any other person designated by management where a potential conflict may affect their ability to carry out their job responsibilities.
- H. Investigators and research personnel.

Management Plan: A written agreement that outlines necessary conditions and prescribed actions to reduce, eliminate, or manage Conflicts of Interest or Outside Activities.

Nepotism: A situation in which an individual's Immediate Family Member(s) are employed by the same organization and fall within the same chain of command as the individual (e.g. the individual supervises or is supervised by an Immediate Family Member).

Outside Activities: Participation in professional activities or other employment on a full-time, part-time, freelance, or voluntary basis that could reasonably be perceived as similar or related to duties associated with employment with DH.

Organizational Conflict of Interest: Organizational conflicts of interest may arise when a non-federal entity with a federal contract or grant award has a relationship with a parent company, affiliate, or subsidiary organization which causes that entity to be unable or appear to be unable to be impartial in conducting a transaction involving the parent company, affiliate, or subsidiary organization. In procurement, organizational conflicts of interest mean that because of relationships with a parent company, affiliate, or subsidiary organization, Denver Health is unable, or appears to be unable, to be impartial in conducting a procurement action involving a related organization.

Significant Financial Interest in Research: As defined in 42 CFR 50, a Financial Interest consisting of one or more of the following interests of an Investigator (and those of the Investigator's Immediate Family Members):

- A. 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.
- B. 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 Immediate Family Members) holds any equity interest, or intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
- C. Significant Financial Interest exclusions:
 - 1. Salary or other income paid by DH to Investigators;
 - 2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
 - 3. 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; and

4. 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.

Significant Relationship: (a) An Outside Activity relationship between a DH employee and their DH supervisor, direct report, or Board Member. (b) Situations that could create real or perceived Nepotism.

POLICY

All decisions of Denver Health (DH) Key Personnel and Contractors who serve as agents of DH are to be made solely on the basis of promoting the best interests of DH. It is expected for each person to:

- A. Avoid actual or potential Conflicts of Interest, including the appearance of a Conflict of Interest;
- B. Demonstrate the highest standards of personal integrity in all actions related to or affecting the business of DH;
- C. Not use a relationship with DH to benefit themselves or any Immediate Family Member;
- D. Not disclose, use, or allow others to use DH information for personal gain;
- E. Not accept nor solicit any fee, compensation, gift, gratuities, favors, payment of expense, or any other thing of monetary value from contractors, parties to subcontracts, vendors, or other outside parties, except as expressly authorized by policies of DH (Please see Gifts and Interactions with Vendors, Code of Conduct);
- F. Not engage in Outside Activities, except as disclosed and expressly authorized;
- G. Not use DH time, property, equipment, supplies, or support services for personal gain, unless expressly authorized by DH policies;
- H. Not represent the interest of another person, business, or other entity against the interests of DH in any claim, proceeding, or litigation in which DH is a party;
- I. Not enter into or approve any transaction that creates an actual or perceived Organizational Conflict of Interest;
- J. Promptly disclose to his/her supervisor of potential Conflict of Interest or Organizational Conflict of Interest.

Enterprise Compliance Services and Human Resources are responsible for the administration and oversight of this policy and procedures. Any other individuals that are affected by the Conflict of Interest procedures are trained on this policy and related procedures on an annual basis, and following any revisions that result in a procedural change.

PROCEDURES

A. DISCLOSURE

1. DH Key Personnel must disclose Outside Activities, Significant Relationships, and

Significant Financial Interests:

- a. When they are on-boarding as a new DH Employee.
 - b. As assigned by Enterprise Compliance Services (ECS) during the annual DH Conflicts of Interest Disclosure Questionnaire Campaign.
 - c. At the point of transfer from a position that does not require annual reporting into a DH position that requires annual reporting (e.g, into a Key Personnel or medical staff position).
 - d. Within 30 days of discovering or acquiring a new Financial Interest (e.g., through purchase, marriage, or inheritance) or engaging in a new Outside Activity.
 - e. For Research: At the time of application for research funding and/or application to the IRB/IACUC for approval of research (i.e., one cannot submit a grant, IRB protocol or IACUC protocol if a current questionnaire is not on file). Research Personnel must disclose any circumstance that may have an impact on the research design, conduct, analysis, or reporting.
 - f. For Research: Within 30 days of receiving sponsored reimbursement or sponsored travel.
 - g. For contractors, in accordance with their contractual agreement with Denver Health
2. Members of the medical staff and DH employees in a management or supervisory role must disclose and obtain written permission prior to engaging in employment outside of DH as follows:
- a. The Chief Human Resources Officer reviews requests from management and supervisory personnel.
 - b. The Chief Medical Officer reviews requests from employed medical staff.

B. MANAGEMENT

1. Enterprise Compliance Services (ECS) reviews Conflict of Interest questionnaires disclosing the actual or potential Conflict of Interest and consults with the affected individual, managers, and supervisors as necessary.
2. When ECS is unable to effectively manage a Conflict of Interest situation alone, they may consult with Human Resources, Office of Research, Office of General Counsel, or other departments as applicable.
3. The following factors are considered, among others, in evaluating an interest or activity for a potential or actual Conflict of Interest:
 - a. Whether the activity or interest may interfere with performance or responsibilities.
 - b. Whether access to confidential information may be affected.
 - c. Whether the conflict may have an impact on DH operations, research, patients, providers, medical staff, Investigators, suppliers, vendors, etc.

- d. The extent to which the conflict would result in financial or personal gain.
 - e. Whether the potential conflict would compromise the scientific integrity of any research or clinical trial conducted at DH.
 - f. Consistency with past Conflict of Interest decisions.
4. When a Conflict of Interest exists, DH may resolve the conflict by pursuing remedial options, documented in a Conflict of Interest Management Plan. Such options may include:
- a. Managing the Conflict of Interest through public disclosure (e.g., in publications and presentations), monitoring of activity, or recusal.
 - b. Minimizing the Conflict of Interest through required actions to reduce risk (e.g., recusal from participation in the selection, award, or administration of a contract or agreement, disclosure of significant relationships, recusal from business discussions or decision-making, alternate reporting lines or monitoring, reassignment of duties).
 - c. Eliminating the Conflict of Interest by not participating in the conflicting activity, divesting from the interest that creates the Significant Financial Interest, or severing the relationship causing the Conflict of Interest.
5. More specifically for research activities:
- a. DH Investigators submitting applications for funding and/or participating in Public Health Service (PHS)-funded research, which includes the National Institutes of Health, must comply with 42 CFR 50 Subpart F for grants and with 42 CFR Part 94 for contracts.
 - b. When carrying out PHS-funded research through a subrecipient (e.g., subcontractor or consortium member), DH determines whether subrecipients will follow the DH Conflict of Interest policy or the subrecipient's conflict of Interest policy and take reasonable steps to ensure compliance. See [Subrecipient Monitoring of Federal Awards](#).
 - c. Members of the DH community may not review, approve, or administratively control contracts, grants, clinical trials, or other business relationships related to research in which the person or an Immediate Family Member of the person has a Conflict of Interest, Significant Financial Interest, or Outside Activity, such as being employed by the sponsor of the research or the technology, that could be affected by the outcome of the research.
 - d. Investigators and Research Personnel are trained on their responsibilities outlined in this policy:
 - i. Prior to engaging in PHS-funded research;
 - ii. Immediately when this policy is revised or upon discovering non-compliance with this policy and procedure; and
 - iii. At least every four years.
 - e. Conflicts of Interest are reported to external funding agencies and sources

for research as follows:

i. Federally Funded Projects

- a. *Initial Reports*. DH reports Significant Financial Interests to the appropriate funding agency/ component prior to distributing funds.
- b. *Updated Information*. DH reports updates of Significant Financial Interests within 60 days of any subsequently identified or modified conflicts or in accordance with applicable rules, regulations or guidelines.
- c. *Annual Reports*. DH provides an annual report that specifies the status of any Significant Financial Interests and any changes to Management Plans. These annual reports are made for the duration of the project(s), including extensions with or without funds if specified by the funding agency/component.
- d. *Non-Compliance*. If an Investigator fails to comply with this policy and has, or appears to have, biased the design, conduct, or reporting of federally funded research, DH promptly notifies the funding agency/ component of the findings and corrective action taken or to be taken.
- e. *Request of the Department of Health and Human Services*. DH promptly makes Financial Interest disclosures, reviews, and Management Plans available to the Department of Health and Human Services upon request.

ii. Non-Federally Funded Projects:

- a. Reporting and management of potential or actual Conflicts of Interest for non-PHS funded projects complies with the sponsors' Conflict of Interest procedures and requirements.

f. Public transparency and accessibility of requested information:

- i. For any PHS-funded research project and as required under 42 CFR 50 Subpart F (b)(5), any person may request information about Significant Financial Interests or Management Plans of Investigators and Research Personnel. The request must be specific enough, however, for the Enterprise Compliance Services department to identify such Investigators or Management Plans. Within five business days of the request, DH provides:
 - a. Investigator's name.

- b. Investigator's title and role with respect to the research project.
 - c. Name of the entity with which the Investigator has a Significant Financial Interest.
 - d. Nature of the Significant Financial Interest.
 - e. Value of the Significant 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 over \$100,000 in increments of \$50,000) or a statement that the Conflict of Interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
- ii. Public disclosure of research Conflicts of Interest are also provided in publications (including news releases), presentations (including posters), and approved media, as appropriate.

C. POLICY VIOLATION

1. A DH Employed Key Person who violates this policy may be subject to appropriate disciplinary action, including termination.
2. Examples of conduct that violate this policy include, but are not limited to:
 - a. Failure to submit applicable Conflict of Interest questionnaires.
 - b. Intentional deception or dishonesty in Conflict of Interest questionnaires or disclosures.
 - c. Repeated omission of industry relationships in questionnaires.
 - d. Failure to comply with Management Plan requirements.
3. Suspected violations are investigated by the Enterprise Compliance Services department. If the employee is also affiliated with University of Colorado Denver | Anschutz Medical Campus, the Enterprise Compliance Services Department collaborates with the University of Colorado Conflict of Interest Committee.
4. For Conflicts of Interest with research, it may be necessary to perform a retrospective review of the activities to determine bias in the design, conduct, or reporting of research.

D. EXCEPTIONS

1. Exceptions to this policy must be approved by the Chief Compliance and Audit Officer and, when research is involved, the Chief Research Officer.

EXTERNAL REFERENCES

- A. OMB 2 CFR 200 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards; Final Rule. <https://www.ecfr.gov/cgi-bin/text->

[idx?node=2:1.1.2.2.1](#)

B. 42 CFR 50, Subpart F – Promoting Objectivity in Research. <https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:1.0.1.4.23#sp42.1.50.f>

DHHA RELATED DOCUMENTS

[Denver Health Code of Conduct](#)

[Methods of Purchasing](#)

[Records Retention](#)

[Gifts and Interactions with Vendors](#)

[Subrecipient Monitoring of Federal Awards](#)

[Employee Travel](#)

[Medical Staff Frequently Asked Questions \(FAQ\)](#)

[All Staff Frequently Asked Questions \(FAQ\)](#)

[COI Questionnaire](#)

[Management Plan](#)

ATTACHMENTS

None

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Approval Signatures

Step Description	Approver	Date
Medical Staff Executive Committee	Kirsten Lund: Physician - OB/ GYN	11/2021
Research Compliance Committee	Catharine Fortney: Chief Compliance And Audit Officer	11/2021
Enterprise Compliance Services	Catharine Fortney: Chief Compliance And Audit Officer	11/2021
	Enid Wade: General Counsel	11/2021
	Catharine Fortney: Chief Compliance And Audit Officer	11/2021
	Sandra Shumaker: Research Compliance Manager	11/2021

Formatting Review

Colette Morris: Program
Manager of Document
Management

11/2021

Catharine Fortney: Chief
Compliance And Audit Officer

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