



Current Status: Active

PolicyStat ID: 6748997



**DENVER HEALTH™**  
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Origination:	08/2019
Effective:	08/2019
Last Approved:	08/2019
Last Revised:	08/2019
Next Review:	08/2022
Owner:	Catharine Fortney: Chief Compliance And Audit Officer
Document Area:	Compliance
Document Type:	Policy
Applicability:	Denver Health

## Conflicts of Interest

Policy

### PURPOSE

To identify, disclose, 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 Employees, Board Members ("Directors"), Affiliates, and Contractors working at all DH entities.

### DEFINITIONS

*Affiliate:* Staff from organizations with Affiliation agreements with DH.

*Conflict of Interest:* An Outside Activity of a DH Employee or one of the Employee's Immediate Family Members that could directly or significantly affect or appear to affect the Employee's performance of DH responsibilities. An Employee's responsibilities could be directly or significantly affected or appear to be affected if the Outside Activity may:

- A. Influence the way the Employee performs his or her DH responsibilities, or influence the Employee's conduct or decisions;
- B. Impair the Employee's judgment in performing his or her DH responsibilities; or
- C. Induce the Employee to disclose confidential or proprietary information acquired through the performance of DH responsibilities.

*Contractor:* Individuals paid by DH in accordance with contractor agreements, either with the individual or a parent agency. These individuals are not Employees of DH and may be self-employed. These individuals are not eligible for Employee benefits provided by DH.

*Employee:* Individuals employed by DH including credentialed members of the DH medical staff who are .5 FTE or higher; Key Personnel for research projects.

*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 the 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 biomedical 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 of record 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 research funds.

*Key Personnel:*

- A. DH personnel in the following departments: Enterprise Compliance Services, 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 that serve on key committees that make compliance, financial, purchasing, as well as pharmacy and therapeutic decisions.
- C. All 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).
- D. Any other person designated by management where a potential conflict may affect their ability to carry out their job responsibilities.
- E. For research, this includes, but is not limited to, the Investigator(s) / Project Director and other individuals who contribute to the scientific development, execution, analysis, and reporting of a project in a substantive, measurable way. The DH Principal Investigator determines the Key Personnel for the research study.

*Management Plan:* A written agreement that outlines conditions and prescribed actions necessary, including reduction or elimination, to manage Conflicts of Interest or Outside Activities.

*Outside Activities:* Participation in professional activities on a full-time, part-time, freelance, or voluntary basis, that are unrelated 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.

*Significant Financial Interest:* A Financial Interest consisting of one or more of the following interests of an Employee (and those of the Employee'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 Employees or other individuals working at DH;
  - 2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Employee 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.

## **POLICY**

All decisions of Directors, or persons employed by, affiliated with, or contracted with DH entities, 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 him/herself or any Immediate Family Member;
- D. Not disclose, use, or allow others to use DH information for personal gain;
- E. Not accept any fee, compensation, gift, payment of expense, or any other thing of monetary value, except as expressly authorized by policies of DH (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; and

- K. Enterprise Compliance Services and Human Resources are responsible for the administration and oversight of this policy and procedure. 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

When an actual or potential Conflict of Interest has been identified, the following procedures must be followed:

### A. DISCLOSURE

1. All Employees are expected to complete a new Conflict of Interest questionnaire to disclose when a relevant change of circumstances occurs, including:
  - a. Onboarding as a new DH Employee;
  - b. New outside employment or Outside Activities;
    - i. In addition, any Employee in a management, medical staff, or supervisory role must obtain written permission prior to engaging in other employment at DH or outside employment as follows:
      - a. The Chief Human Resources Officer reviews requests from management and supervisory personnel; and
      - b. The Chief Medical Officer reviews requests from employed medical staff.
  - c. At the point of transfer from a position that does not require annual reporting into a DH position that requires annual reporting (i.e., into a supervisor, Key Personnel, or medical staff position).
  - d. At the time of application for research funding and/or application to the IRB/IACUC for approval of research. All Research Personnel listed on the IRB or IACUC application confirm that their Conflict of Interest questionnaires on file are correct and complete, or provide updated information when warranted, as well as provide any additional information required regarding Financial Interests related to DH responsibilities (i.e., one cannot submit a grant, IRB protocol or IACUC protocol if a current questionnaire is not on file);
  - e. Within 30 days of discovering or acquiring a new Financial Interest (e.g., through purchase, marriage, or inheritance);
  - f. Within 30 days of Research Key Personnel receiving sponsored reimbursement or sponsored travel. Provided information should include the purpose of the trip, identity of the sponsor/organization, destination, and duration.
2. A [Conflict of Interest questionnaire](#) must be completed **annually** for the following:
  - a. All DH staff in the role of manager/supervisor or above;
  - b. All DH Key Personnel (for research the Key Personnel will be determined by the DH Principal Investigator); and
  - c. All faculty and members of the medical staff.

### B. MANAGEMENT

1. Enterprise Compliance Services 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 Enterprise Compliance Services 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 by the conflict;
  - 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; and
  - f. Consistency with past Conflict of Interest decisions.
4. When a Conflict of Interest exists, DH may resolve the conflict by pursuing remedial options, including the following:
  - a. Manage the Conflict of Interest through public disclosure (e.g., in publications and presentations), monitoring of activity, or recusal;
  - b. Minimize the Conflict of Interest through a Management Plan for the conflicting activity or by limiting participation in the conflicting activity; or
  - c. Eliminate 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. Each Investigator and all Research Personnel must disclose any circumstance that may have an impact on the research design, conduct, analysis, or reporting.
  - e. 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.

f. 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.
- 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 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.

g. Public transparency and accessibility of requested information:

- i. For any PHS-funded research project, 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.
- ii. Within five business days of the request, DH provides:
  - a. Investigator's name
  - b. Investigator's title
  - c. Investigator's role with respect to the research project
  - d. Name of the entity with which the Investigator has a Significant Financial Interest
  - e. Nature of the Significant Financial Interest
  - f. 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.

- iii. 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. An Employee 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 questionnaire
  - 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?rqn=div5&node=42:1.0.1.4.23#sp42.1.50.f>

## DHHA RELATED DOCUMENTS

- A. [Records Retention](#)
- B. [Gifts and Interactions with Vendors](#)
- C. [Subrecipient Monitoring of Federal Awards](#)
- D. [Employee Travel](#)
- E. [Medical Staff Frequently Asked Questions \(FAQ\)](#)
- F. [All Staff Frequently Asked Questions \(FAQ\)](#)
- G. [COI Questionnaire](#)
- H. [Management Plan](#)

## ATTACHMENTS

## Attachments:

### Approval Signatures

Step Description	Approver	Date
	Robin Wittenstein: Chief Executive Officer	08/2019
Medical Staff Executive Committee	Mark Reid: Physician	08/2019
Research Compliance Committee	Catharine Fortney: Chief Compliance And Audit Officer	08/2019
Enterprise Compliance Services	Catharine Fortney: Chief Compliance And Audit Officer	08/2019
	Shachi Mankodi: Sr Asst General Counsel	08/2019
	Wendy Charles: Research Compliance Manager	08/2019
	Gina Eisenach: Dir Compliance & Int Audit	08/2019
Formatting Review	Colette Morris: Program Manager of Document Management	08/2019
	Catharine Fortney: Chief Compliance And Audit Officer	08/2019

### Applicability

Denver Health