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Owner Sandra Shumaker: Director, Compliance
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Applicability Denver Health and Hospital Authority (DHHA)
Document Types Policy

Research Conflicts of Interest

Policy

PURPOSE

To protect the integrity of Denver Health's research functions and ensure compliance with Public Health Service (PHS) regulations for Promoting Objectivity in Research as defined at [42 CFR 50 Subpart F](#) and [45 CFR 94](#).

SCOPE

Individuals engaged in PHS-funded research conducted at Denver Health.

DEFINITIONS

Equity Interest: Any stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measure of market value.

Financial Conflict of Interest (FCOI): a Significant Financial Interest that is related to a research study and could directly and significantly affect the design, conduct, or reporting of the research.

Family Member: For the purposes of this policy, a Family Member includes an individual's spouse or domestic partner and their dependent children.

Institutional Animal Care and Use Committee (IACUC): An appointed committee responsible for the

oversight and evaluation of an institution's animal care and use program, procedures, and facilities.

Investigator: The project direct or principal investigator and any other person, regardless of title, position, or employment status at Denver Health, who is responsible for the design, conduct, or reporting of research.

PHS awarding component: The organizational unit of the PHS in Health and Human Services (HHS) that funds an Investigator's research. This includes the National Institutes of Health (NIH) Institutes and Centers.

Remuneration: includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships).

Significant Financial Interest (SFI): A financial interest (regardless of whether the value is readily ascertainable) held by an Investigator or their Family Members that meets any of the following conditions:

- A. Remuneration received from an outside entity that, when aggregated for the past twelve months, exceeds \$5,000 in value.
- B. Equity interest in a publicly traded entity that, when aggregated for the past twelve months, exceeds \$5,000 in value.
- C. Any equity interest, regardless of value, in a non-publicly traded entity.
- D. Reimbursed or sponsored travel related to an Investigator's institutional or research responsibilities (regardless of whether the exact monetary value is readily available) unless it is provided by a Federal, state, or local government, an accredited public or non-profit institution of higher education (or a research institute affiliated with such an institution), an academic teaching hospital, or a medical center.

The following are excluded from the definition of a Significant Financial Interest:

- A. Salary or other remuneration paid by Denver Health to the Investigator.
- B. Intellectual property rights assigned to Denver Health and agreements to share in royalties related to such rights with an Investigator.
- C. Income from investment vehicles, such as mutual funds and retirement accounts, if the Investigator does not directly control the investment decisions made in these vehicles.
- D. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government, an accredited public or non-profit institution of higher education (or a research institute affiliated with such an institution), an academic teaching hospital, or a medical center.

POLICY

Denver Health complies with Public Health Service (PHS) regulations at 42 CFR 50 Subpart F and 45 CFR 94. All Investigators are required to disclose Significant Financial Interests (SFI) at least annually and within thirty days of becoming aware of a new or previously undisclosed SFI. All Investigators who are members of the Denver Health Workforce must also comply with the Denver Health Conflicts of Interest

policy.

PROCEDURES

A. Investigator Responsibilities

1. Investigators disclose SFIs by completing a Conflict of Interest (COI) Questionnaire through the University of Colorado Denver (UCD) InfoEd system:
 - a. Prior to engaging in research conducted at Denver Health,
 - b. Annually during the UCD COI Disclosure Questionnaire campaign, and
 - c. Within 30 days of discovering or acquiring a new SFI.
2. Investigators complete training on research COIs when they submit their initial and annual COI disclosures through the UCD InfoEd System. Investigators may be required to complete additional training if:
 - a. This policy or the training content is meaningfully revised and new training is assigned; or
 - b. the Sponsored Programs and Research Office (SPARO) or Enterprise Compliance Services (ECS) requires additional training due to identified non-compliance with this policy.
3. Investigators collaborate in the review of SFIs and comply with COI management plans that eliminate, reduce, or mitigate identified FCOIs.
4. Principal Investigators are responsible for:
 - a. Ensuring research team members who meet the definition of an Investigator are listed as study personnel in InfoEd at the time of applying for funding or submitting a protocol for IRB approval for a research study.
 - b. Updating the list of study personnel in InfoEd when a new Investigator joins a research study and notifying SPARO of the update.

B. Institutional Responsibilities

1. SPARO confirms that COI questionnaires are up to date in InfoEd prior to the submission of applications for funding or IRB/IACUC approval for PHS-funded research.
2. The Conflict of Interest Committee (COIC) of the Colorado Multiple Institutional Review Board (COMIRB) reviews disclosures annually and at the time when an Investigator is associated with a new protocol submitted for COMIRB approval or when joining an established study.
3. ECS has a representative on the COIC and reviews disclosures and COIC-issued management plans. ECS may issue a supplemental Denver Health COI management plan with additional provisions to further eliminate, reduce, or manage FCOIs. ECS plans do not override or replace COIC-issued plans. ECS is also responsible for investigating any potential noncompliance with this policy.

C. Subrecipients on Federal funded research awarded to Denver Health

1. When Denver Health engages another entity to conduct some portion of research funded by a Federal agency, SPARO confirms whether the subrecipients will follow this policy or their own. See Denver Health policy [Subrecipient Monitoring of Federal Awards](#).

D. Retrospective Review

1. Untimely or delayed disclosure or identification of a previously undisclosed SFI will be reviewed by SPARO and ECS in coordination with COIC within 60 days to include:
 - a. An interim management plan to manage the FCOI moving forward; and
 - b. A retrospective review, completed within 120 days, to determine whether any PHS funded research (or a portion of it) conducting during the period in which the SFI was not identified resulted in undue bias in the design, conduct or reporting of the research.
 - c. A finalized management plan to address the results of the retrospective review as appropriate.

E. Required PHS Reporting

1. SPARO submits an FCOI report to PHS awarding components when an SFI that could affect PHS-funded research is identified prior to the expenditure of funds in accordance with 42 CFR 50 Subpart F and 45 CFR 94.
2. As appropriate, SPARO submits an updated FCOI report within 60 days of identifying an SFI through retrospective review, and submits a Mitigation Report that includes:
 - a. Key elements documented in the retrospective review.
 - b. A description of the impact of the bias on the PHS-funded research.
 - c. The action plan implemented to eliminate or mitigate the effect of the bias.

F. Public Transparency and Accessibility

1. SPARO provides written responses to requests for FCOI information within 5 business days as long as:
 - a. The request has enough specificity to allow for a response,
 - b. The SFI was disclosed and is still held by the Investigator,
 - c. The SFI has been determined to be related to PHS-funded research, and
 - d. The SFI has been determined to be an FCOI.
2. Written responses to requests will include:
 - a. The Investigators name, title, and role in the PHS-funded research,
 - b. The name of the entity in which the SFI is held,
 - c. The nature of the SFI, and
 - d. The approximate dollar value of the SFI (dollar ranges are permissible) 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.

G. Non-compliance

1. Non-compliance with this policy, in addition to procedures described in the policy, may be subject to the Human Resources [Accountability Based Performance](#) policy.

EXTERNAL REFERENCES

- A. 42 CFR 50, Subpart F – Promoting Objectivity in Research
- B. 42 CFR 94

DHHA RELATED DOCUMENTS

[Conflicts of Interest](#)

[Subrecipient Monitoring of Federal Awards](#)

[Accountability Based Performance](#)

ATTACHMENTS

None

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Approval Signatures

Step Description	Approver	Date
Final Signatory	Sandra Shumaker: Director, Compliance	12/2023
Research Compliance Committee	Sandra Shumaker: Director, Compliance	12/2023
	Amanda Breeden: Sr Director, Contracts and Grants	11/2023
Formatting Review	Brooke Tidball: Project Manager Document Control	10/2023
	Sandra Shumaker: Director, Compliance	10/2023