

Policy Number	TBD
Department	Office of Regulatory Affairs
Author	Manager, Human Subject Protection Program
Last Approved Date	
Approved By / Approving Bodies	Institutional Official, Western Region
Due for Next Review	

TITLE: Financial Conflict of Interest in Research

SCOPE:

Cadence Health	x	Delnor Community Hospital	
Cadence Physician Group		Retail Care Clinic	
Cadence Ambulatory Surgical Center		Cancer Centers	
Central DuPage Hospital		CDH Proton Center	
Convenient Care Centers		Behavioral Health Services Outpatient	

APPLICABLE DEPARTMENT(S): All areas under the scope of the CDH-Delnor Health System Federalwide Assurance.

APPLICABLE STANDARD(S) / REGULATION(S): 42 CFR 50 Subpart F, 21 CFR 54, and NSF: Award and Administrative Guide IV.A.

PURPOSE: The purpose of this policy is to describe the disclosure, evaluation and management, monitoring and enforcement, reporting, and education regarding Financial Conflicts of Interest that could influence the conduct of research or the protection of human research subjects.

DEFINITION(S):

Conflict Review Committee: a group appointed by the CDH-Delnor Health System Institutional Official to provide a review of disclosed Significant Financial Interests, make a determination whether the Significant Financial Interest is a Financial Conflict of Interest, and devise an appropriate management plan. This committee consists of the Institutional Official, the chair of the CDH-Delnor Health System Institutional Review Board, the Human Subject Protection Program manager, and a representative of the Compliance and Integrity Department.

Financial Conflict of Interest: a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

Institution: CDH-Delnor Health System.

Institutional Official: the individual who is legally authorized to act for the Institution, on behalf of the Institution, and has the authority to ensure all the obligations of this policy are carried out.

Institutional Responsibilities: professional responsibilities performed on behalf of the Institution which may include but are not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee membership, and service on panels such as institutional review boards, or data safety monitoring boards.

Public Health Service Awarding Component: the organizational unit of the Public Health Service that funds the research.

Research Personnel: any individual who is responsible for the design, conduct, or reporting of research. These individuals may include, but are not limited to, principal investigators, co-investigators, sub-investigators, and other key personnel.

Significant Financial Interest:

1. A financial interest consisting of one or more of the following interests of the Research Personnel or the Research Personnel's spouse or dependent children that reasonably appears to be related to the Research Personnel's Institutional Responsibilities:
 - a. Publicly traded entity, when the below, aggregated, exceeds \$5,000:
 - i. Income (i.e., salary, consulting fees, honoraria, paid authorship) received from the entity in the 12 months prior to disclosure.
 - ii. Equity (i.e., stock, stock option, or other ownership interest) as determined through reference to public prices or other reasonable measures of fair market value.
 - b. Non-publicly traded entity:
 - i. Income (i.e., salary, consulting fees, honoraria, paid authorship) exceeding \$5,000 in aggregate received from the entity in the 12 months prior disclosure.
 - ii. Any equity interest (i.e., stock, stock option, or other ownership interest).
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Research Personnel and not reimbursed to the Research Personnel so that the exact monetary value may not be readily available), related to his or her Institutional Responsibilities. The disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Travel meeting the above aforementioned requirement will be disclosed with the following details:
 - a. Purpose of the trip.
 - b. Identity of the sponsor or organizer.
 - c. Destination.
 - d. Duration.

A Significant Financial Interest does not include the following types of financial interests:

1. Salary, royalties, or other remuneration paid by the Institution to the Research Personnel if the Research Personnel is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights.
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Research Personnel 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
4. Income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

I. POLICY STATEMENT(S):

CDH-Delnor Health System seeks to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Financial Conflicts of Interest (FCOI).

Research Personnel's Responsibilities:

1. Training

- a. Each Research Personnel shall complete FCOI training designated by the Institution:
 - i. Prior to engaging in non-exempt human subjects research or a Public Health Service(PHS)-funded activity; and
 - ii. At least every 4 years.
- b. In addition, each Research Personnel shall complete FCOI training immediately under any of the following circumstances:
 - i. At the time Research Personnel are new to the Institution.
 - ii. Any time this policy is revised in a manner that affects the training requirements of Research Personnel regarding FCOI.
 - iii. In the event a Research Personnel is found non-compliant with this policy or a written FCOI management plan (Management Plan).

2. Disclosure

- a. Each Research Personnel must disclose all SFI:
 - i. For PHS-funded studies, at the time an application or date of contract proposal is submitted to a PHS Agency; and
 - ii. Upon initiating a study at the Institution; and
 - iii. Annually; and
 - iv. Within 30 days of discovering or acquiring a new SFI.

3. Compliance

- b. Research Personnel must comply with the Management Plan put in place by the Conflict Review Committee (CRC) for a disclosed SFI determined to be an FCOI.

Institutional Responsibilities:

1. Training

- a. The Institution shall provide a training program for all Research Personnel to include the following:
 - i. The Institution's policy on FCOI.
 - ii. The Research Personnel's disclosure responsibilities.
 - iii. Applicable Federal regulations.

2. SFI Disclosure and Review

- a. The Institutional Official (IO) or designee will solicit all Research Personnel to complete the disclosure document at the defined times. Disclosures will be received by the Humans Subject Protection Program (HSPP) and the staff will verify that the disclosure includes the appropriate detail of information and meets the threshold of an SFI as defined in this policy.
- b. The CRC will conduct the following within 60 days of disclosure and prior to expenditure of funds for PHS-funded activities by the applicable Research Personnel:
 - i. The CRC will review SFI and reasonably determine if the SFI could directly and significantly affect the design, conduct, or reporting of the research, thus establishing the existence of an FCOI.
 - ii. Establish a Management Plan for every FCOI that has been determined to exist. Examples of conditions or restrictions that may be imposed to manage FCOIs in research include but are not limited to:
 - 1. Public disclosure of FCOI.
 - 2. Disclosure of FCOI to each research subject when research involves human subjects.
 - 3. Appointment of an independent monitor.
 - 4. Modification of the research plan.
 - 5. Change of personnel or responsibilities, or disqualification of personnel, including Research Personnel, from participation in the research.
 - 6. Reduction or elimination of the SFI.
 - 7. Severance of the relationship(s) that create the actual or potential conflict(s).
 - iii. Monitor the Research Personnel's compliance with the Management Plan until the completion of the research project or until the FCOI has been eliminated.
 - iv. Report the FCOI and Management Plan to the institutional review board (IRB) of record.

3. Enforcement and Non-Compliance

- a. For Research Personnel who have been found to be non-compliant with this policy or an FCOI Management Plan, the IO will:
 - i. Conduct a retrospective review of the Research Personnel's activities and the research project within 120 days to determine whether any research

conducted during the time period of non-compliance was biased in the design, conduct, or reporting. Documentation of the retrospective review shall include at least the following:

1. Project number.
 2. Project title.
 3. Principal Investigator (PI) contact.
 4. Name of the Research Personnel with the FCOI.
 5. Name of the entity with which the Research Personnel has an FCOI.
 6. Reasons for the retrospective review.
 7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed).
 8. Findings of the review.
 9. Conclusions of the review.
- ii. Require FCOI training of involved Research Personnel.
 - iii. Determine appropriate sanctions or other administrative actions appropriate to the non-compliance in accordance with human resources policies, medical staff bylaws, etc., as applicable.
 - iv. For SFI identified that was not previously disclosed, convene the CRC to review the SFI to determine if an FCOI exists and implement a management plan as applicable. This will be completed within 60 days of discovery.
- b. In any case where the Department of Health and Human Services (DHHS) determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a Research Personnel with an FCOI that was not managed or reported by the Institution as required by this policy and applicable regulations, the Research Personnel will be required to:
- i. Disclose the FCOI in each public presentation of the results of the research.
 - ii. Request an addendum to previously published presentation.

4. Reporting for PHS-Funded Research

- a. The IO or designee will be responsible for preparing and submitting the FCOI report to the appropriate PHS Awarding Component as follows:
 - i. Prior to the expenditure of funds.
 - ii. Within 60 days of identification for a Research Personnel who is newly participating in the project.
 - iii. Within 60 days for new, or newly identified, FCOIs for existing investigators.
 - iv. At least annually to provide the status of the FCOI and any changes to the Management Plan, if applicable, until the completion of the project.
 - v. Following a retrospective review to update a previously submitted report, if applicable.
 - vi. Promptly if a bias is found with the design, conduct, or reporting of PHS-funded research and is to include a mitigation report. The mitigation report will include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to

eliminate or mitigate the effect of the bias (e.g., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm, analysis of whether the research project is salvageable).

- vii. Promptly if a Research Personnel fails to comply with this policy or an FCOI Management Plan and such failure appears to have biased the design, conduct, or reporting of the PHS-funded research.
- b. FCOI reports shall include at a minimum:
 - i. Project number.
 - ii. PI contact.
 - iii. Name of the Research Personnel with the FCOI.
 - iv. Name of the entity with which the Research Personnel has an FCOI.
 - v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium).
 - vi. Value of the financial interest 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.
 - vii. A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's Management Plan, including:
 - 1. Role and principal duties of the conflicted Research Personnel in the research project.
 - 2. Conditions of the Management Plan.
 - 3. How the Management Plan is designed to safeguard objectivity in the research project.
 - 4. Confirmation of the Research Personnel's agreement to the Management Plan.
 - 5. How the Management Plan will be monitored to ensure Research Personnel compliance.
 - 6. Other information as needed.

5. Subrecipient Requirements

- a. In instances where the Institution is the primary recipient of PHS-funded research and some or all of the research is carried out through a subrecipient
 - i. The written agreement between the Institution and the subrecipient will establish whether the subrecipient will follow the FCOI policy of the Institution or the FCOI policy of the subrecipient.
 - ii. If the subrecipient will follow their own FCOI policy, then the Institution will obtain a certification from the subrecipient that its FCOI policy complies with 42 CFR 50. In this instance the written agreement will also indicate the requirement for the subrecipient to report identified FCOIs for its Research Personnel in a time frame that allows the Institution to report identified FCOIs to the PHS Awarding Component, as required by regulation.
 - iii. In the instance where the subrecipient will follow the FCOI policy of the Institution, the written agreement will indicate the requirement to solicit and review subrecipient Research Personnel disclosures that enable the Institution to identify, manage, and report identified FCOIs to the PHS awarding component.

6. Maintenance of Records

- a. All FCOI-related records will be maintained for at least 3 years from the date of the closure of the related research.
- b. For PHS-funded research, all FCOI-related records will be maintained for at least 3 years from the date the final expenditures report is submitted to the PHS Awarding Component, or from other dates as specified in 45 CFR 74.53(b) and 92.42(b), where applicable.

7. Public Accessibility

- a. This policy will be available to the public via the Institution's public website.
- b. The Institution will make identified FCOI information publicly available related to PHS-funded research.
 - i. Within 5 business days of a written request of information concerning any SFI disclosed to the Institution that meets the following 3 criteria:
 - 1. The SFI was disclosed and is still held by the Research Personnel.
 - 2. The Institution determines that the SFI is related to PHS-funded research.
 - 3. The Institution determines that the SFI is an FCOI.
 - ii. The information released to the requestor will include at a minimum the following:
 - 1. The Research Personnel's name.
 - 2. The Research Personnel's title and role related to the research.
 - 3. The name of the entity in which the SFI is held.
 - 4. The nature of the SFI.
 - 5. The approximate dollar value of the SFI by dollar range (0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,000; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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.
 - iii. Information related to identified FCOIs will remain available to disclosure via written request for at least 3 years from the date the information was most recently updated.

SEE RELATED DOCUMENT(S):

Circumstances may arise in which we find it necessary to take other steps not specifically designated here. We reserve the right to use professional judgment to do so at our discretion.