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Conflicts of Interest in Research

PURPOSE:

A. The purpose of this policy is to promote objectivity in research by establishing standards for reporting and managing conflicts of interest related to Federally funded research. For purposes of this policy, a conflict of interest in research (COIR) exists when it is determined that an Investigator has a significant financial interest that could directly and significantly affect the design, conduct or reporting of research.

SCOPE:

A. This policy only applies to Federally funded research.

DEFINITIONS:

A. Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

B. Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

C. PHS means the Public Health Service of the U.S.

D. Significant Financial Interest (SFI) means:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that

reasonably appears to be related to the Investigator's institutional responsibilities:

a. With regard to any publicly traded entity, a SFI exists if the value of any remuneration 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**. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

b. With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration 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 (e.g., stock, stock option, or other ownership interest); or

c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this 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 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.

a. The disclosure of sponsored travel must specify the the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

b. Confluence Health will use the conflict resolution process outlined in this policy to determine whether the travel constitutes an FCOI with the PHS-funded research.

E. Significant Financial Interest (SFI) does NOT include:

1. Salary, royalties, or other remuneration paid by Confluence Health to the Investigator if the Investigator is currently employed or otherwise appointed by Confluence Health;

2. Intellectual Property Rights assigned to Confluence Health and agreements to share in royalties related to such rights;

3. 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;

4. 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; or

5. 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:

A. Investigators shall certify as part of a formal COIR process that they have read this policy and shall conduct their research in a manner that promotes objectivity in research. To the extent there is the appearance of, potential for, or actual COIR, Investigators shall disclose the apparent, potential or actual COIR in accordance with the procedures of this policy and participate in a COIR management plan.

PROCEDURES:

A. Investigator Responsibilities

1. Any investigator conducting research at Confluence Health must comply with this policy and complete a COIR Disclosure Form. The COIR Disclosure Form must be completed at a minimum annually and prior to submitting research studies through a non- Confluence Health IRB of record; or prior to submitting a grant; regardless of the source of funding.

2. If an Investigator discovers or acquires a new SFI, or if the value of a previously disclosed financial interest changes such that it constitutes a SFI, or a previously disclosed SFI increases in a significant manner, it is the Investigator's responsibility to update the COIR Disclosure Form within 30 days, providing any information that was not disclosed previously. Examples include: new COIR identified on a research project that was transferred from another institution; updated value of a previously disclosed equity interest.

3. An Investigator must complete training on this policy and Federal FCOI regulations. Training is required prior to engaging in research and must be updated at least every four (4) years. More frequent training updates may be assigned if needed according to this policy.

B. Sanctions

1. Failure of an Investigator to file a complete and truthful annual disclosure or disclosure when a new SFI is discovered or acquired, or failure to comply with any

conditions or restriction directed or imposed, including failure to cooperate with appointed award monitoring bodies, will be grounds for sanctions and/or corrective action pursuant to Confluence Health policy. In addition, Federal regulations may require reports be made to the Federal sponsor of any violations of Federal regulation.

C. Institutional Responsibilities:

1. Accountability

a. The research department manager or designee is responsible for ensuring that all Investigators complete COIR Disclosure Forms and receive COIR training for Investigators. The research department manager is responsible for ensuring that subrecipients comply with the COIR policy of the subrecipient institution. When a non-Confluence Health IRB is used, the research department manager is responsible for ensuring the Investigator has a current COIR disclosure on file at the time of IRB submission and that COIR training is documented and current.

b. The research department manager is responsible for reviewing completed COIR Disclosure Forms and coordinating potential management plans according to the review process set forth in this policy.

c. The research department shall keep and maintain records, of disclosures of relationships between Investigators and potential research sponsors and actions taken to manage any actual or potential conflicts of interests for at least three (3) years beyond the termination or completion of the award or until resolution of any action by any federal agency involving the records, whichever is longer.

d. When a non-Confluence Health IRB is used, the research department manager is responsible for ensuring Investigator has a current COIR disclosure on file at the time of IRB submission and that COIR training is documented and current.

e. The signing official or designee is responsible for certifying that each Investigator submitting a grant, either Federal or non-Federal, has a current COIR disclosure on file at the time of submission and that COIR training is documented and current. When submission involves subrecipients, the signing official will certify that a written agreement is established with subrecipient institution to include terms set forth in this policy.

D. Public Accessibility

1. Prior to Confluence Health's expenditure of any research funds, Confluence Health shall assure public accessibility as follows:

a. Maintain this policy on Confluence Health's public facing website.

b. Respond in writing within five (5) business days to any request for information concerning an SFI disclosed by Confluence Health Investigators that meets all of the following criteria:

i. SFI was disclosed and is still held by the Investigator;

ii. Confluence Health determines that the SFI is related to research being conducted at Confluence Health; and

iii. Confluence Health determines that the SFI is a FCOI.

Information provided will be limited to: Investigator's name; Investigator's title and role in the research; name of entity in which SFI is held; nature of the SFI; and dollar value (in ranges) of SFI, or justification of why value cannot easily be determined.

E. Investigator Training

1. Confluence Health will provide mandatory COIR training for Investigators. Training covers this policy and overview of the Federal regulations. Training is required at least every four (4) years, and immediately under the following circumstances:

a. Confluence Health COIR policies change in a manner that affects Investigator requirements

b. An Investigator is new to Confluence Health

c. Confluence Health finds an Investigator noncompliant with this policy or a COIR management plan

F. Subrecipients

1. If Confluence Health carries out the PHS-funded research through a subrecipient, Confluence Health will incorporate as part of a written agreement with the subrecipient terms that establish whether Confluence Health's or the subrecipient's policy on conflict of interest in research will apply to the subrecipient Investigators.

2. If the sub recipient's policy will apply, the subrecipient will certify as part of the agreement that its policy complies with the PHS regulations on Objectivity in Research. Additionally, the agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to Confluence Health to enable Confluence Health to provide timely reports to PHS.

3. Alternatively, if Confluence Health's policy on conflict of interest in research will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures of significant financial interests to Confluence Health. Such time periods shall be sufficient to enable Confluence Health to comply with timely review, management, and reporting obligations under the PHS regulations

G. Process for Review of Disclosures

1. The research department will solicit and review COIR Disclosure Forms for Investigators at a minimum annually or as new SFIs are disclosed by an investigator. Prior to expenditure of any funds and during the course of an initiated project within 60 days of a new/updated disclosure, the research department must review an investigator's disclosure of SFI and determine if a FCOI exists.
2. The research department may conduct investigations and consult with the Confluence Health Compliance Officer or others as necessary to review potential COIRs.
3. As needed, the research department will consult with the Conflict of Interest Subcommittee of the Compliance Committee for further evaluation, guidance, determination of conditions or restrictions, and development of a conflict management plan. The research department manager or designee will inform those sponsors that require notification of the conflict and actions taken.

H. Management Plan

1. For all determined FCOI, involving research, the research department will establish a management plan to determine how objectivity in research will be maintained. The research department, Confluence Health Compliance Officer, and the COI Subcommittee of the Compliance Committee may work with the Investigator and signing official to impose a plan to manage determined FCOI including, but not limited to the following conditions:
    a. Public disclosure of FCOI (i.e. when presenting or publishing the research);
    b. For research projects involving human subjects research, disclose FCOI in IRB approved
    c. informed consent document;
    d. Monitoring of any research project by independent reviewers;
    e. Modification of the research proposal or plan;
    f. Disqualification or change of personnel or personnel responsibilities from participating in all or a portion of the sponsored research;
    g. Divestiture by an investigator of the financial interest in any research sponsor; or
    h. Severance of any relationship between an Investigator and a research sponsor which may create financial conflicts.
2. The management plan will also describe: the role and principal duties of the Investigator with the FCOI; the conditions of the management plan; how the management plan is designed to safeguard objectivity in the research project;

provisions for monitoring compliance to the COIR management plan; and other information as deemed advisable. The management plan must be signed by the Investigator and others as appropriate. Additionally, documentation of all proceedings will be kept by the research department. Management plans may be provided to a sponsor based on sponsor requirements.

I. FCOI Reporting Requirements to PHS - A FCOI Report to PHS is required for PHS-funded research only.

    1. Initial: For PHS-funded research, prior to expending any PHS funds, the Confluence Health Compliance Officer in collaboration with the research department manager or designee will submit an FCOI Report for determined FCOIs to the PHS. If the determined FCOI is eliminated prior to expenditure of PHS funds, an FCOI Report is not required, provided, however the records relating to the review of the FCOI shall reflect how the FCOI was eliminated. FCOI regulations do not apply to PHS Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Phase 1 programs; FCOI regulations do apply to SBIR/STTR Phase 2 programs.

    2. Annual: For ongoing PHS-funded research, Confluence Health will submit annual reports to the PHS for any FCOI previously submitted. These updates will provide status of each FCOI and any changes to the management plan for the duration of the PHS-funded research project. The report should specify whether the conflict is still being managed or explain why it no longer exists. Confluence Health will submit reports in the time and manner established by the PHS.

    3. New/Updated: If a FCOI is identified subsequent to the initial FCOI Report during an ongoing PHS-funded project, Confluence Health will submit an FCOI Report within sixty (60) days of determination.

    4. Bias: If the failure of the Investigator to comply with this policy or management plan has biased any PHS-funded research, Confluence Health must promptly notify the PHS of the corrective action taken or to be taken.

J. Noncompliance with PHS-Funded Research

    1. The Confluence Health Compliance Officer in conjunction with the research department will, within 120 days of the determination of non-compliance, complete and document a retrospective review of the Investigator's activities and research to determine if there was bias in the design, conduct, or reporting of the research.

    2. Documentation of the retrospective review will include the following information:

        a. Project number;

        b. Project title;

        c. PD/PI or contact PD/PI if a multiple PD/PI model is used;

d. Name of the investigator with the FCOI;

e. Name of the entity with which the investigator has a FCOI;

f. Reason(s) for the retrospective review;

g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

h. Findings of the review; and

i. Conclusions of the review

3. In those cases where, through a retrospective review, bias is determined to have occurred in the course of the Federally-funded research, Confluence Health will promptly notify and submit a report to the PHS Awarding Component. The report will address the impact of the bias on the research project and the corrective actions taken, or to be taken, to eliminate or mitigate the effect of the bias. In those cases where it is determined that bias has not occurred and/or for research that is not funded by the PHS, Confluence Health is not required to notify the PHS.
4. The PHS may require further corrective action to ensure appropriate objectivity in PHS funded research.
5. In the case of a PHS-funded 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 an investigator with a conflicting interest that was not managed or reported by an investigator with a FCOI that was not managed or reported by Confluence Health as required by the regulation, Confluence Health will require the investigator(s) involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

REFERENCES AND RELATED DOCUMENTS:

A. 21 CFR §54.1-6
B. 42 CFR §§ 50.601 – 50.607
C. 45 CFR §94.1-6
D. Confluence Health Conflict of Interest Policy

ADDITIONAL REVIEW AND APPROVAL BY:

Sarah Brown, VP of Risk & Regulatory | Confluence Health Compliance Officer - 9/11/2025

***Note: policy must be published on the Confluence Health website as updates occur.**

Approval Signatures

Step Description	Approver	Date
PolicyStat Administrator	Crista Davis: Regulatory Standards Coordinator	9/18/2025
CEO	Andrew Jones: Chief Executive Officer	9/18/2025
CNO	Kelly Allen: Chief Nursing Officer	9/18/2025
Director	Laurel Aaberg: Pharmacy Director	9/16/2025
Medical Reviewer	Anton Grasch: PHYS MED DIR Research	9/15/2025
	Andrew McIntire: Research Manager	9/15/2025

Standards

No standards are associated with this document