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Financial Conflict of Interest in Research Policy

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TABLE OF CONTENTS

PURPOSE.....	1
SCOPE	1
DEFINITIONS	1
Significant Financial Interest (SFI)	2
POLICY	3
Significant Financial Interest (SFI) Disclosure Requirements	3
NSF and PHS Training Requirements	4
NSF- and PHS-Supported Subrecipient Responsibilities.....	5
OCHIN Responsibilities for PHS-Supported Research	6
OCHIN Responsibilities for NSF-Supported Research	6
COI REVIEW PROCESS	6
Non PHS-Supported Research	7
PHS-Supported Research	7
Review and Management of SFI Disclosures and FCOI Reporting	7
Review of SFIs Not Timely Disclosed or Reviewed	7
Retrospective Review	7
Monitoring of FCOI Management Plans.....	8
Public Accessibility to FCOI Information for PHS-Supported Research	9
SANCTIONS	9
All Research	9
PHS-Supported Research	9





A driving force for health equity

Financial Conflict of Interest in Research Policy

RESPONSIBILITIES.....	9
REFERENCES.....	10
CHANGE RECORD.....	10

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Financial Conflict of Interest in Research Policy

PURPOSE

This policy provides guidance to OCHIN research investigators and workforce members by articulating standards for identifying, addressing, managing, and eliminating conflicts of interest as needed. Additionally, this policy supports the implementation of the following provisions:

- [42 CFR Part 50](#) and [45 CFR Part 94](#) (“[PHS Objectivity in Research Rule](#)”) for research supported by the U.S. Public Health Service (PHS) or any other federal agency or extramural sponsor that has adopted the PHS Objectivity in Research Rule
- [National Science Foundation’s \(NSF\) Grantee Standards](#) regarding conflicts of interest

Further, this policy establishes a process for ensuring that any conflicts OCHIN research investigators may have in connection with OCHIN research projects are fully disclosed, reviewed in accordance with established procedures, and satisfactorily managed, reduced, or eliminated.

SCOPE

This policy applies to OCHIN workforce members (as defined below) who conduct funded research activities on behalf of OCHIN, including but not limited to: contractors, research investigators, research associates and analysts, medical informaticists, practice coaches, and business intelligence analysts. All OCHIN research is subject to this policy, regardless of funding source.

DEFINITIONS

Term	Definition
Business Interest	Any position, such as officer, director, or board membership (such as an advisory board) with an entity related to a research project, regardless of the compensation of the position
Financial Conflict of Interest (FCOI)	A significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-supported research
FCOI Management Plan	A management plan prepared by OCHIN in the event that an investigator is determined to have an FCOI per this policy
Financial Interest	Anything of monetary value, whether or not the value is readily ascertainable
Immediate Family	Spouse, domestic partner, parents (biological and adopted), and each dependent
Institutional Responsibilities	An investigator’s work on behalf of OCHIN, including but not limited to research, professional responsibilities, and OCHIN committee memberships
Investigator	The project director or principal investigator and any other person (regardless of title or position) who is proposing to be or is responsible for the design, conduct, or reporting of research, including, but not limited to, study coordinators, data managers, collaborators, or consultants



A driving force for health equity

Financial Conflict of Interest in Research Policy

Term	Definition
Manage	Taking action to address an FCOI, which can include reducing or eliminating the FCOI to ensure – to the extent possible – that the design, conduct, and reporting of research is free of bias
NSF-Supported Research	A research project for which funding is sought or received from the National Science Foundation (NSF)
Period of the Award	The timeframe of the OCHIN research project as stated in the award document, including any extensions
PHS-Supported Investigator	An investigator who is participating or planning to participate in a research project funded by the U.S. Public Health Service (PHS) or by an entity that has adopted the PHS Objectivity in Research Rule
PHS-Supported Research	A research project for which funding is sought or received from a U.S. Public Health Service (PHS) agency or an entity that has adopted the PHS Objectivity in Research Rule
Related	A Significant Financial Interest (SFI) is considered to be related to a research project if the relationship or SFI: (1) could be affected by the research project; or (2) is in an entity whose financial interests could be affected by the research project.
Remuneration	Salary and any form of payment for services not otherwise identified as salary (for example, consulting fees, honoraria, or paid authorship), including equity interests (for example, stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value)
Research	A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research
Significant Financial Interest	Refer to the Significant Financial Interest (SFI) section below.
Subrecipient Investigator	An investigator who is not an OCHIN employee or contractor and who participates in an OCHIN research project overseen by OCHIN through a subcontract, sub-award, or other agreement
Workforce Member	Includes OCHIN Board members, OCHIN staff, contracted and temporary staff, and other individuals (for example, consultants) who perform work on behalf of OCHIN or are acting on OCHIN's behalf and in situations in which the person's actions could be identified with OCHIN, even if the person is not formally acting on OCHIN's behalf

Significant Financial Interest (SFI)

A significant financial interest (SFI) is defined as follows:



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Financial Conflict of Interest in Research Policy

- A financial interest consisting of one or more of the following interests of the investigator or their immediate family that reasonably appears to be related to the investigator's institutional responsibilities:
 - With regard to any publicly traded entity, an SFI exists if the value of any remuneration (as [defined above](#)) received from the entity in the 12 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;
 - With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure when aggregated exceeds \$5,000 or when the investigator or their immediate family holds any equity interest (for example, stock, stock options, or other ownership interest);
 - Intellectual property rights and interests (for example, patents and copyrights) upon receipt of income related to such rights and interests; or
 - A business interest with any entity related to a research project, whether or not remuneration is received.
- For PHS-supported investigators only, 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 the investigator's institutional responsibilities
 - Refer to the [Significant Financial Interest \(SFI\) Disclosure Requirements](#) section for the information that must be disclosed pertaining to this type of SFI.
- Any other financial interest or external commitment that may interfere with an investigator's ability to oversee or participate in research without bias

POLICY

To maintain the public trust, protect the integrity of professional judgment, and ensure appropriate stewardship of resources and compliance with applicable state and federal laws, external relationships must not be or appear to be influenced by factors other than the pursuit of knowledge, the best interests of OCHIN members, and appropriate stewardship of resources.

As a recipient of funding to support research, OCHIN must ensure that research is carried out responsibly and with integrity.

Significant Financial Interest (SFI) Disclosure Requirements

Investigators engaging in or proposing to engage must fully disclose whether they or their immediate family have a significant financial interest (SFI) related to the research.



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Financial Conflict of Interest in Research Policy

Research Type	Disclosure Requirements
Research supported by the NSF	<p>SFI disclosures must be made:</p> <ul style="list-style-type: none"> • No later than the date of submission of a proposal; • Updated at the time of Notice of Award; • Within 30 days of discovering or acquiring a new SFI (for example, through purchase, marriage, or inheritance); and • Annually updated during the period of award to reflect any change in the value or status of the SFI.
Research supported by the PHS	<p>SFI disclosures must be made:</p> <ul style="list-style-type: none"> • No later than the date of submission of a proposal; • Updated at the time of Notice of Award; • Within 30 days of discovering or acquiring a new SFI (for example, through purchase, marriage, or inheritance); and • Annually updated during the period of award to reflect any change in the value or status of the SFI. • Additionally, for 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 the investigator's institutional responsibilities, the disclosure must include, at a minimum the purpose of the trip and the identity of the sponsor/organizer, the destination, and the duration. OCHIN will determine if additional information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI.
All other research (not supported by the NSF or PHS)	<p>SFI disclosures must be made:</p> <ul style="list-style-type: none"> • Prior to the initiation of the research; • Within 30 days of discovering or acquiring a new SFI (for example, through purchase, marriage, or inheritance); and • Annually updated during the period of award or duration of the research to reflect any change in the value or status of the SFI.

NSF and PHS Training Requirements

NSF- and PHS-supported investigators must complete training as follows:

- Prior to submitting a proposal for NSF- or PHS-supported research;
- At least every four years during the period of the award; and
- Immediately when any of the following apply:
 - OCHIN revises this Financial Conflict of Interest in Research Policy or its associated procedures in any manner that affects NSF- or PHS-supported investigators;
 - An NSF- or PHS-supported investigator is new to OCHIN; or



A driving force for health equity

Financial Conflict of Interest in Research Policy

- OCHIN finds that an NSF- or PHS-supported investigator is noncompliant with this Financial Conflict of Interest in Research Policy or Financial Conflict of Interest Management Plan.

NSF- and PHS-Supported Subrecipient Responsibilities

This section applies in any circumstances in which a portion of an NSF- or PHS-supported research project is carried out through an NSF- or PHS-supported subrecipient investigator.

When an NSF- or PHS-supported research project is funded in whole or in part by the NSF, PHS agency, or by an entity that has adopted the PHS Objectivity in Research Rule, OCHIN incorporates terms into the written agreement with the subrecipient institution to establish whether OCHIN's Financial Conflict of Interest in Research Policy applies or the subrecipient institution's COI policy applies.

Refer to the table below for guidance.

Circumstances and Requirements	Applicable COI Policy
<p>NSF- or PHS-supported subrecipient investigators are subject to OCHIN's Financial Conflict of Interest in Research Policy if the subrecipient investigator is not affiliated with an institution that maintains a COI policy that is compliant with the NSF's Grantee Standards or the PHS Objectivity in Research Rule (whichever is applicable based on the prime sponsor of the project). If OCHIN's Financial Conflict of Interest in Research Policy applies:</p> <ul style="list-style-type: none"> • The subrecipient agreement must specify the time period (both prior to proposal submission and throughout the period of award) wherein the subrecipient investigators are required to disclose SFIs related to the proposed research. The time periods must be sufficient to enable OCHIN to comply in a timely manner with the review, management, and reporting obligations set forth in this policy. • Subrecipient investigators must complete and submit the OCHIN Conflict of Interest Statement of Disclosure. 	<p>OCHIN's Financial Conflict of Interest in Research Policy applies.</p>
<p>When the subrecipient agreement stipulates that the subrecipient institution's COI policy applies, the subrecipient institution must also certify in the subrecipient agreement that its COI policy complies with either the NSF's Grantee Standards or the PHS Objectivity in Research Rule (whichever is applicable based on the prime sponsor). Further, the written agreement must specify the time period within which the subrecipient institution must report all identified FCOIs to OCHIN. This time period shall be sufficient to enable OCHIN to provide timely reporting of the FCOI to the funding agency pursuant to the timelines set forth in this policy.</p>	<p>The subrecipient institution's Conflict of Interest Policy applies.</p>



A driving force for health equity

Financial Conflict of Interest in Research Policy

OCHIN Responsibilities for PHS-Supported Research

OCHIN upholds the following responsibilities pertaining to PHS-supported research:

- Make this Financial Conflict of Interest in Research Policy available to the public on the following website: <https://ochin.org/research>.
- Inform each investigator of the requirements of this policy, the investigator's responsibilities regarding disclosure of SFIs, and the requirements of [42 CFR Part 50](#) and [45 CFR Part 94](#).
- Require each investigator to complete training related to this policy and the requirements of [42 CFR Part 50](#) and [45 CFR Part 94](#) as follows:
 - Prior to engaging in any PHS-supported research;
 - At least every four years; and
 - Immediately when any of the following circumstances apply:
 - OCHIN revises its Financial Conflict of Interest in Research Policy or related procedures in any manner that affects the requirements of investigators;
 - An investigator is new to OCHIN; or
 - OCHIN finds that an investigator is noncompliant with this policy or management plan.
- The Human Protections Administrator or designee must solicit and review disclosures of SFIs from each investigator who is planning to participate in, or is participating in, PHS-supported research.
- Maintain records relating to all PHS-supported investigator disclosures of financial interests and the institution's review of and response to such disclosure (whether or not a disclosure resulted in the institution's determination of a financial conflict of interest) and all actions under this policy or retrospective review, if applicable, for at least three years from the date the final expenditure report is submitted to the PHS or, where applicable, from other dates specified in [45 CFR 75.361](#).

OCHIN Responsibilities for NSF-Supported Research

For NSF-supported research only, if OCHIN determines that an investigator's SFI is related to the research but cannot be satisfactorily managed such that the NSF-supported research will proceed without the imposition of conditions or restrictions, OCHIN must notify the NSF Office of General Counsel, as specified in the [NSF Grantee Standards](#).

COI REVIEW PROCESS

The following sections outline OCHIN's responsibilities pertaining to COI review and management.



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Financial Conflict of Interest in Research Policy

Non PHS-Supported Research

If OCHIN determines that any SFI may affect the design, conduct, or reporting of non-NSF- or PHS-supported research, steps must be taken to manage or eliminate the conflict.

If OCHIN determines that a management plan is required in order for the non-NSF- or PHS-supported research to proceed, then the project may be monitored by OCHIN to ensure compliance with the management plan.

PHS-Supported Research

This section applies to OCHIN's review and management of disclosures for PHS-supported research.

Review and Management of SFI Disclosures and FCOI Reporting

Prior to the expenditure of funds for any PHS-supported research, OCHIN determines, in consultation with the investigator, whether any SFI disclosed is related to PHS-supported research. If so, OCHIN must fulfill the following responsibilities:

- Determine whether the SFI constitutes an FCOI.
- Take appropriate action to manage FCOIs, including creating an FCOI Management Plan.
- Report any FCOIs and associated FCOI Management Plans to the PHS Awarding Component in the manner directed by such component, initially and annually for the duration of the related period of the award (including extensions with or without funds).
- In cases where OCHIN identifies an FCOI related to PHS-supported research and eliminates such FCOI prior to the expenditure of funds, OCHIN is not required to submit an FCOI report to the funding agency.

Review of SFIs Not Timely Disclosed or Reviewed

If OCHIN identifies an SFI that was not disclosed by a PHS-supported investigator in accordance with the timeframes specified in this policy and the PHS Objectivity in Research Rule or for any reason was not previously reviewed by OCHIN, OCHIN must fulfill the following responsibilities within 60 days:

- Review the SFI and determine whether it is related to the research, and if so, determine whether an FCOI exists.
- If an FCOI exists, implement – at least on an interim basis – a management plan that specifies the actions that have been and will be taken to manage the FCOI going forward.
- Submit an FCOI report to PHS.

Retrospective Review

If, during the course of reviewing an SFI not timely disclosed or reviewed, OCHIN determines that an FCOI exists for PHS-supported research or that a PHS-supported investigator has failed to comply with



A driving force for health equity

Financial Conflict of Interest in Research Policy

an FCOI Management Plan, OCHIN must complete a retrospective review of the investigator's activities and the project within 120 days to determine whether any portion of the research was biased in the design, conduct, or reporting prior to the identification and management of the FCOI or during the period of the investigator's noncompliance with the FCOI Management Plan.

If bias was found, OCHIN must fulfill the following responsibilities:

- Document the retrospective review, including but not limited to the following elements:
 - Project number
 - Project title
 - Principal Investigator/Project Director or contact PI/PD if a multiple PI/PD model is used
 - Name of the investigator
 - Entity with which the investigator has an FCOI
 - Reason(s) for the retrospective review
 - Detailed methodology used for the retrospective review (such as methodology of the retrospective review process, the composition of the retrospective review panel, and documents reviewed)
 - Findings of the retrospective review (i.e., facts and observations)
 - Conclusions of the retrospective review (i.e., determination and recommended actions)
- Promptly notify the funding agency of the corrective action taken or to be taken.
- Submit a mitigation report to the funding agency, which shall include, at a minimum:
 - The elements enumerated above (for documenting a retrospective review)
 - A description of the impact of bias on the PHS-Supported Research project
 - OCHIN's plan of action or actions taken to eliminate or mitigate the effect of the bias (for example, impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm, and analysis of whether the research project is salvageable)
- Thereafter, submit FCOI reports annually for the period of award for the related research.

Monitoring of FCOI Management Plans

Upon identifying an FCOI and implementing an FCOI Management Plan, OCHIN must monitor the investigator's compliance with the FCOI Management Plan on an ongoing basis until the completion of the PHS-supported research.



A driving force for health equity

Financial Conflict of Interest in Research Policy

Public Accessibility to FCOI Information for PHS-Supported Research

For PHS-supported research, OCHIN makes information about FCOIs identified through our COI review and management process publicly available by responding in writing to requests for such information within five business days of receiving such requests. Public disclosures of a PHS-supported investigator's FCOI information include the following:

- Name, title, and role of the investigator
- Name of the entity in which the SFI is held
- Nature and approximate dollar value or range of the SFI, 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

SANCTIONS

All Research

Failure to submit disclosures as required by this policy and related procedures may be grounds for disciplinary action under the provisions of any applicable OCHIN policy. Failure to comply with policy requirements may also result in the termination of current awards or contracts or ineligibility of the investigator to receive future awards or contracts for research.

PHS-Supported Research

In cases in which the failure of an investigator to comply with this policy or an FCOI Management Plan appears to have biased the design, conduct, or reporting of PHS-supported research, OCHIN must promptly notify the PHS Awarding Component.

In any case in which the Department of Health and Human Services (DHHS) determines that a PHS-supported research project involving 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 an FCOI that was not managed or reported by OCHIN as required by 42 CFR Part 50 or 45 CFR Part 94, OCHIN requires the conflicted investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

RESPONSIBILITIES

The VP of Research is responsible for ensuring implementation and oversight of this policy. They (or any OCHIN executive) may suspend all relevant research activities until the FCOI is resolved or other action deemed appropriate by OCHIN.



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Financial Conflict of Interest in Research Policy

REFERENCES

- [42 CFR Part 50](#)
- [45 CFR Part 75.361](#)
- [45 CFR Part 94](#)
- [OCHIN Website: Research](#)
- [PHS Objectivity in Research Rule](#)
- [National Science Foundation Grant Policy Manual, Grantee Standards](#)

All policies are subject to change. Please refer to the [Corporate Policy Library](#) for the most recent approved version. Compliance with corporate policies is a required term of employment with OCHIN.