Purpose: This policy informs OCHIN research investigators and staff about situations that generate conflicts of interest related to research, provides mechanisms for investigators and OCHIN to manage those conflicts of interest that arise and describes situations that are prohibited.

Scope: The scope of this policy is OCHIN workforce members, interns and other research investigators to the extent that they conduct research in OCHIN or under the supervision of the OCHIN research director or appointee. This policy applies to all financial conflicts of interest regardless of funding source.

Policy: It is the policy of OCHIN that research investigators and staff should conduct their affairs so as to avoid or minimize conflicts of interest and must respond appropriately when conflicts of interest occur. Every investigator and staff have an obligation to become familiar with and abide by the provisions of this policy.

Definitions:
1. Significant Financial Interests: 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
2. Institutional Official: Individual within OCHIN that is responsible for review of disclosures of significant financial interests. This individual holds the title of OCHIN Integrity Officer.
3. Public Health Service (PHS): Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Conflict of Interest:

Significant Financial Interest (SFI):
- With regard to a publicly traded company, a significant financial interest 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;

- With regard to any non-publicly traded entity, a significant financial interest 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
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 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)

**Not Significant Financial Interest:**
- Salary royalties or other remuneration paid by the Institution that the investigator is employed by
- Intellectual property rights assigned to OCHIN and agreements to share in royalties related to such rights
- Income from investment vehicles as long as the investigator does not directly control the investment decisions made on those vehicles
- Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, an institution of higher education, academic teaching hospital, medical center or a research institute that is affiliated with an institution of higher education
- Income from a service on advisory committees or review panels for a federal, state or local government agency, an institution of higher education, academic teaching hospital, medical center or a research institute that is affiliated with an institution of higher education

**Disclosure of Financial Interests:**
- **Annual Disclosures:** All investigators must disclose their SFI that are related to the investigator’s institutional responsibilities to the institutions through the Integrity Officer on an annual basis. All forms should be submitted to the Integrity Officer or Compliance Department by January 31st for the previous calendar year or as determined by the Integrity Officer.
• **Ad hoc Disclosure:** In addition to annual disclosures certain situations require ad hoc disclosure. All investigators must disclose their SFI to OCHIN through the Integrity Officer within thirty days of their initial hire or engagement of the SFI.

**Review and Decision of the Integrity Officer and OCHIN**

- If there is a found SFI on a disclosure form, it will be reviewed by the Integrity Officer to determine if there is an existing financial conflict of interest (FCOI). If there is a determined FCOI there will need to be a determined mitigation plan to eliminate or reduce the found FCOI.
- All found FCOI’s need to be reported to the NIH per 42 CFR Section 50 and available for public request.
- If non-compliance of the mitigation is found the investigator will be subject to discipline, including removal from PHS funded activity and/or research activity as deemed appropriate.

**Training:**

There is an expectation for all employees that are involved in research to have an understanding of why this exists and the processes that OCHIN has in place to prevent any FCOI’s. This training will include an overview of what OCHIN’s policy is, disclosure responsibilities of the investigator, federal regulation, and understanding of non-compliance. This training must be completed before beginning on any research that is PHS funded, regardless of OCHIN being an awardee or subrecipient. If proof of completing FCOI training through another organization is submitted prior to beginning research, this requirement is satisfied.

**Transparency:**

This policy and the accompanying procedure will be made available to the public via OCHIN’s external website. Any found FCOI’s for OCHIN investigators will be made available to the public on OCHIN’s external website. These need to be available for at least three years from the date the data was most recently updated. When an FCOI is found an OCHIN is a subrecipient, the awardee of the grant must be notified as soon as possible to allow for their reporting of the FCOI.

**References:**

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3.
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