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## **Disclosure of Financial Interests & Management of Conflicts of Interests: Public Health Service (PHS) Research Awards**

### **1. Overview**

Scientific integrity and operational excellence are core values at Omniox. As recipients of Public Health Service (PHS)-sponsored research funds, a component of those core values is ensuring compliance with National Institutes of Health (NIH) and PHS requirements, including 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." NIH policy ([NIH Financial Conflict of Interest Guidelines](#)) requires institutions subject to the requirements of the FCOI regulation to maintain an up-to-date, written, enforced FCOI policy that complies with the regulation, and to post the policy on their publicly accessible Web site. The overarching goal for this policy is to promote and encourage transparency in order to avoid distorting NIH funding decisions; NIH staff consider reports in light of other disclosures, e.g. other support, biographical sketch data, and foreign components, etc., and provide a holistic approach to award and risk management principles. This policy applies to all NIH grants and cooperative agreements, except Phase I SBIR/STTR applicants and recipients, for budget periods beginning on or after October 1, 2020.

Omniox's policy requires that each investigator, subrecipient, subgrantee and collaborator affiliated with Omniox, by NIH or any other applicable grant or contract, be in compliance with 42 CFR Part 50, Subpart F for PHS grants and cooperative agreements (and 45 CFR Part 94 for contracts). For purposes of financial disclosure only, this regulation also covers the spouse and dependent children of the investigator and key personnel.

### **2. Definitions**

#### **Financial Conflict of Interest (FCOI)**

A Financial Conflict of Interest (FCOI) exists when Omniox reasonably determines that a Significant Financial Interest (defined below) could directly and significantly affect the design, conduct or reporting of NIH or PHS-funded research.

#### **Investigator**

An Investigator is any person (including subrecipients, subgrantees and collaborators) who is responsible for the design, conduct or reporting of research funded by NIH or PHS.

#### **PHS Awarding Component**

The PHS awarding component is any sub-agency of the Public Health Service or Department of Health and Human Services (e.g., NIH).

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## **Principal Investigator**

The individual ultimately responsible for the appropriate scientific and financial conduct of a sponsored research project. On occasion, co-principal investigators who share responsibility for a project.

## **Research**

PHS research is any project governed by PHS regulation, and for the purposes of this policy, excludes applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

## **Significant Financial Interest (SFI)**

Significant Financial Interest is defined by the regulations as:

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 reasonable appears to be related to the Investigators institutional responsibilities:
  - a. With regard to any 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 and the value of any equity interest in the entity as of the date of disclosure, when aggregated exceeds \$5,000. For the 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 in stock, stock options or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value;
  - b. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remunerations 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 interests (e.g. stock, stock options, 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, medical center, or research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with

the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.

3. The term significant financial interest does not include the following types of financial interests: salaries, royalties or other remuneration paid by the institution to the Investigator if the Investigator 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; any ownership interest in the Institution held by the investigator, if the Institution is a commercial or for profit organization; income from investment vehicles, such as mutual funds and retirements accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; 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, research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for 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.

### 3. Training Requirement

Omniox Investigators are required to complete training related to FCOI:

- a) Prior to engaging in research related to any PHS-funded grant;
- b) At least every 4 years;
- c) Immediately, if:
  - the Institution revises its FCOI policy that affects requirements of Investigators
  - an Investigator is new to an Institution or if a change in an individual's role on a grant now designates them as an Investigator
  - an Investigator is not in compliance with the policy or management plan

Information and other resources developed by NIH can be accessed through the NIH website (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>). If any conflicts of interest are found or known, they must be disclosed.

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## 4. Disclosures/Reporting Process

### Disclosure

#### a. Principal Investigators (PIs)

PIs must identify all Investigators on the award (that is, all individuals who will have responsibility for designing, conducting, or reporting the research to be funded by PHS) who are required to disclose Significant Financial Interests (SFI).

#### b. Collaborators/ Subrecipients

Collaborators from other institutions, who share responsibility for the design, conduct or reporting of research results, and who will be *conducting research under a subaward* from Omniox are expected to comply with the policies and procedures of the organization at which they are employed. Subawards issued by Omniox will ask the subrecipient institution to certify that its policy is in compliance with Department of Health and Human Services (HHS) conflict of interest regulations, and unless the subrecipient does not have a HHS-compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators and, if a Financial Conflict of Interest is identified, for sending prompt notification to Omniox of the conflict and of the subrecipient institutions plan to manage, reduce or eliminate the identified conflicts, so that Omniox can report identified FCOIs to the NIH as required by the regulation.

Collaborators who share responsibility for the design, conduct, and reporting of research results, and who will participate in research under an independent consulting agreement issued by Omniox should be identified as Investigators by the Omniox PI and must complete the Omniox disclosure forms. If, upon review, Omniox determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, these collaborators will be expected to adhere to the mitigation plans put in place to eliminate, reduce or manage the identified conflicts of interest.

Investigators seeking PHS funding or receiving PHS support are required to disclose all SFI related to their Institutional Responsibilities:

- a) At the time of application for PHS-funded research
- b) Annually during the period of the award
- c) Within 30 days of discovering or acquiring a new SFI

These Investigators shall electronically submit disclosure of SFI form(s) to Omniox's designated official in accordance with the FCOI process.

Within 10 days of receiving an SFI disclosure, or prior to the expenditure of any funds of an award, Omniox's designated official(s) will review Investigator SFI disclosures and:

- a) determine if any SFIs relate to PHS-funded research;
- b) determine if an FCOI exists (SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research);
- c) Develop and implement management plans, as needed to manage FCOIs, including reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias. The management plan may include elements such as:
  - a. the role and principal duties of the conflicted Investigator;
  - b. conditions of the management plan;
  - c. how the plan will safeguard objectivity in the research activity;
  - d. confirmation of the investigators agreement to the plan; and
  - e. how the plan will be monitored

If no FCOI is found, the disclosure forms will be filed in an SFI binder.

If during the course of an ongoing PHS Research Activity, Omniox identifies an SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, the Designated Official will review the SFI within sixty (60) days to determine whether it is related to PHS Activities and whether an FCOI exists. If an FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis. In addition, whenever a FCOI is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose a SFI that was later determined to be a FCOI, or Omniox's failure to review or manage the FCOI, or because the Investigator failed to comply with a previously implemented management plan, Omniox must within one hundred twenty (120) days of the determination of non-compliance complete a retrospective review of the Investigator's activities and the PHS Activities. The purpose of this retrospective review is to determine if the ongoing PHS Activity was biased in its design, conduct or reporting. Based on the results of the retrospective review, the previously submitted FCOI report must be updated to specify the actions that Omniox will take to manage the identified FCOI going forward.

## Reporting

If an FCOI is identified, it will be put on the FCOI report through the eRA Commons FCOI module by the Authorized Organization Representative:

- a) prior to expending any funds
- b) within 60 days of identification for an Investigator who is newly participating in the project
- c) within 60 days for new, or newly identified, FCOIs for existing Investigators

- d) at least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
- e) Following a retrospective review to update a previously submitted report, if appropriate.

If FCOI are eliminated before research funds are expended, Omniox is not required to submit a report to the PHS funding agency.

An FCOI report will contain at a minimum:

- The name of the investigator with the FCOI
- The name of the entity with which the investigator has an FCOI
- The nature of the SFI
- The value of the financial interest
- Description of how the financial interest relates to the NIH-funded research and why the institution determined that the financial interest conflicts with such research
- Description of the key elements of the institution's management plan, including other required information as required by 42 CFR 50, Subpart F

If any interests are identified as conflicting subsequent to the initial report, they must be reported to Omniox within 30 days. Omniox will then report it to the PHS awarding component that has issued the award within 60 days. Each investigator must submit an updated disclosure of an SFI not less than annually. If a PHS-funded project is conducted by an investigator with a conflict that was not disclosed or managed, Omniox may require the Investigator disclose the conflict in each public presentation related to the results of the research and to request an addendum to previously published presentations.

If bias is found with the design, conduct, or reporting of NIH-funded research, Omniox will promptly notify the PHS funding agency and will submit a mitigation report that includes all reporting elements as required by regulation. If an investigator fails to comply with Omniox's FCOI policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, Omniox will promptly notify the PHS funding agency and take corrective action for noncompliance with Omniox's policy or management plan.

In any case which the Department of Health and Human Services (HHS) determines that a PHS-sponsored 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 Financial Conflict of Interest that was not managed or reported by Omniox as required by this policy and Federal regulation, Omniox may require the Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

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## **5. Records Management**

The records of all financial disclosures and all actions taken by Omniox will be maintained for at least three years from the date of submission of the final expenditures report.

## **6. Public Access to Information**

This policy must be posted on Omniox's publicly accessible website. If you have any questions regarding FCOI policy, please send your inquiry to [info@omniox.com](mailto:info@omniox.com).

## **7. Compliance and Penalties for Non-Performance**

Failure to comply with this policy may lead to disciplinary or corrective action including but not limited to, removal from research project, suspending or terminating project, imposition of award conditions such as denying use of funds for parts of or all activities, suspension of funding, withholding further awards from project or program, and any other remedies that may be legally available. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause. Similarly, agreements with subrecipient organizations may be terminated for cause if that organization fails to comply with its obligations under the PHS regulations. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations and Omniox policy. In extreme cases of bias, the Investigator may lose the right to receive any future NIH funding.

Policy History:

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