OAI, INC.
Policy on Financial Conflicts of Interest in Research (FCOIR)
August 2018

These provisions meet the minimum requirements in Code of Federal Regulations (CFR) Section 42, Part 50, Subpart F --Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is sought

I. Policy Statement

OAI seeks to promote objectivity in research supported by Public Healthy Services (PHS) by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from financial interests. The FCOIR Policy informs investigators about situations that generate financial conflicts of interest related to research and provides mechanisms for investigators and OAI to eliminate or manage financial conflicts of interest that arise.

II. Definitions

Financial Conflict of Interest: A financial conflict of interest (FCOI) exists when OAI through its designated officials, reasonably determines that an investigator’s significant financial interest (SFI) could directly and significantly affect the design, conduct, or reporting of the research.

Research: a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. Any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

Investigator: Investigator includes any person who is responsible for the design, conduct, or reporting of research, regardless of title or position.

Senior/Key Personnel: The Project Director or Principal Investigator and any other person identified as senior/key personnel by OAI in the grant application, progress report, or any other report submitted to the PHS.

Significant Financial Interest: An SFI is defined in 42 C.F.R. § 50.603. SFI means a financial interest consisting of one or more of the following interests of the investigator (and spouse and dependent children) that reasonably appears related to the investigator’s OAI responsibilities with regard to anything of monetary value, including but not limited to:

- salary or other payments for services (e.g., consulting fees or honoraria)
- equity interests (e.g., stocks, stock options or other ownership interests)
- intellectual property rights (e.g., patents, copyrights and royalties from such rights).
The following are not considered to be in an SFI:

- Salary, royalties, or other remuneration from OAI;
- Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- An equity interest that when aggregated for the Investigator and the Investigator’s spouse and dependent children, meets both of the following tests: Does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity
- Salary, royalties or other payments that when aggregated for the Investigator and the Investigator’s spouse and dependent children over the next twelve months, are not expected to exceed $10,000.

III. Disclosure

Investigators must disclose any SFI that reasonably appears to be related to the investigator’s OAI responsibilities. Investigators must disclose SFIs annually and within 30 days of discovery or acquisition of a new or change in an SFI. Disclosures are made using the Potential Conflict of interest reporting form.

IV. Review

The Executive Director will review all financial disclosures and determine whether a SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. If a conflict exists, the Executive Director will determine what actions should be taken to manage, reduce, or eliminate the conflict of interest.

V. Management of Conflicting Interests

Management of FCOIs may include, but is not limited to; public disclosure, monitoring by independent reviewers, modification of the research plan, reduction or elimination of the investigator’s role in certain aspects of the study, divestiture of significant financial interests, ending relationship that created the actual or potential conflict, and additional monitoring.

Reviews and determinations must occur prior to expenditure of funds for new projects, within 60 days of newly disclosed SFIs, and within 60 days of the addition of new investigators to projects.

VI. Reporting

When OAI determines that an SFI is related to sponsored research, the Senior Director of Operations or their delegate must submit reports as required by the sponsor. The Senior Director of Operations must submit the FCOI Report:

- prior to the expenditure of funds;
- within 60 days of identification for an investigator who is newly participating in the project;
- within 60 days for new, or newly identified, FCOIs for existing investigators.

After the FCOI Report is initiated, the Senior Director of Operations or their delegate must provide to the sponsor status updates and identify changes in management plans, at least annually, until the completion of the project.
VII. Noncompliance and Enforcement Mechanism

The following are examples of noncompliance with the FCOIR Policy:

a. failure to submit a timely disclosure;
b. submission of an incomplete, erroneous or misleading initial, updated or annual disclosure;
c. failure to disclose information as required by the FCOIR Policy; and
d. failure to comply with prescribed management plans.

When noncompliance is identified, the Senior Director of Operations or their delegate will implement a management plan within 60 days.

In addition, the Executive Director must conduct a retrospective review of the investigator’s research activities on the project to determine if there is bias in the design, conduct, or reporting of the research resulting from the financial conflict of interest. The retrospective review must be completed within 120 days of the determination of noncompliance. If bias is found in the course of the retrospective review, the Executive Director office must promptly notify the sponsor and submit a mitigation report that addresses the impact of the bias on the research and OAI’s plan of action to eliminate or mitigate the effect of the bias.

VIII. Training

The FCOIR policy will be reviewed annually during staff meetings for all staff including investigators.

IX. Subrecipient Compliance

If OAI carries out the research through use of a subrecipient, OAI must require the subrecipient to comply with either OAI’s FCOIR Policy or the subrecipient’s financial conflicts of interest policy. If the latter, then the subrecipient must certify that its policy complies with the PHS regulations. The subrecipient agreement must specify deadlines for the subrecipient to submit all SFI disclosures or reports of conflicts to OAI so that OAI can meet its own reporting obligations.

X. Public Access to Information

Upon written request, OAI must make available to the public within five business days certain information about the SFIs held by senior/key personnel that constitute a FCOI related to the research. The minimal information to be provided is described at 42 C.F.R. § 50.605(a)(5)(ii). The Executive Director or their delegate will coordinate requests and responses.

XI. Administrative Action and Sanctions

Failure by an investigator to comply with the requirements for financial disclosure, and management of conflicts may result in sanctions and administrative actions. Administrative actions may include delay in award execution or suspension of the research project. Sanctions, when necessary, will be consistent with the OAI’s policy Business Ethics: Practice of Ethical Behavior.

XII. Confidentiality

To the extent allowed by law and OAI policies, any information obtained in connection with FCOIR
proceedings shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the process.

XIII. Records Retentions

Records of all financial disclosures and all actions taken by OAI with respect to each conflicting interest will be maintained for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

XIV. Sponsor Oversight

OAI will comply with all reasonable requests for additional information or oversight by the sponsor agency.