



FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

Enacted: 8/1/2023

Revised: 8/20/2023

PURPOSE:

The purpose of the Financial Conflict of Interest (FCOI) policy is to maintain the highest level of compliance and ethics within the organization and to meet the mandates of various business agreements, grants, donations, and other Federal program requirements, including all National Institutes of Health (NIH) grants and cooperative agreements. This policy outlines the major regulatory requirements defined individuals must adhere to, including Investigators under NIH grants. **42 CFR Part 50 Subpart F shall be the guiding Federal mandate that directs this policy.**

PROCEDURE:

1. OVERVIEW

- a. This written policy and corresponding enforcement shall be reviewed on an annual basis against prevailing regulatory requirements and other best practices.
- b. This written policy shall be furnished to any requestor and shall also be publicly accessible via the Opio website.
- c. All applicable individuals – including NIH Grant Investigators – shall remain in compliance with the procedure, with applicable training, oversight, and reporting to support adherence to the requirements of the policy.
 - i. An **Investigator** is defined as 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 PHS/NIH, or proposed for such funding, which may include collaborators or consultants.
- d. All requests for evidence and documentation of procedures shall be made available upon request.

2. TRAINING

- a. All applicable individuals – including NIH Grant Investigators – shall receive a copy of Opio's FCOI Policy prior to beginning any work under any relevant funding source and shall be trained at least every four (4) years or when policy is revised or in cases of non-compliance (**42 CFR 50.604(b, 1-3)**)
 - i. Training resources can be found at [FCOI Training | grants.nih.gov](https://www.nih.gov/grants/financial-conflict-of-interest)

3. DISCLOSURE, REVIEW, AND MONITORING

- a. The Investigator / individual must disclose all foreign and domestic significant financial interests (SFI) of \$5,000 and greater (and those of the Investigator / individual's spouse and dependent children) (**42 CFR 50.604(e)(1)-(3)**) which include:
 - i. Remuneration (e.g. salary, consulting fees, honoraria, etc.), royalties, equity interest, and reimbursed or sponsored travel from an associated / affiliated entity (ex. the organization, business, etc. that the funded study is supporting).
 - ii. Financial interests received from a foreign institution of higher education or the government of another country.

- b. Applicable individuals shall complete the “Opio Financial Conflict of Interest Disclosure” form annually during the period of applicable award(s) and within 30 days of acquiring a new SFI **(42 CFR 50.604(d))**.
- c. As a pre-revenue start-up company, Opio shall designate review of an Investigator’s SFI to its outsourced financial consulting firm (currently: **engageCFO, Burlington, VT**), its legal counsel and/or other retained organization. The Investigator may be involved in making the determination of whether the SFI is related to the PHS/NIH-funded research **(42 CFR 50.604(f))**.
- d. An FCOI exists when the Institution, **through its designated official(s)**, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. If an FCOI exists, Opio will:
 - i. Appoint an individual mentor / consultant (e.g. external entity) to provide adequate oversight / record keeping / disclosure, including **(42 CFR 50.605(a)(1))**:
 - 1. Review of all Investigator SFI disclosures
 - 2. Determine if any SFIs related to PHS/NIH-funded research
 - 3. Determine if an FCOI exists (e.g., the SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research)
 - 4. Develop and implement a management plan to manage the FCOI(s)
 - a. When an Investigator who is new to participating in the research project or when an existing Investigator discloses a new SFI, the designated official(s) shall within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI **(42 CFR 50.605(a)(2))**
 - b. Whenever Opio identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS/NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage such FCOI going forward **(42 CFR 50.605(a)(3) and (i) – (iii))**
 - c. Opio and/or its designees shall take actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance



with management plans until completion of the project **(42 CFR 50.604 (g); 42 CFR 50.605(a)(4))**

4. REPORTING REQUIREMENTS

- a. Initial, annual (i.e., ongoing) and revised FCOI reports, including all required information defined in the regulation shall be sent to applicable requestors and/or to the NIH via the eRA Commons FCOI Module for the Institution and its subrecipients, if applicable, as required by the regulation and as stated below **(42 CFR 50.604(h); 42 CFR 50.605(b))**:
 - i. Prior to the expenditure of funds
 - ii. Within sixty (60) days of identification for an Investigator who is newly participating in the project
 - iii. Within sixty (60) days for new, or newly identified, FCOIs for existing Investigators
 - iv. 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). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
 - v. After a retrospective review to update a previously submitted report, if new information is discovered following completion of the review **(42 CFR 50.605(a)(3)(iii))**.
- b. NIH and/or other relevant parties shall be notified promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research and include the requirement to submit a Mitigation Report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation **(42 CFR 50.605(a)(3)(iii))**.
- c. NIH and/or other relevant parties shall be notified if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research **(42 CFR 50.606(a))**. Opio shall take corrective action for noncompliance with Opio's policy and/or the management plan.

5. MAINTENANCE OF RECORDS

- a. Opio shall maintain all FCOI-related records relating to all Investigator disclosures of financial interests and the Institution's review of, and response, to such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable **(42 CFR 50.604(i))**:
 - i. For at least three (3) years from the date the final expenditures report is submitted to the PHS (NIH).
 - ii. Or, where applicable, from other dates specified in **45 CFR 75.361** for different situations.

6. ENFORCEMENT MECHANISMS AND REMEDIES FOR NONCOMPLIANCE

- a. Opio shall establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance (e.g., letters

of reprimand, restriction on the use of funds, etc.) **(42 CFR 50.604(j))**, as determined based on circumstances and with input by external consultants and/or legal counsel.

- b. Opio shall complete a retrospective review within 120 days of the Institution's determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including **(42 CFR 50.605(a)(3))**:
 - i. Failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest;
 - ii. Failure by the Institution to review or manage such a financial conflict of interest;
 - iii. Failure by the Institution to review or manage such a financial conflict of interest;
 - iv. The retrospective review shall include the minimum following elements **(42 CFR 50.605(a)(3)(ii)(B))**:
 - 1. Project Number
 - 2. Project Title
 - 3. PD/PI or contact PD/PI if multiple PD/PI model is used;
 - 4. Name of the Investigator with the FCOI;
 - 5. Name of the entity with which the Investigator has an FCOI;
 - 6. Reasons for the retrospective review;
 - 7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);
 - 8. Findings of the review; and
 - 9. Conclusions of the review
- c. Opio shall ensure that in any case in which the Department of Health and Human Services determines that a PHS/NIH-funded research 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 an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to **(42 CFR 50.606(c))**:
 - i. Disclose the FCOI in each public presentation of the results of the research, and
 - ii. To request an addendum to previously published presentations.

7. SUBRECIPIENT REQUIREMENTS

- a. Opio does not and, under the dictates of this procedure, will not award its funds to subrecipient entities. In the event this policy changes, this policy / procedure shall be amended in accordance with the requirements of this document and the guidance of **42 CFR 50.604(c)**.

8. PUBLIC ACCESSIBILITY REQUIREMENTS

- a. Opio shall make the FCOI policy publicly accessible on Opio's company website, as well as information concerning identified FCOIs held by senior/key personnel. Publicly accessible information will:
 - i. Include the minimum elements as provided in the regulation
 - ii. Be made available within five (5) business days of a written request



1. Responses to written requests should include detail that has been updated at least annually
2. Responses to written requests should include detail that has been updated, within sixty (60) days of a newly identified FCOI
3. Remain available for three (3) years from the date the information was most recently updated



FINANCIAL CONFLICT OF INTEREST (FCOI) DISCLOSURE FORM
Revised: 8/20/2023

NAME: Amber Norbeck

ROLE: Principal Investigator (ex. Investigator / Researcher, etc.)

I attest that I have reviewed the Opio FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

Opio is required to gather and retain details of relevant individuals as it pertains to Financial Conflict of Interest (FCOI) as it relates to certain Federal and other funding sources that the organization receives. Conflict of Interest and corresponding procedures are defined within the Opio Financial Conflict of Interest (FCOI) policy. Disclosure is required regarding financial interests (SFI) of \$5,000 and greater, including financial interests in the 12 months preceding this disclosure and value of equity interest as of the date of disclosure. Disclosure also includes intellectual property (IP) rights and interests (e.g., patents, copyrights), upon the receipt of income related to such rights and interests, in addition to reimbursed or sponsored travel.

Disclosure is also required for all financial interests received from a foreign institution of higher education or the government of another country when such income meets the \$5,000 threshold for disclosure.

I DO NOT have any Financial Conflict of Interest (FCOI) to report
I (or on behalf of my spouse and/or dependent children) DO have a Financial Conflict of Interest (FCOI) to report:
1. Please provide Entity Name of Conflict to be Disclosed:
2. Please explain the nature of the conflict:
- The value of the SFI.
- A distinction whether the SFI is from a publicly traded or non-publicly traded entity.
- A description of the nature of the SFI (e.g. salary, royalties, consulting fees, honoraria, paid authorship, reimbursed or sponsored travel (trip purpose, sponsor / organizer, destination, and duration), etc.)
- Whether the SFI is related to any Public Health Service application and/or funded project and an explanation for the relatedness.
(Please use additional sheets if necessary)

Opio’s Designated Official(s) makes the determination whether the SFI is an FCOI (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research). “Significantly” means “the financial interest would have a ‘material effect on the research’”.

SIGNED: [Signature]
DATE: 8/21/23