

## Policy on Financial Conflict of Interest (FCOI)

### 1. Covered Institution

EicOsis, LLC, “Company” or “Institution” is covered under this policy as required by the National Institutes of Health (NIH) and applicable US. regulations. The Company is responsible for determining whether SFI relates to NIH-funded research and if it is a Financial Conflict of Interest (FCOI).

### Purpose

The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from an Investigator’s financial conflicts of interest (and/or of the Investigator’s spouse and/or dependent children). This policy complies with the following federal regulations:

- [Title 42 Code of Federal Regulations \(CFR\), Part 50](#)

### 2. Scope

This policy applies to Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research funded by National Institute of Health (NIH).

If a research project involves subcontractors, subgrantees, or subawardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should National Institute of Health (NIH) funds be subcontracted by Institution to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

### 3. Definitions

**Investigator:** means the project director or principal investigator and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of research funded by the NIH, which may include, for example, collaborators or consultants.

**Institution:** means any domestic or foreign, public, or private, entity or organization (excluding a federal agency) applying for or receiving NIH research funding.

**Financial Interest** means anything of monetary value or potential monetary value held by the Investigator, the Investigator’s spouse and/or dependent children, regardless of whether the value is readily ascertainable.

**Financial Conflict of Interest** means a Significant Financial Interest (see below) related to a research program or project that could directly and significantly affect the design, conduct or reporting of research.

**Significant Financial Interest (SFI)** means

- A financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator’s spouse and/or dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:
  - I. The value of any remuneration received from a publicly traded entity in the twelve months prior to the disclosure is considered a significant financial interest when the value of any equity interest in the entity as of the date of the 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 interests includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
  - II. Regarding 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 (and/or the Investigator’s spouse and/or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  - III. 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 in excess of \$5,000 related to their company responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by Federal, state, or local government agency located in the United States, an United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an United States institution of higher education.

Note: Reimbursed or sponsored travel from a foreign government, which includes local, provincial, or equivalent governments of another country or foreign institutions of higher education must be disclosed when such income is more than \$5,000. The details of the disclosure will include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

- The term *significant financial interest* **does not include** the following types of financial interests:
  - I. salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution
  - II. b. intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights
  - III. any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization
  - IV. income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles
  - V. income from seminars, lectures, or teaching engagements sponsored by a Federal,

state, or local government agency located in the United States, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education

- VI. Any income derived from serving on advisory committees or review panels for federal, state, or local government agencies located within the United States, as well as from an educational institution that is affiliated with a U.S. institution of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with a U.S. institution.

*Note:* Income from seminars, lectures, or teaching engagements and from service on advisory committees or review panels received from a foreign government. This includes local, provincial, or equivalent governments of another country or foreign institutions of higher education must be disclosed when such income meets the threshold for disclosure.

**Responsibilities** – Investigator responsibilities are defined by the Institution on behalf of the Institution, including but not limited to research, research consultation, teaching, professional practice, membership of institutional committees, and service on panels such as Institutional Review Boards and Data and Safety Monitoring Boards.

**Financial interest** – means anything of monetary value, whether or not the value is readily ascertainable.

**Manage** – means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

**Senior/Key Personnel** – means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under the regulation.

Individual financial conflicts of interest are addressed in this policy; however, institutions may also have conflicts of interest when their financial interests, or those of an Institution official acting within their authority on behalf of the Institution, might adversely affect or appear to adversely affect Institution processes for conducting, reviewing, or overseeing research. Normally, institutional conflicts of interest will be resolved in accordance with this policy if they are identified via the process described below.

#### 4. Policy

All investigators who conduct research on NIH-funded institutional projects are required to disclose all significant financial interests (SFIs) that are relevant to their institutional research responsibilities within 30 days of becoming aware of a new SFI or after eliminating a financial conflict of interest.

**Investigators are required to complete the annual disclosure form even if they have no financial interest to report.** A PI is also required to disclose transactions when submitting a research proposal to the Institution's Chief Business Officer (CBO), also known as the administrator.

#### 4. Policy (continued)

Company Responsibility:

- i. Provide a written copy to each Investigator.
- ii. Add the policy to the company's secure shared drive and a public website.

#### 5. Training

NIH-funded Investigators must complete FCOI training prior to engaging in research related to any NIH-funded grant or contract and at least every four years thereafter. Training must also be completed *as soon as reasonably possible* under the following circumstances:

- This policy changes in a manner that affects Investigator requirements
- An Investigator is new to a subrecipient and will be working on NIH- funded research
- An Investigator is found to be noncompliant with this policy or their approved action plan

Training requires Investigators to acknowledge they've read:

- Institution's FCOI Policy.
- NIH's FCOI tutorial on 42 CFR Part 50 Subpart F, necessary for all involved in NIH-funded projects. Certificates of completion should be filed in the company's records. Training is mandated before any NIH-funded research begins, after FCOI policy updates, upon non-compliance, or when joining the company, and must be repeated every three years. The course can be accessed online at any time by visiting:  
<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

#### 6. Disclosure, Review, and Monitoring

Investigators must report SFIs (including those of their spouses and dependent children) that are pertinent to their institutional duties and meet or surpass the SFI criteria established by this policy, through the company's Significant Financial Interest Form. The following disclosures must be made:

- i. At the NIH-funded research application stage
- ii. Annually throughout the award duration
- iii. Within 30 days of identifying or obtaining a new SFI.

Institution CBO will serve as the designated institutional official, and is tasked with eliciting and evaluating SFI disclosures from Investigators (and those of the Investigator's family) connected to their institutional duties to ascertain any FCOIs.

Investigators may help determine if an SFI exists.

An SFI is related to NIH-funded research if:

- The SFI could notably influence the design, conduct, and reporting of NIH-funded research. In such cases, appropriate actions will be considered based on the SFI Disclosure Form. This may necessitate a management plan that specifies the terms and conditions to adhere to this policy (refer to Enforcement Mechanisms).

- It belongs to an entity that could be adversely affected by the research.

Examples of SFI include:

- An investigator (and/or the investigator's spouse and/or dependent children) enters into a paid consultancy relationship with an outside entity who is interested in the investigator's (and/or the investigator's spouse and/or dependent children) receiving royalty payments or non-royalty payments in connection with ongoing research;
- Investigators (and/or their spouses and/or dependent children) who have equity interests in ongoing research (e.g., stocks, stock options, warrants);

Should an SFI be identified as an FCOI, the company will manage it at its discretion. This might include public disclosure, the appointment of an independent monitor, modifications to the research plan, or the Investigator's removal from the NIH-funded research.

Before utilizing any NIH funds, the CBO is required to:

- i. Assess all SFI disclosures from Investigators
- ii. Decide whether any SFIs relate to the NIH-funded research
- iii. Ascertain the existence of any FCOIs and, if they exist,
- iv. Formulate and enforce a management plan to address the FCOIs.

Should a new Investigator join, or an existing Investigator report a new SFI in an NIH-funded research project, the CBO must, within 60 days, evaluate the SFI disclosures, ascertain the presence of an FCOI, and if one is found, initiate a management plan outlining the measures taken and to be taken to address the FCOI.

If the company discovers an SFI that an Investigator did not disclose in a timely manner or that the company has not previously assessed during an ongoing NIH-funded research project, the CBO is required to, within 60 days, review the SFI disclosures, decide if an FCOI is present, and if affirmative, implement a management plan detailing the actions undertaken and those planned for future management of the FCOI.

The company is tasked with overseeing FCOIs for all Investigators, including those of a subrecipient Investigator, ensuring adherence to management plans until the research project is concluded.

## **7. Reporting Requirements to NIH**

Institution is required to submit initial, yearly, and updated FCOI reports containing all details mandated by 42 CFR Part 50 Subpart F to the NIH through the eRA Commons FCOI Module for both the Institution and its subrecipients, where relevant, as outlined below:

- i. Before using any funds
- ii. Within 60 days of discovering an FCOI for an Investigator who is new to the project
- iii. Within 60 days upon finding new or previously unidentified FCOIs for current Investigators
- iv. Annually, concurrent with the submission of the annual progress report, detailing the FCOI's status and any modifications to the management plan until the project's conclusion
- v. Following a retrospective review to amend an earlier report if additional information comes to light after the review is completed.

Institution is obligated to immediately inform NIH if bias is detected in the design, execution, or reporting of NIH-funded research. A Mitigation Report will be provided to outline steps taken to counteract the impact of the bias in line with 42 CFR Part 50 Subpart F. The report will include all required components such as the entity name, the Investigator with the FCOI, the nature and value of the SFI(s), among others, as specified by 42 CFR Part 50 Subpart F.

Institution must immediately inform NIH if an Investigator breaches Institution's FCOI policy or if there's evidence suggesting that an FCOI management plan may have skewed the design, execution, or reporting of NIH-funded research. When such noncompliance or influence on research outcomes occurs, the company must implement corrective measures.

## **8. Maintenance of Records**

Institution shall preserve all records pertaining to Investigator financial interest disclosures, and the company's examination and response to these disclosures—irrespective of whether a disclosure led to an FCOI determination—along with all proceedings in accordance with the company's policy or retrospective analysis, as applicable:

- i. For a minimum of 3 years following the submission date of the final expenditure report to the NIH.
- ii. Or, if relevant, from dates specified in 45 CFR 75.361 for different situations.

## **9. Enforcement Mechanisms and Remedies and Noncompliance**

To manage, mitigate, or eradicate actual or potential conflicts of interest, the management plan might necessitate various actions, including but not limited to:

- I. Making significant financial interests known to the public.
- II. Independent evaluation of research protocols.
- III. Independent oversight of the research.
- IV. Altering the research strategy.
- V. Prohibiting participation in part or all of the funded research.
- VI. Selling off significant financial interests.
- VII. Cutting ties that pose actual or potential conflicts.

Should an Investigator fail to adhere to the FCOI policy or management plan of Institution, disciplinary or administrative measures will be enforced, which could include a formal reprimand, restrictions on fund usage, forfeiture of compensation, or dismissal.

If there is noncompliance due to untimely disclosure or management of an SFI or an FCOI, Institution will conduct a retrospective assessment within 120 days to address:

- I. Non-disclosure of a significant financial interest by the Investigator which the company deems to be an FCOI.
- II. The company's failure to evaluate or manage an FCOI.
- III. The Investigator's non-compliance with the FCOI management plan.

The retrospective review will be documented and will include, at minimum, the following:

- I. Project number
- II. Project title

- III. PD/PI and contact information
- IV. Name of Investigator with the FCOI
- V. Name of the entity with which the Investigator has an FCOI
- VI. Reasons for the retrospective review
- VII. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed)
- VIII. Findings of the review
- IX. Conclusions of the review.

If a project funded by NIH involves clinical research evaluating the safety or effectiveness of technology from Institution and is designed, conducted, or reported by an Investigator with an FCOI not managed or reported as mandated by 42 CFR Part 50 Subpart F, Institution will mandate that the Investigator reveal the FCOI in all public disclosures of the research findings and seek an amendment to any previously published presentations of the research.

All management strategies must be endorsed by both the Investigator and Institution's CEO.

## **10. Subrecipient Requirements**

When applicable, Institution will comply with all subrecipient requirements according to 42 CFR 50.604(c) and NIH Grants Policy Statement 15.2.1.

Institution will determine through a formal agreement if the subrecipient will adopt Institutions FCOI policy or their own. If the subrecipient's policy is adopted:

- I. Institution will acquire confirmation that the subrecipient's FCOI policy is consistent with 42 CFR Part 50 Subpart F
- II. Institution will mandate in the subrecipient contract that the subrecipient must promptly report any FCOIs of its Investigators to enable the company to fulfill reporting obligations to the NIH as dictated by 42 CFR Part 50 Subpart F
- III. As an alternative, Institution will include a provision in the subrecipient contract obligating the subrecipient to submit and allow review of Investigator disclosures, assisting the company in identifying, managing, and reporting FCOIs to the NIH.

## **11. Public Accessibility Requirements**

- I. Include 42 CFR Part 50 Subpart F's minimum elements.
- II. Be accessible within 5 business days upon request
- III. Be updated annually, with current information provided upon request
- IV. Be revised within 60 days following the identification of a new FCOI, with current information provided upon request
- V. Remain available for 3 years after the latest update.

## 12. Significant Financial Interest (SFI) Disclosure Form

Institution will provide an internet-based SFI disclosure form that is available to all employees and subcontractors:

- Investigator's name
- Entity name in which the Investigator (and spouse and dependent children) has an SFI
- Disclosure requirement that is consistent with the institution's definition of SFI
- Disclosure of financial interests in the 12 months preceding the disclosure and value of each equity interest as of the date of disclosure
- Disclosure of intellectual property (IP) rights and interests (e.g., patents, copyrights), upon the receipt of income related to such rights and interests. Institutions should note that they may impose a \$5,000 threshold in the SFI definition for IP rights and interests as described in the [Final Rule](#) on page 53265). If the institution utilizes the narrative from the regulatory definition of SFI as stated in 42 CFR 50.603, the threshold for disclosure related to such interests is \$0.
- Disclosure of reimbursed or sponsored travel may include a threshold for disclosure as provided in NIH's FAQs [E.9.](#) and [E.24.](#) If the institution does not include a threshold for disclosure, the threshold is \$0. The policy must specify the details of such disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- Clarify that disclosure is required for all financial interests received from foreign institutions of higher education or the government of another country when such income meets the threshold for disclosure (e.g., income in excess of \$5,000) (see FAQs [E.9.](#), [E.21.](#), [E.24.](#), [E.36.](#) and [E.37.](#)) Note the 20 U.S.C. Code 1001(a) citation within the SFI definition, refers to institutions of higher education located in the United States or a federal, state, or local government agency within the United States.
- The value of the SFI.
- Indicate whether the SFI is from a publicly traded or non-publicly traded entity. Also note that disclosure requirements for equity interest differ for each.
- Describe the nature of the SFI (e.g., salary, royalties, consulting fees, honoraria, paid authorship, reimbursed or sponsored travel).
- Indicate whether the SFI is related to any NIH application or NIH-funded project and an explanation for the relatedness to assist with the institution's designated official(s) review.  
Some information to consider:
  - The institution'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).
  - Per the preamble in the [Final Rule](#) (page 53261), "significantly" means "...the financial interest would have a 'material effect on the research' ...".



## 13. Useful FCOI and NIH Resources

Subscribe to the NIH Guide to Grants and Contracts at [NIH Guide LISTSERV: Subscribe to Weekly TOC E-Mail with New NIH Guide Postings and Funding Opportunities](#)

[NIH Guide Notices Related to Financial Conflict of Interest | grants.nih.gov](#) are posted at this NIH website.

FCOI Regulation 42 CFR Part 50 Subpart F at [eCFR :: 42 CFR Part 50 Subpart F -- Promoting Objectivity in Research](#)

FCOI Webpage at [Financial Conflict of Interest | grants.nih.gov](#)

FCOI Training Webpage at [FCOI Training | grants.nih.gov](#)

FCOI FAQs at [Frequently Asked Questions \(FAQs\) | grants.nih.gov](#)

Foreign Grant webpage at [Information For Foreign Grants | grants.nih.gov](#) and [Important Highlights of FCOI Regulatory Requirements for Foreign Institutions | grants.nih.gov](#)

NIH's Welcome Wagon letter at [NIH "WELCOME WAGON" LETTER Information for New Recipient Organizations | grants.nih.gov](#) and FCOI information at <https://grants.nih.gov/grants/funding/welcomewagon.htm#fcoi>

## 14. Version History

Version 1.2.

Revision history: updated to comply with CHECKLIST FOR POLICY DEVELOPMENT RELATED TO THE 2011 FINANCIAL CONFLICT OF INTEREST (FCOI) REGULATION, PROMOTING OBJECTIVITY IN RESEARCH ([42 CFR Part 50 Subpart F](#)) revision 11-20-2023

Updated: 11/20/2023

Reviewed by:

Approved by: