

Financial Conflict of Interest (FCOI) Policy

Integrated Sensors, LLC, August 18, 2021

I. INTRODUCTION

Objective research is of paramount importance to Integrated Sensors, LLC. (“I-S”). I-S’s financial conflict of interest (FCOI) policy meets the expectation that the design, conduct, and reporting of research will be free from bias resulting from financial interests. This policy provides a framework to comply with requirements of 42 CFR 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research” for which PHS Funding is Sought” (FCOI Regulation), of the Federal Register pertaining to PHS-funded research, and is intended to ensure the research is free from bias due to financial conflicts of interest, and that potential financial conflicts of interests are identified, managed, reduced, or eliminated (see link below).

REVIEW 42CFR 50: https://ecfr.io/Title-42/sp42.1.50.f#se42.1.50_1604

II. SCOPE

This Policy describes types of Financial Conflict of Interest (FCOI), identifies when disclosure should be provided, and explains I-S’s administration and enforcement procedures. The policy is applicable to Senior/Key Personnel/Investigators as defined below, who participate in I-S’s research. Participation includes having an active role in device and/or software development, as well as the reporting of study results. I-S being a hardware development company does not work with any biological materials, pharmaceuticals, patient protocols or clinical trials.

III. DEFINITIONS

Designated Official(s):

Person(s) responsible for the implementation of the FCOI Policy, designated by I-S.

Equity Interest:

Any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Financial Interest:

Anything of non-trivial monetary value, regardless of whether the value is readily ascertainable.

Financial Conflict of Interest (FCOI)

A significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Immediate Family:

Investigator/senior/key personnel’s spouse or domestic partner and dependent children.

Investigator:

The project director or principal investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include subgrantees, contractors, consortium participants, collaborators or consultants.

Institution:

Any domestic or foreign, public or private, entity or organization (excluding a federal agency) that submits a proposal or that receives PHS research funding. I-S is considered an “Institution” for the purposes of this policy.

Institutional responsibilities:

Any key/senior personnel/investigator’s professional responsibilities conducted on behalf of I-S and as defined by I-S, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards (IRB) or Data and Safety Monitoring Boards (DSMB).

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).

Regulation or FCOI regulation:

42 CFR Part 50 Subpart F, Promoting Objectivity in Research, which applies to both grants and cooperative agreements.

Remuneration:

Salary and any payment for services, including consulting fees, honoraria, and paid authorship.

Research:

A systematic investigation, study, or examination designed to develop or contribute to generalizable knowledge relating broadly to public health including behavioral and social-sciences research, basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a device, software, diagnostic test or drug). The term includes any such activity for which research funding is available from PHS but excluding applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Senior/Key Personnel:

The Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by the I-S in the grant application, progress report, or any other report submitted to the PHS/NIH by I-S under the regulation.

Significant Financial Interest (SFI):

Financial interest consisting of one or more of the following interests of the investigator/senior/key personnel (and those of the investigator/senior/key personnel’s spouse and dependent children) that reasonably appears to be related to the Investigator/senior/key personnel’s institutional responsibilities:

- With regard to any publicly traded entity a SFI 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;

- 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/senior/key personnel (or the Investigator/senior/key personnel's spouse or dependent children) holds any equity interests (e.g., stock, stock options, or other ownership interest) or intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Investigator/senior/key personnel must also disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator/senior/key personnel and not reimbursed to the investigator/senior/key personnel so that the exact monetary value may not be readily available) related to their responsibilities to I-S; 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. I-S'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 I-S's FCOI policy, I-S Designated 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.
- The term significant financial interest (SFI) does not include the following types of financial interests: salaries, royalties or other remuneration paid by I-S to the investigator/senior/key personnel if the investigator/senior/key personnel is currently employed or otherwise appointed by I-S, including intellectual property rights assigned to I-S and agreements to share in royalties related to such rights; any ownership interest in I-S held by the investigator/senior/key personnel; income from investment vehicles, such as mutual funds and retirements accounts, as long as the investigator/senior/key personnel 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.

Small Business Innovation Research (SBIR):

The extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

IV. POLICY AND MANAGEMENT

A financial conflict of interest related to I-S's activities may occur when an investigator/senior/key personnel employed or appointed by I-S has a significant financial interest that compromises, or appears to compromise, that individual's independence and objectivity in the discharge of his/her I-S responsibilities in the design, conduct, or reporting of I-S's research. Investigators/senior/key personnel should avoid conflicts and the potential for conflicts resulting from financial arrangements with third parties that could have a special interest in an I-S research product or protocol.

Disclosure: Senior/key personnel/investigators are required to disclose SFIs (and those of the investigators, senior/key personnel's immediate family). This disclosure will be made at least annually during the award period [to include any information that was not disclosed initially to I-S or updated information regarding any previously disclosed SFI] and within 30 days of discovering or acquiring a new SFI (such as through purchase, marriage or inheritance).

I-S will name "Designated Official(s)" to manage the FCOI policy. The designated official(s) will take 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.

If a determination is made that a FCOI exists, I-S's Designated Official(s) will recommend a suitable action plan or management plan to eliminate or manage the FCOI consistent with the objectives of this policy.

The action plan shall provide for its periodic review and updating at least annually. In the event that there is no reasonable way to manage a FCOI then the investigator/senior/key personnel may be prohibited from participating in the related Research until such a time as the FCOI is eliminated.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create financial conflicts; and
- I-S shall review the proposed action plan or management plan and can approve, modify and approve additional work. Final review and determination must be completed prior to the expenditure of any PHS funds for the applicable Research.

A conflict should be managed, reduced, or eliminated within sixty (60) days of its identification by designated official(s). I-S's Designated Official(s) shall be responsible for monitoring and enforcing any management plan.

This shall also apply when, in the course of an ongoing PHS-funded research project, an investigator/senior/key personnel who is new to participating in the research project discloses a significant financial interest or an existing investigator/senior/key personnel discloses a new significant financial interest to I-S.

Enforcement

If a senior/key personnel/investigator fails to comply with I-S's FCOI policy, within 120 days of discovery by I-S, I-S shall complete a retrospective review of the senior/key personnel/investigator's activities to determine potential bias.

If a bias is found, I-S shall submit a mitigation report to the NIH, in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias.

I-S will work with the investigator/senior/key personnel to set up an FCOI management plan to mitigate the situation.

Companywide, I-S is required to mandate that senior/key personnel/investigator disclose the FCOI in each public presentation with research results if it was not reported up front. In extreme cases of bias, the investigator/senior/key personnel may lose the right to work on the project.

V. TRAINING, REPORTING, AND RECORD KEEPING

Training: All persons subject to the I-S Financial Conflict of Interest Policy will be required to train on the policy by reading and affirming their understanding of, and intent to comply with the FCOI policy and every four (4) years thereafter. Immediate training will be required if I-S revises this policy in a manner that affects the investigator/senior/key personnel, when an investigator/senior/key personnel is new to I-S, or as a result of a finding of noncompliance with this policy or a management plan, or other related misconduct.

I-S's senior/key personnel or investigators/study directors may also demonstrate understanding of FCOI by using the NIH web-based training which can be accessed by the online link below.

WEB-BASED TRAINING:

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

Unless otherwise covered by a third-party FCOI Policy as agreed with I-S, each investigator/senior/key personnel is required to complete training on I-S's FCOI Policy by reading and affirming the policy or demonstrate training on the NIH web based training on the following occasions:

- Prior to engaging in research related to any PHS-funded grant,
- At least every 4 years, and
- Immediately if:
 1. I-S revises the FCOI Policy in a manner that affects requirements of investigator/senior/key personnel,
 2. An investigator/senior/key personnel is new to I-S, or

3. An investigator is not in compliance with the FCOI Policy or management plan.

Reporting: As required by 42 CFR Part 50, Subpart F, I-S shall file a report with the NIH providing information on every identified FCOI and the manner in which the FCOI is being or has been managed, reduced, or eliminated. Reports shall include the elements required by these regulations. I-S will notify NIH promptly if bias is found with the design, conduct, or reporting of NIH-funded research, and file a Mitigation Report in accordance with federal regulations.

Records Management: The records of all financial disclosures and all actions taken by I-S will be maintained for at least three years from the date of submission of the final expenditures report.

VI. ADDITIONAL CONSIDERATIONS

Subrecipients: When carrying out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), I-S must incorporate by written agreement (e.g., subaward contract) that the investigator/senior/key personnel of the subrecipient institution is required to either:

- Comply with the I-S's FCOI Policy, or
- Comply with the FCOI Policy of the subrecipient institution and have said institution certify that its policy complies with 42 CFR Part 50 Subpart F.

The written agreement, under either policy above, must specify the time period for the subrecipient to provide investigator/senior/key personnel disclosure and report of any FCOI to I-S.

It is suggested that at least 30 days from the reporting deadline for I-S's annual disclosures, or in cases of discovery or acquiring new SFI a maximum of 10 business days be considered to which the subrecipient is to report to I-S, to enable I-S to comply timely with its review, management, and reporting obligations.

I-S will provide FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient investigator/senior/key personnel prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

VII. Public Accessibility

I-S's Financial Conflict of Interest Policy shall be posted on the public portion of the I-S website. In addition, upon receipt of a written request for information concerning identified FCOI's held by Senior/Key Personnel (as defined by regulation), I-S will make that information available within five (5) business days of the request. The information shall include all elements required by 42 CFR Part 50, updated through the date of the response.