

FRAUNHOFER USA INC POLICY ON FINANCIAL CONFLICTS OF INTEREST IN RESEARCH PROJECTS FUNDED BY THE PUBLIC HEALTH SERVICE (PHS)

As of January 1, 2024

I. Purpose

Fraunhofer USA, Inc. ("FhUSA") adopts this Policy and Procedures as required to implement and to comply with U.S. Public Health Service ("PHS") regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). The purpose of this Policy is to comply with PHS regulatory requirements and their goal of promoting objectivity in PHS Funded Research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements and contracts will be free from bias resulting from Investigators' Financial Conflicts of Interest.

II. Applicability

A. This Policy applies to any application for or receipt of research funding from PHS, including without limitation the National Institutes of Health ("NIH"), whether such funding is by means of a grant, cooperative agreement, or contract. However, this Policy shall only apply to PHS Funded Research with an issue date of the Notice of Award on or after January 1, 2024.

B. This Policy applies to each Investigator of PHS Funded Research.

C. Any Investigator conducting PHS Funded Research is also subject to: (a) FhUSA Policy on Conflicts of Interest.

D. Notwithstanding anything contained herein, this Policy does not apply to any Small Business Innovation Research Program ("SBIR") or Small Business Technology Transfer ("STTR") Program Phase I applications.

III. Definitions

A. COI Official: FhUSA Grants and Contracts Manager.

B. COI Committee: The composition of a conflict of interest committee will be determined on a case-by-case basis by the officers of Fraunhofer USA.

C. Financial Conflict Of Interest ("FCOI"): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS Funded Research.

D. Institutional Responsibilities: An Investigator's professional responsibilities on behalf of FhUSA including, without limitation, research, education, administrative, and/or service responsibilities, and which may include for example such activities as research, research consultation, teaching, professional practice, committee memberships, and service on panels such as the Institutional Review Board, Institutional Animal Care and Use Committee, or data and safety monitoring board or committee.

E. Investigator: 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 PHS Funded Research, or proposed for such funding, which may include, for example, collaborators or consultants.

F. Manage: Taking action to address a Financial Conflict of Interest, which may include reducing or eliminating the Financial Conflict of Interest, to ensure to the extent possible that the design, conduct, and reporting of PHS Funded Research will be free from bias.

G. Management Plan: A plan to Manage a Financial Conflict of Interest.

H. PHS Funded Research: Any Research which is funded by PHS, including any PHS Unit.

I. PHS Regulations: PHS regulations promoting objectivity in research (set forth at 42 CFR §50.601 et seq. and 45 CFR §94.1 et seq.), as they may be amended, supplemented, or replaced from time to time, and any other similar PHS regulations that may be promulgated.

J. PHS Unit: The organizational unit of the PHS that funds PHS Funded Research. PHS Units are the agencies within the Department of Health and Human Services (HHS) designated as components of PHS, as may be changed from time to time, including: (1) the Agency for Healthcare Research and Quality (AHRQ), (2) the Agency for Toxic Substances and Disease Registry (ATSDR), (3) the Centers for Disease Control and Prevention (CDC), (4) the Food and Drug Administration (FDA), (5) the Health Resources and Services Administration (HRSA), (6) the Indian Health Service (IHS), (7) the National Institutes of Health (NIH), (8) the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Office of the Inspector General (OIG).

K. Research: A systematic investigation, study, or experiment 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 (e.g., a published article, book, or book chapter), and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Unit through a grant, cooperative agreement, or contract, whether authorized under the Public Health Service Act (42 U.S.C. §201 et seq.) or other statutory authority, including without limitation a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

L. Senior/Key Personnel: This term includes the project director or principal investigator and any other personnel considered to be essential to work performance in accordance with 48 CFR §352.242-70, and identified as key personnel in the sponsored project proposal and award.

M. Significant Financial Interest:

1. One or more of the following financial interests (i.e. anything of monetary value, whether or not the value is readily ascertainable) of an Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- a. Remuneration of any value from any entity during the twelve (12) months preceding the disclosure, including without limitation salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);
- b. Any equity interest in any entity (including any stock, stock option, or other ownership interest);
- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests;
- d. An asset in a blind trust, if (i) the Investigator is aware that the asset is in the trust, or (ii) if the trust is not managed by an independent fiduciary; or
- e. 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);

2. The term "Significant Financial Interest" does not include the following:

- a. Salary, royalties, or other remuneration paid by FhUSA to the Investigator if the Investigator is currently employed by FhUSA, including intellectual property rights assigned to FhUSA and agreements to share in royalties related to such rights;
- b. 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;
- c. An asset in a blind trust, but only if (i) the asset is not known to the Investigator (e.g. it was purchased by the trust with proceeds from assets originally placed in the trust), and (ii) the trust is managed by an independent fiduciary;
- d. 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; or a research institute that is affiliated with an institution of higher education;
- e. Income from service on advisory committees or review panels of: 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; or
- f. 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; a medical center; or a research institute that is affiliated with an institution of higher education.

IV. Requirements

A. Designation, etc.

1. The COI Official is designated as FhUSA's institutional official with overall responsibility for the solicitation and review of disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, PHS Funded Research.
2. The COI Committee, if established, is responsible for making determinations regarding Significant Financial Interests, Financial Conflicts of Interest and Management Plans, as provided herein.
3. Input and advice may be solicited throughout such processes, as appropriate, from other FhUSA personnel, federal agencies and from others unaffiliated with FhUSA who may have relevant expertise.

B. Training

1. Each Investigator who is planning to participate in, or is participating in, PHS Funded Research must complete training related to financial conflicts of interest (regardless of whether or not a Financial Conflict of Interest exists).
2. Such training must be completed:
 - a. Prior to engaging in PHS Funded Research;
 - b. At least every four (4) years;
 - c. If the Investigator is new to FhUSA, within sixty (60) days of the commencement of employment (but not later than the beginning of PHS Funded Research by the Investigator);
 - d. Whenever FhUSA revises this Policy in a manner that affects the requirements of Investigators; and/or
 - e. When so directed as a result of an Investigator's non-compliance with this Policy or any Management Plan.
3. Training, or access to training, shall be provided by FhUSA and shall include information regarding this Policy, PHS regulations, and the Investigator's responsibilities under this Policy and the PHS Regulations to disclose Significant Financial Interests of the Investigator (and of the Investigator's spouse and dependent children).

C. Disclosure of Significant Financial Interests

1. Each Investigator who is planning to participate in, or who is participating in, PHS Funded Research shall disclose any Significant Financial Interest (including of the Investigator's spouse and dependent children) through his/her Supervisor to the COI Official or designee, if it reasonably appears that a Significant Financial Interest is related to the Investigator's Institutional Responsibilities. Such disclosures shall be made as part

of the application submission process. Alternatively, if no such Significant Financial Interest exists, the Investigator shall so certify as part of the application submission process.

2. Disclosures of Significant Financial Interests (or certifications that no such Significant Financial Interests exist) shall be made by each Investigator as follows:

a. At or before the time of submission of an application for PHS Funded Research;

b. At least annually during the period of the PHS Funded Research award;

i. The annual disclosure shall include: (a) any new information that was not disclosed to the COI Official or designee either initially or subsequently (e.g. any Financial Conflict of Interest identified on a PHS Funded Research project that was transferred from another institution); and (b) updated information regarding any previously disclosed Significant Financial Interest (e.g. the updated value of a previously disclosed equity interest);

ii. Annual updates shall be required of all Investigators participating in a PHS Funded Research project, regardless of whether or not a Significant Financial Interest was previously disclosed.

c. Within thirty (30) days of the discovery or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

3. The disclosures shall include without limitation the following information:

a. The nature and amount of remuneration received from any entity in the twelve (12) months preceding the disclosure;

b. The name and address of the entity;

c. If there is an equity interest in the entity, any value as of the date of disclosure; and

d. With respect to reimbursed or reimbursable travel expenses that require disclosure: the purpose of the trip; the identity of the sponsor/organizer; the destination; and the duration of the travel.

4. The COI Administrator shall notify the Investigator and/or Unit Head if further information is needed, including without limitation a determination or disclosure of monetary value, in order to decide whether the disclosed Significant Financial Interest constitutes a Financial Conflict of Interest with PHS Funded Research. The Investigator and/or Unit head shall provide any such additional information, as requested.

D. Determination of Financial Conflicts of Interest

1. Prior to FhUSA's expenditure of any funds under a PHS Funded Research project, all Investigator disclosures of Significant Financial Interests shall be reviewed and the following determinations shall be made, as applicable, and consistent with this Policy and the PHS Regulations.
2. The COI Official, or committee as needed, shall determine, in its reasonable discretion, whether any Significant Financial Interest is related to PHS Funded Research.
 - a. A Significant Financial Interest is related to PHS Funded Research if (as reasonably determined by the COI Official, or Committee as needed):
 - i. the Significant Financial Interest could be affected by the PHS Funded Research; or
 - ii. the Significant Financial Interest is in an entity whose financial interest could be affected by the PHS Funded Research.
3. If the Significant Financial Interest is related to PHS Funded Research, the COI Official, or Committee as needed, in its reasonable discretion, shall then determine whether a Financial Conflict of Interest exists.
 - a. A Financial Conflict of Interest exists if the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS Funded Research.
4. The COI Official, or Committee as needed, may involve the Investigator, Center Director, and others, as provided herein, in the determination of whether a Significant Financial Interest is related to PHS Funded Research and/or whether a Financial Conflict of Interest exists.
5. If it is determined that (a) Significant Financial Interest is related to PHS Funded Research and (b) a Financial Conflict of Interest exists, the COI Official, or Committee as needed, shall communicate the determination to the Investigator and the Center Director.

E. Management of Financial Conflicts of Interest / Management Plan

1. If it is determined that a Financial Conflict of Interest exists, FhUSA will undertake such actions as are deemed necessary to Manage the FCOI.
2. The COI Official, or Committee as needed, will work with the Investigator and the Investigator's supervisor and Center Director to develop an appropriate Management Plan. The purpose of the Management Plan is to establish rules and procedures that provide a reasonable expectation that the PHS Funded Research associated with the Investigator's Financial Conflict of Interest will be free from bias. The Management Plan must specify the actions that have been, and shall be, taken to Manage any Financial Conflict of Interest in accordance with this Policy and the PHS Regulations.
3. The COI Official, or Committee as needed, may require additional information from the Investigator, supervisor and/or Center Director and may seek input and advice from

others, as provided herein, in connection with the development and/or implementation of a Management Plan.

4. Actions, conditions, or restrictions that may be required under the Management Plan may vary depending upon the nature and extent of the Financial Conflict of Interest. Examples of actions, conditions, or restrictions that might be imposed to Manage a Financial Conflict of Interest include but are not limited to:

- a. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the Research);
- b. For Research projects involving human subjects, disclosure of financial conflicts of interest directly to participants;
- c. 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;
- d. Modification of the Research plan;
- e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
- f. Reduction or elimination of the Significant Financial Interest (e.g., sale of an equity interest); and/or
- g. Severance of relationships that create financial conflicts.

5. The Investigator's Center Director is responsible for: (a) ensuring that steps set forth in the Management Plan are implemented; and (b) taking reasonable steps to ensure the Investigator's compliance with the Management Plan.

F. Reporting of Financial Conflicts of Interest

1. The COI Official, or Committee as needed, shall be responsible for ensuring that all Financial Conflict of Interest reports and other information are submitted to the PHS Unit, as required by the PHS Regulations.

2. Such FCOI reports must be filed:

- a. Prior to FhUSA's expenditure of funds under a PHS Funded Research project;
- b. Within sixty (60) days, with respect to any Significant Financial Interest that is identified as a Financial Conflict of Interest subsequent to the initial FCOI report during an ongoing PHS Funded Research project (e.g. upon the participation of an Investigator who is new to the PHS Funded Research project); and
- c. Annually with respect to any Financial Conflict of Interest previously reported with regard to an ongoing PHS Funded Research project.

G. New Significant Financial Interests during Ongoing PBS Funded Research

1. This Section applies: (a) whenever an Investigator discloses a Significant Financial Interest that was developed or acquired after Research under a PHS-funded award had begun; or (b) whenever, in the course of an ongoing PHS Funded Research project, an Investigator who is new to participating in the Research project discloses a Significant Financial Interest.

2. In any such event, within sixty (60) days of the disclosure, the COI Official, or Committee as needed, shall: (a) review the disclosed interest; (b) determine whether it is related to the PHS Funded Research; and (c) if so, determine whether a Financial Conflict of Interest exists.

3. If a Financial Conflict of Interest exists, FhUSA shall 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 Financial Conflict of Interest going forward. The COI Official, or Committee as needed, shall report to the PHS Unit as required by the PHS Regulations.

4. Depending on the nature of the disclosed interest, additional interim measures may be taken with regard to the Investigator's participation in the PHS Funded Research between the date of disclosure and the completion of the review process.

H. Retrospective Review and Mitigation Report

1. If a Significant Financial Interest is not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by FhUSA during an ongoing PHS Funded Research project (e.g., was not timely reviewed or reported by a subrecipient), the COI Committee (or designated Subcommittee) shall, within sixty (60) days of the disclosure: (a) review the disclosed interest; (b) determine whether it is related to the PHS Funded Research; and (c) if so, determine whether a Financial Conflict of Interest exists.

i. If a Financial Conflict of Interest exists, FhUSA shall 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 Financial Conflict of Interest going forward. The COI Official, or Committee as needed, shall report to the PHS Unit as required by the PHS Regulations.

ii. Depending on the nature of the Financial Conflict of Interest, the COI Official, or Committee as needed, may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS Funded Research project between the date that the Financial Conflict of Interest or the Investigator's non-compliance is determined and the completion of the retrospective review process.

2. In addition, whenever a Financial Conflict of Interest is not identified or Managed in a timely manner (including failure by the Investigator to disclose a Significant Financial Interest that is determined to constitute a Financial Conflict of Interest; failure by FhUSA to review or Manage such a Financial Conflict of Interest; or failure by the Investigator to comply with a Management Plan), the COI Official, or Committee as needed, shall,

within one hundred twenty (120) days of the determination of non-compliance: (a) complete a retrospective review of the Investigator's activities and the PHS Funded Research, or portion thereof, conducted during the time period of the non-compliance; and (b) determine whether or not there was bias in the design, conduct, or reporting of the PHS Funded Research. The COI Official, or Committee as needed, shall document the retrospective review as required by the PHS Regulations.

i. Based on the results of the retrospective review, if appropriate, the COI Official, or Committee as needed, shall update the previously submitted Financial Conflict of Interest report, specifying the actions that will be taken to Manage the Financial Conflict of Interest going forward. If bias is found, the COI Official, or Committee as needed shall notify the PHS Unit promptly and submit a mitigation report to the PHS Unit, in accordance with the PHS Regulations. Thereafter, the COI Official, or Committee as needed, shall submit Financial Conflict of Interest reports annually.

I. Monitoring / Internal Reporting

Whenever a Management Plan is implemented, the Investigator's Center Director shall be responsible: (a) to monitor and to take reasonable steps to ensure Investigator compliance with the Management Plan on an ongoing basis until the completion of the PHS Funded Research project; and (b) to report to the COI Official, or Committee as needed, or designee any non-compliance with the Management Plan.

J. Public Accessibility

1. Prior to FhUSA's expenditure of any funds under a PHS Funded Research project, FhUSA shall ensure public accessibility of information concerning any disclosed Significant Financial Interest that meets the following three criteria: (a) the Significant Financial Interest was disclosed and is still held by Senior/Key Personnel; (b) FhUSA determines that the Significant Financial Interest is related to the PHS Funded Research; and (c) FhUSA determines that the Significant Financial Interest is a Financial Conflict of Interest.
2. Such information shall be made accessible via written response to any requestor within five (5) business days of the COI Officials', or Committee's, receipt of a written request. Such information shall include at a minimum the information required by the PHS Regulations. The response will note that the information provided is current as of the date of the response and is subject to updates, on at least an annual basis and within sixty (60) days of FhUSA's identification of a new Financial Conflict of Interest, and that such updates should be requested subsequently by the requestor.
3. Information concerning the Significant Financial Interests of an individual subject to this section shall remain available for responses to written requests, for at least three (3) years from the date that the information was most recently updated.

K. Subrecipient Collaborations (FhUSA as Prime Recipient)

1. If FhUSA carries out PHS Funded Research through a subrecipient (e.g., subcontractors, or consortium members), FhUSA's Grants and Contracts Department shall be responsible to ensure that there is a written agreement with the subrecipient which contains terms that establish whether this Policy or the financial conflicts of interest policy of the subrecipient will apply to the subrecipient's Investigators.

a. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement shall require that the subrecipient certify as part of the agreement that its policy complies with this Policy and the PHS Regulations. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to this Policy for disclosing Significant Financial Interests that are directly related to the subrecipient's work for FhUSA;

b. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to FhUSA. Such time period(s) shall be sufficient to enable FhUSA to provide timely Financial Conflict of Interest reports, as necessary, to the PHS Unit as required by this Policy and the PHS Regulations;

c. Alternatively, if the subrecipient's Investigators must comply with FhUSA's financial conflicts of interest policy, the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to FhUSA. Such time period(s) shall be sufficient to enable FhUSA to comply timely with its review, management, and reporting obligations under this Policy and the PHS Regulations.

2. The COI Official, or Committee as needed, shall be responsible to provide Financial Conflict of Interest reports to the PHS Unit regarding all financial conflicts of interest of all subrecipient Investigators consistent with this Policy and the PHS Regulations, i.e., prior to the expenditure of funds and within sixty (60) days of any subsequently identified Financial Conflict of Interest.

L. FhUSA as a Subrecipient

1. If FhUSA is a subrecipient of PHS Funded Research where another entity is the prime recipient, FhUSA's Grants and Contracts Department shall be responsible to ensure that there is a written agreement with the prime recipient which contains terms that establish whether this Policy or the financial conflicts of interest policy of the prime recipient will apply to FhUSA's Investigators.

2. If the agreement specifies that FhUSA's Investigators must comply with the prime recipient's financial conflicts of interest policy, then FhUSA's Investigators shall so comply with the prime recipient's policy, and this Policy shall not apply.

3. If the agreement specifies that FhUSA's Investigators must comply with this Policy, then FhUSA's Investigators shall so comply with this Policy, and this Policy shall apply.

M. Record Retention

1. The COI Official, or Committee as needed, shall retain all records relating to Investigator disclosures of financial interests; the review of and response to such disclosures (whether or not a disclosure resulted in the determination of a Financial Conflict of Interest); and all actions under this Policy or retrospective review, if applicable.
2. Such records shall be retained for at least three (3) years from the date of submission of final expenditure reports to PHS for each PHS-funded project (or where applicable from other dates specified in the PHS Regulations for different situations).
3. Such records may be destroyed within ninety (90) days following the expiration of the three (3) year retention period, unless there is relevant pending or active administrative or legal action or otherwise required by applicable law or organizational policy.

N. Noncompliance

1. It shall be considered a violation of FhUSA policy, subject to disciplinary action in accordance with applicable policies, if an Investigator: (a) fails to disclose a Significant Financial Interest as required herein; (b) fails to comply with an established Management Plan; (c) fails to provide timely annual report information or other required information; or (d) fails to comply with any other requirement of this Policy.
2. If the failure of an Investigator to comply with this Policy or a Management Plan appears (in the reasonable judgment of the COI Official, or Committee as needed) to have biased the design, conduct, or reporting of PHS Funded Research, the COI Official, or Committee as needed, shall be responsible to promptly notify the PHS Unit of the corrective action taken or to be taken, as required by the PHS Regulations.
3. In the event that the U.S. Department of Health and Human Services determines that a PHS Funded Research project involving 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 FhUSA in accordance with the PHS Regulations and this Policy, such Investigator shall be required to disclose the Financial Conflict of Interest in each public presentation of the results of the Research and to request an addendum to previously published presentations.