



**ASTER LABS, INC.
POLICY ON FINANCIAL CONFLICTS OF INTEREST
IN FEDERALLY-SPONSORED RESEARCH ACTIVITIES**

Effective Date: 1-August-2022

STATEMENT OF PURPOSE AND MANAGEMENT COMMITMENT

ASTER Labs, Inc. is strongly committed to promoting objectivity in Research. This policy (hereafter "Policy") implements federal disclosure requirements pertaining to objectivity in Research promulgated by the U.S. Public Health Service (hereafter "PHS") in 42 CFR Part 50 and 45 CFR Part 94. These federal regulations require ASTER Labs, Inc. (hereafter "ASTER Labs") to maintain an appropriate written policy on financial conflict of interest (hereafter "FCOI") disclosure as a condition to receiving PHS-funded grants and contracts.

This Policy is enacted to:

- Establish standards that provide a reasonable expectation that Research projects are designed, conducted, and reported objectively, by managing financial conflicts of interest that may occur between an Investigator's personal financial interests and ASTER Labs' research interests under PHS grants and contracts;
- Establish an ASTER Labs Financial Conflict of Interest Committee responsible for enforcing the Policy;
- Establish a process of disclosure and independent review when an Investigator has Significant Financial Interest(s). When ASTER Labs through its FCOI Committee, determines that such an interest might reasonably appear to affect the Research directly and significantly, ASTER Labs will take steps to manage the conflict;
- Inform Investigators of their responsibilities under the Policy; and
- Facilitate financial conflict of interest training for all affected Investigators.



APPLICABILITY

This policy and associated procedures are immediately applicable to all sponsored program activity at ASTER Labs, for which research funding from Federal agencies is received, including from the Public Health Service (PHS) of the U.S. Department of Health and Human Services (DHHS), (i.e., CDC, NIH, HRSA, AHRQ, ATSDR, etc.), National Science Foundation (NSF), National Aeronautics and Space Administration (NASA), and other relevant agencies. This policy applies to each Investigator who plans to participate in, or is participating in, such research. This policy does not, however, apply to SBIR/STTR Phase I applications and programs.

This Policy applies to all ASTER Labs-employed Investigators. If ASTER Labs conducts PHS-funded Research through a subrecipient (e.g., subcontractor or consortium member), ASTER Labs requires the sub-recipient certify that it has a Financial Conflict of Interest policy compliant with 42 CFR Part 50 and 45 CFR Part 94. If the sub-recipient cannot certify that it has a PHS-compliant financial conflict of interest policy, the sub-recipient shall be required to follow this Policy in its entirety.

DISCLOSURE OF FINANCIAL INTERESTS

When an Investigator submits an application for Research for potential funding by the PHS, the Investigator must complete an ASTER Labs **Financial Conflict of Interest Disclosure Form**. If the Investigator has a significant financial interest (SFI, as defined below), the SFI must be disclosed on the FCOI Disclosure Form, detailing the interest, as required. When an Investigator does not have an SFI, the Investigator must still complete the Disclosure Form upon submission of an application for PHS-funded Research, but can check the box stating that no SFI exists.

Each Investigator must update his or her financial disclosures by completing a new Disclosure Form annually, or as necessary throughout the period of the PHS-funded Research project if the Investigator acquires any new SFIs that have not been previously disclosed.

DEFINITIONS

Financial Conflict of Interest (FCOI) – A significant financial interest that could directly and significantly affect the design, conduct, or reporting of Federally-funded research.

FCOI Committee (FCOIC) – A Committee appointed by the CEO of ASTER Labs to solicit and review completed Disclosure Forms from each Investigator who is planning to participate in, or who is participating in, PHS-funded Research, to determine whether any reported SFI is a FCOI, and to establish a Management Plan for the FCOI.

FCOI Report – Report of a financial conflict of interest made to a Federal awarding agency.

Investigator – An Investigator is any individual responsible for the design, conduct, or reporting of Research funded by the PHS. This includes the Principal Investigator, Co-Investigators, and any other individual, regardless of title or position, who is responsible for designing, conducting, or reporting of this Research.

Investigator's Professional Responsibilities – For ASTER Labs-employed Investigators, the Investigator's professional responsibilities on behalf of ASTER Labs, including the conduct of Research (including hardware/software design, prototype construction, experimental testing, modeling/simulation, and project management), business development, and corporate services/management. For sub-recipients, the Investigator's professional responsibilities on behalf of the employing entity, as so defined by that entity.

Immediate Family – Refers to Investigators' spouse and dependent children or other adults who qualify as dependents under the Internal Revenue Code definitions.

Manage – 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.

Research – A systematic investigation, study, experiment or other research and development work designed to develop or contribute to generalized knowledge relating broadly to public health. The term encompasses basic and applied research (e.g., engineering analyses, a technical published article or progress report), and product development (e.g., prototype and technology development).

Significant Financial Interest (SFI) – A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- (i) With regard to any 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 and the value of any equity interest in the entity as of the date of 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 interest 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) With regard to 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 (or the Investigator's spouse 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 must disclose the occurrence of any reimbursed or sponsored travel (i.e., travel 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), related to their institutional responsibilities; 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, a medical center, or a research institute that is affiliated with an Institution of higher education. Details of this disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with ASTER Labs FCOI policy, the FCOIC will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

The term *Significant Financial Interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by ASTER Labs, Inc. to the Investigator if the Investigator is currently employed or otherwise appointed by ASTER Labs, including intellectual property rights assigned to ASTER Labs and agreements to share in royalties related to such rights; any ownership interest in ASTER Labs held by the Investigator; 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; 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; 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.

POLICY

Responsibilities of an Investigator:

Each Investigator is required to review and understand this FCOI Policy.

Each Investigator who is planning to participate in Federally-funded research is required to disclose to ASTER Labs designated official(s) the Investigator's SFIs (and those of the Investigator's spouse and dependent children) no later than the time of application for Federally-funded research using the ASTER Labs FCOI Disclosure Form.

Each Investigator who is participating in Federally-funded research is required to submit an updated disclosure of SFIs at least annually or within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI that was not listed on the original FCOI Disclosure Form.

ASTER Labs' FCOIC is responsible to ensure that procedures are in place to require each sub-recipient (i.e., consultant, consortium member) to certify that it has a FCOI Policy that complies with 42 CFR Part 50 and 45 CFR Part 94 and to notify ASTER Labs whether it has identified any FCOIs with respect to the PHS-funded research, at the time of application and then either annually within the period of the award, or within thirty (30) days of discovering or acquiring a new FCOI that was not originally reported to ASTER Labs.

If a sub-recipient does not have its own FCOI Policy, the Investigator will disclose identified SFIs to ASTER Labs at the appropriate times as prescribed under 42 CFR Part 50 and 45 CFR Part 94, from filing of the application through the period of the PHS-funded Research project. See Section 4 under Responsibilities of ASTER Labs.

Responsibilities of ASTER LABS Regarding Investigator FCOIs:

1. Review of Disclosures of SFIs and Management of FCOIs

A. Review and Management

Prior to ASTER Labs' expenditure of any funds under a PHS-funded Research project, the FCOI Committee will:

- Review all Investigators' SFI Disclosure Forms;
- Determine whether any SFI relates to PHS-funded Research;
- Determine whether a FCOI exists; and,
- Develop and implement a Management Plan that specifies the actions that have been and will be taken to manage such a FCOI, should a FCOI be found.



The FCOIC will, within thirty (30) days, perform the same above steps whenever in the course of an ongoing PHS-funded Research project an Investigator who is new to participating in the Research project discloses an SFI, an existing Investigator discloses a new SFI, or the FCOIC identifies a SFI that was not disclosed in a timely manner by an Investigator (or, for whatever reason, was not previously reviewed by the FCOIC).

B. Examples of conditions or restrictions that may be imposed to manage a FCOI include, but are not limited to:

- Public disclosure of the FCOI;
- Oversight of the FCOIC, or its duly appointed officials, including taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the FCOI;
- Replacement of an Investigator with a FCOI, or revision of the Investigator's responsibilities involved with the Research; disqualification of the Investigator from participation in all or a portion of the Research; or other removal of the FCOI.

2. Record Keeping Responsibilities

On behalf of ASTER Labs' FCOIC, the Contracts Department will retain records regarding each Investigator's SFI disclosure(s), the FCOIC's official determinations, and actions regarding management of a FCOI for a minimum of three (3) years beyond the date of the final expenditure report submitted to PHS under an award.

3. Public Accessibility

ASTER Labs will ensure accessibility of this FCOI Policy by making it available to the public on the ASTER Labs company website.

In those instances where the FCOIC has determined there to be a FCOI, prior to the expenditure of funds under the affected PHS-funded project, the FCOIC will ensure that the information required to be publicly disclosed by the U.S. Public Health Service (PHS) in 42 CFR Part 50 and 45 CFR Part 94 has been made available to the public on ASTER Labs' website. The information regarding FCOIs will be maintained and updated on the ASTER Labs Inc. website as required by the PHS in 42 CFR Part 50 and 45 CFR Part 94.

4. Compliance of Sub-Recipient

ASTER Labs' FCOIC has established internal procedures to ensure that a sub-recipient (i.e., consultant or consortium member) that participates in PHS-funded Research projects follow its official FCOI Policy pertaining to PHS-funded Research. If the sub-recipient does not have an official FCOI Policy the sub-recipient is subject to all aspects of this Policy, beyond certification and reporting of FCOIs.

5. FCOI Reporting Responsibilities

A. Initial FCOI Report

Prior to ASTER Labs' expenditure of any funds under a PHS-funded Research project, ASTER Labs will provide to the PHS awarding component an FCOI report regarding any Investigator's SFI found by the FCOIC to be an FCOI and ensure that ASTER Labs has implemented a Management Plan to adequately manage the conflict.

In cases in which the FCOIC has identified a FCOI and eliminated it prior to the expenditure of PHS-awarded funds, ASTER Labs does not need to submit a FCOI report to the PHS awarding component.

B. Subsequent FCOI Reports

For any SFI that the FCOIC identifies as a FCOI after the FCOIC's initial FCOI report has been filed with the PHS awarding component during an ongoing PHS-funded Research project, including whenever in the course of an ongoing PHS-funded Research project an Investigator who is new to participating discloses an SFI, or an SFI is identified that was not disclosed in a timely manner by an Investigator, ASTER Labs will provide to the PHS awarding component an additional FCOI report regarding the newly identified FCOI within sixty (60) days of the FCOIC's finding.

During the period of performance of the PHS-funded Research project, updated FCOI reports will be submitted annually to the PHS awarding component, to report the status of the FCOI and any changes made by the FCOIC with respect to management of the FCOI.

C. Contents of FCOI Report

Any FCOI report required will include sufficient information to enable the PHS awarding component to understand the nature and extent of the financial conflict, and to assess the appropriateness of ASTER Labs' management plan. Specific elements of the ASTER Labs FCOI report filed will be in compliance with the requirements of 42 CFR Part 50 and 45 CFR Part 94.

D. Internal Procedures

The FCOIC has established internal procedures to ensure that the certification requirements of 42 CFR Part 50 and 45 CFR Part 94 will be provided to the PHS awarding component prior to award of PHS-funded research.

The FCOIC has established internal procedures to ensure that the reporting of FCOIs for all Investigators and sub-recipients to the PHS awarding component will follow the requirements of 42 CFR Part 50 and 45 CFR Part 94.

6. Investigator FCOI Training

The FCOIC requires that each Investigator complete FCOI training via the NIH Conflict of Interest Training Course, available at:

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

The NIH course certification will be printed, signed by the Investigator, and collected by ASTER Labs' FCOIC. FCOI training is required:

- Prior to engaging in PHS-funded Research;
- At least every four (4) years from the initial training; and
- Within thirty (30) days after ASTER Labs' FCOI Policy has been revised in a manner that affects Investigator requirements, or upon a finding by the FCOIC that the Investigator has been noncompliant with respect to ASTER Labs' FCOI Policy.

Each Investigator must repeat the training if he or she is found by the FCOIC to be noncompliant with ASTER Labs' FCOI Policy, or with a management plan.

ENFORCEMENT OF THIS POLICY

Failure to comply with this Policy, including failure of an Investigator to file a complete or timely SFI Disclosure Form to ASTER Labs, or to update or to comply with any conditions or restrictions imposed on the conduct of PHS-funded Research under this Policy, including a Management Plan, will be grounds for discipline up to and including termination.

If the failure of an Investigator to comply with this Policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded Research, ASTER Labs will promptly notify the PHS awarding component of the corrective action taken or to be taken. PHS awarding components may impose special award conditions or may suspend or terminate an award, or take other actions, should non-compliance with this Policy be found.



CONTACT

ASTER LABS, Inc.

www.asterlabs.com

info@asterlabs.com

Address: 155 East Owasso Lane, Shoreview, MN 55126

Telephone: +1-651-484-2084

POLICY HISTORY

Version 22-001: 1-August-2022

ATTACHMENT

Attachment A: ASTER Labs FCOI Disclosure Form



ATTACHMENT A

ASTER Labs, Inc. – Financial Conflict of Interest Disclosure Form

Persons completing this form are expected to have read and understood the ASTER Labs, Inc. Financial Conflict of Interest Policy on Federal Grants and Contracts. If you have any questions regarding that policy, contact a member of the Financial Conflict of Interest Committee prior to signing this document.

1. Are you, or is any member of your Immediate Family, an employee, consultant, officer, director, partner, trustee, or any other agent of any commercial enterprise (other than ASTER Labs) participating on an ASTER Labs project?

☐ Yes ☐ No If yes, please describe on a separate page the nature and extent of your/their relationship(s).

2. Do you, or does any member of your Immediate Family, have any Significant Financial Interest, such as ownership, equity, stock or stock options, within any commercial enterprise (other than ASTER Labs) participating on an ASTER Labs project?

☐ Yes ☐ No If yes, please describe on a separate page the nature and extent of your/their relationship(s).

3. Do any other conditions exist between you, or any member of your Immediate Family, and any commercial enterprise which could reasonably be perceived by an outside observer as a potential conflict of interest?

☐ Yes ☐ No If yes, please describe on a separate page the nature and extent of your/their relationship(s).

I certify that:

I have read the ASTER Labs, Inc. Policy on Financial Conflict of Interest on Federal Grants and Contracts.

I have made all required financial disclosures.

(If I am the program leader, principal investigator or project director) I have made every effort to ensure that all Investigators (see policy for definition) responsible for the design, conduct or reporting of the research have submitted required disclosures.

Signature _____ Date: _____

Typed/Printed Name: _____

Disclosure Type:

☐ Initial

☐ Annual

☐ Project Specific:

Project Title: _____

Project Sponsor: _____

Special Notes (if any): _____