

1. Micro-Leads Inc. Financial Conflict of Interest (FCOI) Policy

Effective 2021

1. Policy Statement

As a professional research corporation, Micro-Leads is committed to protecting the integrity and objectivity of its research activities by ensuring that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest. Micro-Leads has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest.

The procedures described in this policy were created and designed primarily to comply with the specific regulatory requirements for U.S. Public Health Service (PHS)-sponsored research but are also intended to provide a basic framework and standards for identifying, evaluating, and managing potential financial conflicts of interest relating to Micro-Leads research activities. For non-PHS research, the specific steps, timing, determinations, documentation, and notifications may be tailored as appropriate but will remain focused on maintaining Micro-Leads' high standards for research integrity and effectively eliminating or managing actual or potential financial conflicts of interest.

This policy and related procedures have been developed to identify, manage, mitigate, neutralize, or eliminate actual, apparent, and potential financial conflicts of interest. The policy was written to be in conformance with the Code of Federal Regulations (CFR) 42, Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought^[1] and 45 CFR Part 94, Responsible Prospective Contractors.

[1]These regulations do not cover Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program Phase I applications or awards but do apply to applicants and recipients under the SBIR/STTR Program Phase II. SBIR is the extramural research program for small business that was established by the Awarding Components of PHS and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the STTR Program, which was established by Pub. L. 102-564.

2. Scope and Responsibility

All Micro-Leads Investigators, personnel, and collaborators must comply with this policy. This policy may be updated or amended, as required or deemed necessary.

The Designated Official or Signing Official will be responsible for the solicitation and evaluation of any SFIs (Significant Financial Interests) and FCOIs, FCOI reporting, and the development and implementation of any management plans. The Designated Official or Signing Official may delegate this responsibility. This responsibility may also be designated to an alternative responsible official in the event that the Designated Official or Signing Official has an SFI that requires evaluation.

3. Definitions

Designated Official is the individual designated by Micro-Leads to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests.

Equity interest includes any stock, stock option, or other ownership interest, and its value may be determined through reference to public prices or other reasonable measures of fair market value.

Financial Conflict of Interest (FCOI): An SFI (defined below) that could directly and significantly affect the design, conduct, or reporting of research as determined by Micro-Leads through the Designated Official.

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

Immediate family refers to an Investigator's spouse and dependent children.

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 research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Institutional Responsibilities: For the purpose of this policy, Institutional Responsibilities include the Micro-Leads sponsorship of medical device development programs. This includes product formulation, discovery research, and the oversight and sponsorship of pre-clinical research and clinical trials, and manufacturing and formulation development.

PHS means the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50, Subpart F, and 45 CFR Part 94. Any sub-agency or other component of the PHS, including NIH.

PHS-funded Research means research funded under PHS grants, cooperative agreements, or contracts.

Public Health Service Act, or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Remuneration includes, for example, salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Research means 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). For PHS-Funded Research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.

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:

- With regard to any publicly traded entity a SFI exists if the value of any remuneration received from the entity in the twelve (12) 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 SFI exists if the value of any remunerations from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interests (e.g. stock, stock options, or other ownership interest);
- Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
- 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) related to 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, medical center, or research institute that is affiliated with an Institution of higher education.

Exclusions: SFIs do not include the following types of financial interests:

- salaries, royalties or other remuneration paid by Micro-Leads to the Investigator if the Investigator is currently employed or otherwise appointed by Micro-Leads, including intellectual property rights assigned to Micro-Leads and agreements to share in royalties related to such rights;
- any ownership interest in Micro-Leads 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, 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.

4. Disclosures, Reviews, and Reporting

4.1 Investigator Disclosure

New Funded Research/New Investigators: All Investigators planning to participate in PHS-funded Research must disclose any SFIs (and those of the Investigator's spouse and dependent children) prior to the submission of an application for PHS-funded Research or prior to participating in any PHS-funded Research (to the extent an Investigator is added to the Research project after the initial application).

SFI Updates: Each Investigator participating in PHS-funded Research must submit an updated financial disclosure at least annually. Each annual disclosure must include any information that was not previously disclosed and any updated information regarding any previously disclosed SFI. Each Investigator must also submit an updated disclosure within thirty (30) days of discovering or acquiring a new SFI.

Form of Disclosure: Disclosures must be provided to Designated Official or Signing Official and must be provided on the Micro-Leads SFI form, attached to this policy as Appendix 1. With respect to reimbursed or sponsored travel, disclosures shall include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip. Designated Official or Signing Official will determine whether further information on reimbursed or sponsored travel is needed. Such additional information may include the monetary value of the travel.

4.2 Financial Interest Review

Prior to expenditure of any PHS funds and beginning performance of a grant project; or, within sixty (60) days of an SFI disclosure, if during the course of PHS-funded research a new Investigator discloses a SFI, or an existing Investigator discloses a new SFI, Designated Official or Signing Official will review the SFI to determine if it is related to PHS-funded research and, if so, whether the SFI constitutes a conflict of interest. An SFI will be deemed to be related to PHS-funded research when Designated Official or Signing Official reasonably determines that the SFI: could be affected by the PHS-funded Research; or the relevant entity is one whose financial interest could be affected by the Research. An FCOI exists when Micro-Leads, through Designated Official or Signing Official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research.

When reviewing an SFI, Designated Official or Signing Official may involve the Investigator in the determination of whether an SFI is related to the PHS-funded research.

4.3 Reporting

For PHS-funded research in particular, as part of the funding application or proposal and prior to performing any work on the research, each Investigator who is planning to participate in the research is required by regulation to complete a Significant Financial Interest Disclosure (SFID) Form and submit the SFID Form to Micro-Leads' Administrator. This requirement also applies to Investigators who are or who work for subgrantees, subcontractors, or collaborators on PHS-funded research. SFID Forms will be provided to Investigators in conjunction with the annual training and will be otherwise made available. Micro-Leads' Administrator will review SFID submissions with the Designated Official. The information reported on the SFID Form includes a listing of the Investigator's known significant financial interests and those of his/her immediate family that reasonably appear to be related to the research or that are in entities whose financial interests could be affected by the research.

Micro-Leads Investigators in non-PHS-funded research who have any significant financial interest that may reasonably appear to be affected by the research are also expected to complete the SFID Form and submit it to Micro-Leads' Administrator.

Investigators are expected to submit an updated SFID Form during the period of the award as necessary (at least annually for PHS-funded research). The annual update will typically be done in conjunction with completion of the annual training. Such disclosures shall include any information that was not previously disclosed; any change in information regarding any previously disclosed significant financial interest; or, within 30 days of discovery or acquisition, any new significant financial interest (e.g., an interest acquired through purchase, marriage, or inheritance).

4.4 Determination and Management of Financial Conflicts of Interest

Upon receipt of a completed SFID, the Designated Official shall determine whether an Investigator's significant financial interest is related to the subject research and, if so, whether the interest constitutes a financial conflict of interest under this policy and any applicable regulations. The Investigator may be required to submit additional information as part of the process. A disclosed interest may be related to the subject research either because the interest could be affected by the research or because it is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

If the Designated Official determines that a financial conflict of interest exists, a financial conflicts of interest management plan will be implemented and monitored on an ongoing basis. The management plan will include appropriate steps to manage, reduce, or eliminate the conflict. The following are examples of conditions or restrictions that might be imposed:

- Disclosure to research participants or the public of significant financial interests (e.g., when presenting or publishing the research);
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification of staff from participation in all or a portion of the research;
- Reduction or divestiture of a financial interest; or
- Severance of relationships that create actual or potential conflicts.

In addition to the conditions or restrictions described above, Micro-Leads may require the management of conflicting financial interests in other ways as it deems appropriate.

4.5 External Reporting Requirements

Micro-Leads will disclose financial conflicts of interest as required by applicable laws or regulations. Before expending any funds under a PHS award, Micro-Leads will ensure public accessibility by posting financial conflicts of interest information on a publicly available web site or by responding in a timely manner to written requests as required under the regulations. The Designated Official will also report to the PHS Awarding Component, as detailed in the regulations, the existence of any financial conflict of interest that has not been eliminated and will ensure that Micro-Leads has implemented a plan to manage the conflict.

Retrospective Review. If a financial conflict of interest is identified after its initial reporting and during ongoing research (e.g., through participation of a new Investigator) and has not been eliminated, Micro-Leads will provide the PHS Awarding Component with an update within 60 days. If the financial conflicts of interest report involves a significant financial interest that was not disclosed by an Investigator or not previously reviewed or managed by Micro-Leads (e.g., not reviewed or reported by a subrecipient in a timely manner), Micro-Leads will undertake a retrospective review within 120 days. Such retrospective review will determine whether there was bias in the design, conduct, or reporting of the PHS-funded research, or portion thereof, conducted prior to the identification and management of the conflict. The Signing Official or Designated Official shall conduct a retrospective review of the Investigator's activities and the PHS-funded research to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. If bias is found, Micro-Leads will promptly notify the PHS Awarding Component and submit a mitigation report. Upon request, Micro-Leads will provide HHS with information relating to any Investigator disclosure of significant financial interests; Micro-Leads' review of, and response to, such disclosure; and whether the disclosure resulted in Micro-Leads' determination of a financial conflict of interest. The report shall include:

- Project number;
- Project Title;
- PD/PI or contact PD/PI if a multiple model is used;
- Name of the Investigator with the FCOI;
- Reasons(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusion of the review.

Based on the results of the retrospective review, if appropriate, Micro-Leads shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Micro-Leads shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, the above elements documented in the retrospective review, a description of the impact of the bias on the research project, and the Micro-Leads' plan of action or actions to eliminate or mitigate the effect of the bias (e.g., impact on the Research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

4.6 Annual Reports

If Micro-Leads has previously reported an FCOI to the PHS Awarding Component, on an annual basis and for the duration of the PHS-funded research project (including extensions with or without funds), Micro-Leads shall provide the PHS Awarding Component with a report that addresses the status of the FCOI and any changes to the management plan. The annual FCOI report shall specify whether the financial conflict

is still being managed or explain why the FCOI no longer exists. All such annual reports shall comply with any requirements communicated to Micro-Leads by the PHS Awarding Component.

5. Management of a FCOI

In the event of an FCOI, Designated Official or Signing Official shall, on a case-by-case basis, develop and implement a management plan specifying any actions that have been, and will be, taken to address the FCOI. Management plans shall aim to reduce or eliminate the FCOI to ensure (to the extent possible) that the design, conduct, and reporting of research will be free from bias.

This may include, but is 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 FCOI;
- 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); or
- Severance of relationships that create financial conflicts.

To the extent deemed necessary by Designated Official or Signing Official, Micro-Leads may also implement an interim management plan until the need for a full management plan can be determined or a full management plan can be developed.

If HHS determines that a PHS-funded clinical project, with the purpose of evaluating 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 Micro-Leads, the involved Investigator must disclose the FCOI in each public presentation of the results of the research and request an addendum to any previously published presentations.

Designated Official or Signing Official shall be responsible for monitoring the Investigator's compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

6. Public Disclosure

Within five (5) business days of a request, Micro-Leads will provide a written response to a request for information concerning any SFI that:

- was disclosed and is still held by the project director, principal investigator, or any other persons identified as senior/key personnel in the applicable grant application, progress report, or other PHS report;
- is related to the PHS-funded research; and
- is an FCOI.
- The information that is made available will include:
 - the Investigator's name;
 - the Investigator's title and role with respect to the research project;
 - the name of the entity in which the SFI is held;
 - the nature of the SFI; and
 - the approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000;

amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Information must remain available for disclosure for at least three years from the date that the information was most recently updated.

7. Records Management

Micro-Leads shall maintain records of all Investigator financial interest disclosures, its review of the disclosed financial interest, its response to the disclosure, its determination of whether the disclosure results in an FCOI, and all actions taken under this policy or under a retrospective review. All records must be maintained for at least three (3) years from the date of the final expenditure report submitted to PHS, throughout the completion of any litigation, claim, negotiation, audit or other action involving the records, or other dates specified by law, governmental authority, or regulation, whichever is later. Micro-Leads shall make all information relating to an Investigator financial interest disclosure, Micro-Leads' review and response, and whether or not the disclosure resulted in a determination of an FCOI promptly available to HHS representatives.

8. Compliance, Enforcement Mechanisms, and Penalties for Non-Performance

If an Investigator knowingly fails to comply with this policy (e.g., fails to identify an actual or potential financial conflict of interest), Micro-Leads may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research. In addition, for PHS-funded research, failure to comply with this policy or the applicable regulations shall result in the following: If the Investigator's failure to comply with this policy or a financial conflicts of interest management plan has biased the design, conduct, or reporting of the PHS-funded research, Micro-Leads shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;

- Micro-Leads will make available to HHS all records pertinent to financial conflicts of interest and the management of those conflicts; and
- If HHS determines that a clinical PHS-funded research project 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 neither disclosed nor managed, Micro-Leads shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

9. Subawards for PHS Research Effort

Subawards for research funded by a PHS Institution will be documented via a written agreement. This written agreement will specify whether this FCOI policy or the subrecipient's FCOI policy will apply to the relationship.

To the extent that the subrecipient's FCOI policy will apply, the subrecipient must certify in its agreement with Micro-Leads that its FCOI policy complies with 42 C.F.R. Part 50, Subpart F. The agreement must also specify that, the subrecipient will be responsible for identifying all SFIs and determining whether an SFI constitutes an FCOI. The agreement must further specify that the subrecipient will be responsible for developing and monitoring a management plan, to the extent applicable. At Micro-Leads' discretion, Micro-Leads may participate in the determination of whether an SFI constitutes an FCOI and in the

development of a management plan. Micro-Leads will be responsible for submitting any required reports to NIH.

To the extent that Micro-Leads' FCOI policy will apply, the agreement will specify the timeframe within which the subrecipient must report to Micro-Leads all SFI's directly related to the subrecipients work for Micro-Leads. Micro-Leads will be responsible for analyzing the SFI to determine whether it is an FCOI, for developing a management plan, and reporting to NIH. Micro-Leads may request the assistance of the subrecipient with the foregoing analysis and management plan development and monitoring.

10. Public Accessibility

This policy will be available via Micro-Leads' publicly accessible website.

11. Training Requirement

Investigators receive training to promote objectivity in research and to ensure Investigator compliance with regard to the applicable regulations and significant financial interest disclosure obligations. The training module and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH FCOI Training Website:

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

Micro-Leads requires Investigators to complete such training annually, and when any of the following occurs:

- Micro-Leads revises its financial conflicts of interest policy or procedures in any manner that affects the Investigator's obligations;
- An Investigator is new to Micro-Leads; or
- Micro-Leads finds that an Investigator is not in compliance with this policy or a financial conflicts of interest management plan.

12. Point of Contact

Questions regarding this policy can be directed to Designated Official at FCOI@Micro-Leads.

APPENDIX A

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MICRO-LEADS SIGNIFICANT FINANCIAL INTEREST (SFI) DISCLOSURE FORM

Investigator Name (Last, first, middle):	Work Phone:	Date of Disclosure:	Date FCOI Training Received:
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If you are a Micro-Leads Investigator as defined in the Micro-Leads FCOI Policy, continue to Parts 1, 2 and 3 of this form.

Only Non-Micro-Leads Investigators complete this section	
Employer's Name:	
Choose one of the following two options and follow the instructions indicated for that option	
<input type="checkbox"/>	I am employed by an institution with a Financial Conflict of Interest Policy that complies with PHS regulations. Choose one of the following two options.
<input type="checkbox"/>	I have disclosed my significant financial interests and the work scope for this project to the FCOI Designated Official at my institution and he/she has determined that I have no financial conflict with working on this project STOP AND SUBMIT THIS FORM TO FCOI@micro-Leads.com
<input type="checkbox"/>	I have disclosed my significant financial interests and the work scope for this project to the FCOI Designated Official at my institution and he/she has determined that I may have a financial conflict with working on this project. The FCOI management plan prepared by this Official will be submitted separately. STOP AND SUBMIT THIS FORM TO FCOI@Micro-Leads.com
<input type="checkbox"/>	I am not employed by an institution with a compliant FCOI Policy and therefore agree to comply with Micro-Leads' Financial Conflict of Interest Policy, including completing the FCOI training identified by Micro-Leads and disclosing my significant financial interests to Micro-Leads . CONTINUE TO COMPLETE PARTS 1, 2 AND 3 OF THIS FORM.

Part 1. ASSETS						
For you, your spouse and your dependent children, identify assets with a fair market value of \$5,000 as of the date of disclosure. Assets include stocks, bonds, tax shelters, pensions, annuities, real estate, commodity futures, trades and business and partnership interests. Refer to the Definitions in the FCOI policy for additional information.						
<input type="checkbox"/>	I do not have any assets requiring disclosure. CONTINUE TO PART 2 OF THIS FORM.					
<input type="checkbox"/>	I disclose the following assets. After completing this section, CONTINUE TO PART 2 OF THIS FORM.					
Name of asset	Asset belongs to (Employee, Spouse, Dependent Child, or combination)	(X) if no longer held	Asset Type (pension, stock, dividends, interest, real estate, capital gains)	Approximate value of the financial interest		
				\$5,000 - \$19,999 increments of \$5,000 (e.g. \$5,000 to \$10,000)	\$20,000 - \$100,000 Increments of \$20,000	\$100,000 and above by increments of \$50,000

Part 2. SOURCES OF EARNED INCOME AND TRAVEL					
<p>For you, your spouse and your dependent children, identify sources of earned income which generated over \$5,000 in income as of the date of the disclosure. Sources of Earned Income include salaries received from other than your current employer, fees, honoraria and travel. Refer to the definitions below Part 3 for additional information.</p>					
<input type="checkbox"/>	<p>I do not have any sources of earned income or travel requiring disclosure. CONTINUE TO PART 3 OF THIS FORM.</p>				
<input type="checkbox"/>	<p>I disclose the following sources of earned income or travel. After completing this section, CONTINUE TO PART 3 OF THIS FORM.</p>				
			Approximate value of the financial interest		
Name of Earned Income Source(s)	Income Recipient (Employee, Spouse, Dependent Child, or combination)	Income Type (salary, consulting fees, honoraria, etc.)	\$5,000 - \$19,999 increments of \$5,000 (e.g. \$5,000 to \$10,000)	\$20,000 - \$100,000 Increments of \$20,000	\$100,000 and above by increments of \$50,000
<p>For travel disclosures, please provide the following additional detail</p>					
Travel Sponsor	Destination	Duration	Purpose		

Part 3
<p>UPON COMPLETION OF THIS DISCLOSURE FORM, PLEASE EMAIL IT AS AN ATTACHMENT TO fcoi@micro-leads.com.</p> <p>Submission of this form confirms your belief that all information provided is true, complete, and accurate to the best of your knowledge.</p>