

# GOVERNMENT AGENCY FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

## MICROVI BIOTECH INC.

### FINANCIAL CONFLICT OF INTEREST TRAINING AND DISCLOSURE REQUIREMENTS

Updated January 12, 2021

**PREAMBLE:** In this policy, Microvi Biotech Inc. (“Microvi”), provides how it shall identify, manage and enforce dedicated procedures to address potential Financial Conflicts of Interest in relation to research or research & development (R&D) funded by the U.S. and State governments, including the Department of Health and Human Services (HHS) Public Health Service (PHS) agencies. The purpose of this policy is to ensure that R&D conducted by Microvi is free from financial bias or the appearance thereof. This policy applies to any investigator associated with Microvi who is participating or is planning to participate in PHS funded research. Compliance with this policy is mandatory for any PHS funded investigators associated with Microvi.

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#### 1. DEFINITIONS

**Biotechnology-related Entities** include any organization or entity (including publicly traded and private companies) that provides biotechnology products or services, including but not limited to:

1. Medical and/or pharmaceutical companies
2. Biotechnology service providers or consulting firms
3. Biotechnology informatics or data-processing companies
4. Biotechnology device and equipment manufacturers and distributors
5. Industrial biotechnology companies
6. Other organizations that could be impacted by biotechnology-related research
7. Any other entity that could be materially affected by the conduct or results of the funded R&D.

**Employee** refers to all individuals paid and classified as employees by Microvi, including full and part-time employees.

**Financial Conflict of Interest (FCOI)** refers to the significant financial interests which could directly and significantly impact the conduct of R&D based on PHS funding.

**Financial Interest** refers to monetary value, whether or not the value is readily available or retrievable.

**Government Agency** refers to agencies of the U.S. and State governments, including the Department of Health and Human Services (HHS) Public Health Service (PHS) agencies.

**Institutional Responsibilities** refers to the responsibilities of an Investigator in relation to projects funded by Government Agencies, including such activities as research, technical review, publications, service on Microvi committees, and other relevant work performed as part of the administration and management of R&D projects.

**Investigator** refers to 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.

**PHS** refers to the Public Health Service of the United States 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.

**Research or Research & Development (R&D)** refers to the inquiry, design and study of hypotheses related to knowledge and science, including specific disciplines within the branches of science and social sciences. The term encompasses technology development, basic and applied research, and any such activity for which funding is available from PHS agencies.

**Significant Financial Interest** refers to 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.

## 2. OVERVIEW AND RESPONSIBILITIES

Federal regulations have been issued by the U.S. HHS pertaining to financial conflicts of interest and the imperative to maintain the integrity of research funded by the PHS and associated agencies.

Individuals who participate in PHS-funded research must receive this policy, complete training on financial conflicts, be informed of the Investigator's disclosure responsibilities, and be provided instructions on how to disclose personal financial interests which could influence the conduct of R&D or present the appearance of a financial conflict. Such training shall include information on federal regulations such that investigators are able refer to the full text of the regulations published in the Federal Register for more information. This policy applies to other Government Agency funding and Investigators must refer to the full text of the regulations applicable to such Government Agency-funded R&D.

As detailed in this Policy, all Microvi investigators are required to receive training on financial conflicts of interest and disclose relevant Financial Interests within one year of having conducted work in relation to a Government Agency-funded project. Moreover, financial disclosures are required if the individual expects to work on a Government Agency-funded project in an upcoming year, or at any time if the individual is identified in a grant proposal. Key individuals related to the management and administration of Government Agency-funded projects must also complete training and provide relevant disclosures if they are involved in any substantial way in the conduct of a Government Agency-funded project.

The requirements of this Policy should be read and understood in conjunction with Microvi's Employee Handbook and other associated agreements in relation to preventing, recognizing and mitigating conflicts of interest in the course of work conducted at Microvi.

All Microvi Investigators are responsible for completing training related to Financial Interests, disclosing any such Interests, mitigating the risk of significant financial interests, and assisting Microvi with any identified FCOI. All disclosed Financial Interests will be reviewed by Microvi's Legal Department to provide guidance to the Investigator and Microvi management with respect to Significant Financial Interests which may present an FCOI. Should any FCOI be identified, the Legal Department will provide further guidance to Microvi to work with the Investigator and other relevant stakeholder parties to manage the FCOI (see below).

### 3. REPORTING AND TRAINING REQUIREMENTS

All Microvi Investigators must disclose any and all Financial Interests related to R&D conducted at Microvi that is funded by Government Agency in writing. Moreover, all Investigators must be trained in identifying conflicts of interest, including any FCOI, as part of their initial employment at Microvi, prior to engaging in research related to any PHS-funded grant, and at least every four (4) years thereafter. Moreover, FCOI training shall occur immediately when Microvi revises its FCOI policy such that it affects the requirements of Investigators, when an Investigator is new to Microvi, or when an Investigator is not in compliance with this policy or the FCOI management plan. Failure to complete the training, disclosure and required updates per this Policy could result in disciplinary action, up to and including termination.

Written disclosure will be saved in electronic format that is capable of being backed-up for security purposes. The screening of conflicts of interest must be conducted before any proposal for R&D funded by the Government Agency is submitted if the Investigator is named in the proposal or otherwise contributes a significant portion of the design, execution or implementation of the

proposal. Investigators who are not named in the proposal must complete training and any written disclosures prior to beginning work on any project funded by Government Agency. As noted in the Definitions, all of the processes described in this policy also apply to subrecipient Investigators to the extent allowed by law.

Subrecipients will be subject to contracted obligations to Microvi, including whether the subrecipient will follow the FCOI policy of Microvi or the subrecipient. If the subrecipient FCOI policy is to be followed, then the subrecipient must provide certification that its FCOI policy complies with federal regulations. Moreover, the subrecipient must report identified FCOIs for its investigators within sixty (30) days such that Microvi will have sufficient time to report identified FCOIs to the NIH. If the Microvi FCOI policy is to be followed, then the subrecipient will be subject to Microvi's requests and review of all subrecipient Investigator disclosures to enable Microvi to identify, manage and report identified FCOIs to the NIH.

Certification of financial interests must be updated on a continual basis, not more than 60 days upon the development of a new or change in an existing Financial Interest. For example, the following situations require an updated written disclosure upon discovery, receipt or acquisition: purchase or inheritance of stock or stock options, change in the employment of a spouse or domestic partner, or other interest. All employees covered by this Policy must recognize their continuing obligation to disclose Financial Interests in a timely manner to ensure that Microvi is compliant with its reporting and certification requirements under Government Agency regulations.

Microvi will provide initial, annual (i.e., ongoing) and revised FCOI reports to the NIH for itself and all subrecipients, as applicable. These reports include the following instances: 1) Prior to the expenditure of fund 2) Within 60 days of identification for an Investigator who is newly participating in the project 3) Within 60 days for new, or newly identified, FCOIs for existing Investigators, 4) At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project, 5) Following a retrospective review to update a previously submitted report, if appropriate.

If bias is found in the design, conduct and/or reporting of PHS-funded research, Microvi will promptly inform the NIH program director of the PHS-funded research, including the submission of a Mitigation Report. Moreover, if an Investigator fails to comply with Microvi's FCOI policy or implementation of the FCOI management plan appears to have created bias in the design, conduct and/or reporting of PHS-funded research, Microvi will notify NIH and take corrective action for the noncompliance with Microvi's policy or the management plan.

Retrospective reviews will be documented and completed within 120 days of Microvi's determination of noncompliance in the following cases: (i) Failure by the Investigator to disclose a Significant Financial Interest that is determined by Microvi to constitute a Financial Conflict of Interest; (ii) Failure by Microvi to review or manage such a Financial Conflict of Interest; or (iii) Failure by the Investigator to comply with a Financial Conflict of Interest management plan. The retrospective review will determine whether any NIH-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 the DHS determines that PHS-funded 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 an FCOI that was not managed or reported by the Microvi as required by the regulation, the Microvi shall require the Investigator involved to Disclose the FCOI in each public presentation of the results of the research, and to request an addendum to previously published presentations.

#### 4. IDENTIFYING SIGNIFICANT FINANCIAL INTERESTS

Microvi's Legal Department, led by Microvi's Head of Legal, will solicit and review disclosures of Significant Financial Interests of Investigators (and those of the Investigator's spouse and dependent children) related to an Investigator's institution responsibilities. In this process, Microvi's Legal Department will review all disclosed Financial Interests, identify any Significant Financial Interests, and evaluate whether the Significant Financial Interest is an FCOI. Generally, a Significant Financial Interest is a Financial Interest that is likely to have a material effect on the Research. For the purposes of Government Agency-funded R&D, Significant Financial Interest means a Financial Interest of an Investigator or household in any Biotechnology-related Entity if the Financial Interest appears to be reasonably related to the Investigator's Institution Responsibilities at Microvi and the aggregate value of all interests in a Biotechnology-related Entity exceeds \$15,000.

Without limitation, examples of Financial Interests which may potentially qualify of a Significant Financial Interest include: salary, wages, consulting fees, pension benefits, board membership, directorship, service as an officer, ownership of equity interest (e.g. stock options, bonds or other ownership), intellectual property rights from which royalty or revenue is received, and gifts valued greater than \$50.

Sponsored travel related to an Investigator's Institutional Responsibilities refer to travel expenses paid on behalf of an Investigator or family member. Such sponsorships can be relevant Financial Interests unless such travel is by federal, state or local government agencies, institutions of higher education, academic institutions, and associated research entities. Should any reimbursed or sponsored travel be accepted by an Investigator, the following information will be provided to evaluate the Financial Interest: the purpose of the trip, the identity of the sponsor/organizer, the destination, the source of funding, and the duration. In accordance with this policy, it will be determined 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.

For the purpose of evaluating Significant Financial Interests, any of the following are excluded: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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. Note that these exclusions only apply to U.S. institutions and all financial interests received from a foreign institution of higher education or the government of another country are required to be disclosed.

Investigators are required to disclose Significant Financial Interests (including those of the Investigator's spouse and dependent children) during the following instances: No later than at the time of application for PHS-funded research, at least annually during the period of the award, and within 30 days of discovery or acquiring a new Significant Financial Interest.

## 5. REVIEW AND EVALUATION OF DISCLOSED FINANCIAL INTERESTS FOR FCOI

Prior to the expenditure of funds by Microvi, the company's Head of Legal will review all Investigator disclosures of Significant Financial Interests and determine if any such Significant Financial Interests relate to PHS-funded research. If a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of PHS-funded research, and in accordance with the guidelines above and further detailed below, the Legal Department will determine that an FCOI exists and proceed to develop and implement a management plan to manage the FCOI. When an Investigator is new to participating in a PHS-funded project, or an existing Investigator discloses a new Significant Financial Interest, the Legal Department will review disclosures of SFIs, make determination of FCOIs, and implement a management plan if necessary. In the case that Microvi identifies a Significant Financial Interest that was not disclosed in a timely manner by the Investigator, or was not previously reviewed by Microvi's Legal Department, the review process will occur within sixty days, including review of Significant Financial Interest disclosures, determination of FCOIs, and implementation of management plan(s).

Disclosing a Financial Interest does not, in itself, create an illegal conflict of interest. Rather, each Financial Interest disclosure will be reviewed by Microvi's Legal Department. The Legal Department is responsible for determining when an actual or potential conflict of interests exists in a given situation. In other words, the determination of a Significant Financial Interest (one which could directly and significantly affect Government Agency-funded R&D) will be done by the Legal Department, which will also provide guidance for taking action as necessary to manage such conflicts. This will include the development of a management plan to be implemented with the relevant research unit and corporate manager, with full participation by the Investigator.

As detailed above, Microvi will take appropriate steps to address and manage an FCOI to ensure that Microvi's R&D is free from financial bias or the appearance of bias. Some examples of how financial conflicts of interests may be addressed and managed include: public disclosure of an Investigator's Significant Financial Interests (with full participation by the Investigator); disclosure

of FCOI directly to participants in R&D involving human subjects; monitoring of R&D by reviewers who do not have FCOI and who are capable of protecting the integrity of the R&D; modification of the research plan such as changing personnel or personnel responsibilities; disqualification of personnel from participation in all or a portion of an R&D project; reduction or elimination of a Significant Financial Interest; and severance of relationships (e.g., consulting activities) that create actual or potential conflicts.

Records pertaining to an FCOI shall be retained for a period of at least three (3) years from the date the final expenditure report is submitted to the NIH, as well as other dates specified in 45 CFR 75.361, where applicable.

This FCOI policy is posted at Microvi's public website located at: [www.microvi.com](http://www.microvi.com). Moreover, information concerning identified FCOIs held by senior/key persons will be made publicly available on the Microvi website upon five (5) calendar days of a written request. This public information will be updated annually on Microvi's website as well as within sixty (60) days of a newly identified FCOI. This information shall remain available for three years from the date the information was most recently updated.