

Financial Conflict of Interest Policy

I. PURPOSE, SCOPE AND APPLICATION

This Financial Conflict of Interest Policy (the “Policy”) has been issued by Tavo Biotherapeutics, Inc. (“Tavo”), in accordance with 42 C.F.R. Part 50, Subpart F. All Investigators, and in some cases other individuals, are subject to specific requirements regarding the disclosure and management of financial conflicts of interest with regard to PHS-sponsored research in order to ensure the research will be conducted free of bias resulting from Investigator Financial Conflicts of Interest.

PHS regulations require Tavo to maintain a written policy on conflict-of-interest disclosure as a condition for receiving PHS awards. Therefore, Tavo has established this Policy to require disclosure, and identification and management, of financial conflicts of interest for all Investigators supported by PHS research awards. This Policy only applies to projects that use PHS funding. Specifically, this Policy applies to all PHS grants or cooperative agreements, or applications for PHS grants or cooperative agreements. Tavo’s policy will also apply when Tavo is a subrecipient or subcontractor on a PHS-sponsored award held by another non-federal entity, with the exception of SBIR/STTR Phase I applications.

At its core, this Policy relies upon candid disclosures from individuals involved in PHS-funded research and other programs. As with every United States Government-funded grant, contract, or other program, a range of laws and regulations cover individuals and for-and non-profit entities involved in these programs. Individuals who are required to make disclosures under this Policy will be required to certify that each disclosure and updated disclosure is true, complete, and accurate.

II. DEFINITIONS

Financial Interest means anything of monetary value, regardless of whether the value is readily ascertainable.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct, reporting or funding of a PHS project.

Examples of FCOIs include, **but are not limited to**, the following:

1. Investigator (and/or an Investigator's spouse and/or dependent children) entering into a paid consultancy with an outside entity that has an interest in the Investigator's ongoing research;
2. Investigator (and/or an investigator's spouse and/or dependent children) receiving royalties or non-royalty payments related to ongoing research; and
3. Investigator (and/or an investigator's spouse and/or dependent children) having an equity interest (e.g., stocks, stock options, warrants) related to ongoing research.

Institutional Official means the Tavo Chief Business Officer, Dr. Troy Wu, or his designee, who

will ensure compliance with this Policy and related PHS regulations. The Institutional Official will be responsible for soliciting and reviewing disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research in addition to significant financial interest disclosures from other relevant Tavo employees.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of Tavo, which may include, for example: activities such as research, research consultation, teaching, professional practice, and institutional committee memberships.

Investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the purpose, design, conduct, or reporting of a project funded by PHS or proposed for funding by PHS. This may include, for example, collaborators or consultants.

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

Senior/key Personnel means the project director or principal investigator and any other person identified as senior/key personnel by Tavo in the grant application, progress report, or any other report submitted to the PHS by Tavo.

Significant Financial Interest (SFI) means:

1. A financial interest consisting of one or more of the following interests of an Investigator (and/or of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 - a. 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 the 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 interests include any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - b. Regarding 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 (and/or the Investigator's spouse and/or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators must also disclose any reimbursed or sponsored travel related to an Investigator's Institutional Responsibilities, including that which is paid on behalf of the

investigator so that the exact monetary value may not be readily available. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip. Examples of travel costs include, but are not limited to: costs related to lodging, meals, and transportation, including airfare, rental car, gas, or taxis/ubers.

- a. This does not include travel that is reimbursed or sponsored by a federal, state, or local government agency, a United States Institution of higher education (as defined in 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.
3. The term “significant financial interest” does not include the following types of financial interests:
 - b. Salary, royalties, or other remuneration paid by Tavo to the Investigator if the Investigator is currently employed or otherwise appointed by Tavo, including intellectual property rights assigned to Tavo and agreements to share in the royalties related to those rights;
 - c. Any ownership interest in Tavo held by the Investigator;
 - d. 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;
 - e. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local agency, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
 - f. Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education in the United States, as defined in 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education.

III. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

Who Must Make a Disclosure: All individuals who meet the definition of “Investigator,” as defined above, should complete a Significant Financial Interest (“SFI”) Disclosure. This includes, for example, the Project Director, Principal Investigators, Co-Investigators, Study Coordinators, study staff, consultants, etc.

What Must Be Disclosed: All significant financial interests, as defined above, **including significant financial interests of a spouse or dependent children.**

When Must an SFI Disclosure Be Made: SFI Disclosures should be completed no later than the time of application for the PHS award, or when a new Investigator first becomes engaged in the

applicable study. Disclosures must be updated at least annually. New conflicts should be reported within 30 days of being discovered or the acquisition of a new SFI by submitting a new SFI Disclosure.

What Time Period Does the Disclosure Cover: The obligation to make such disclosures applies to circumstances arising for the duration of the applicable award, the preceding 12 months prior to completing the SFI Disclosure, and until the project is completed.

Examples of Interests that Should be Disclosed: All relationships with commercial entities, other than Tavo, whose products/services are being used/tested or are in direct competition with those being used/tested should be disclosed to Tavo, including but not limited to:

- Ownership of stock, equity, or other financial interest in a company/entity which has products that might be used in or benefit from or be harmed by the results of the study.
- Employment, office or directorship in any company/entity involved or potentially involved with the study.
- Personal compensation from any company/entity involved or potentially involved with the study.
- Involvement with grants, contracts, research, training or other support (restricted or unrestricted) from any company/entity involved or potentially involved with the study.
- Travel grants to attend educational symposia provided by any company/entity involved or potentially involved with the study. This includes serving in one of the aforementioned consulting/advisory arrangements.
- Intellectual property rights (i.e. copyright, patent, trademark) related to the activities of the study.
- Relationship with a company/entity that may affect academic advancement or status, such as sponsorship of an endowed chair or establishment of a fund for use by the study investigator.

Note that this is not a complete list of what must be disclosed.

IV. FCOI PROCEDURES

Review of Disclosures

1. Tavo has identified Dr. Troy Wu as its Institutional Official to solicit and review SFI Disclosures.
2. The individual acting as the Principal Investigator or Project Director for any given project should provide a list of individuals who meet the definition of

“Investigator” within the required disclosure timeline to the Institutional Official.

3. SFI Disclosures for all Investigators in the relevant studies should be maintained by the Institutional Official.
4. Once submitted, SFI Disclosures will be reviewed by Dr. Troy Wu, the Institutional Official, to determine whether a Financial Conflict of Interest (FCOI), as defined above, exists.
5. If necessary, the Institutional Official will obtain additional information from the Investigator and other individuals to help determine whether the SFI disclosed is related to a proposed or existing PHS-funded research. An Investigator’s significant financial interest is related to PHS-funded research when the Institutional Official reasonably determines that the significant financial interest:
 - a. could be affected by the PHS-funded research;
 - b. or is in an entity whose financial interest could be affected by the research.
6. An FCOI exists when the Institutional Official reasonably determines that the **significant financial interest in question could directly and significantly affect** the purpose, design, conduct, or reporting of the PHS-funded research.
7. If an FCOI is identified, then the Institutional Official will determine what action needs to be taken to manage the FCOI as outlined in the section below.

Management of FCOIs

1. If an FCOI is identified, one or more approaches to the management of the FCOI may be exercised at the discretion of Tavo, decided on an individual basis according to the policies and procedures of Tavo. The action plan may include, but are not limited to, one or all of the following, as deemed appropriate:
 - Public disclosure of relevant significant financial interests (e.g., when presenting or publishing the project). This could include, for example, disclosure to review panels such as the IRB, IACUC, personnel working on the project, and patients participating in a clinical trial.
 - Appointment of an independent monitor capable of taking measures to protect the purpose, design, conduct, and reporting of the research against bias resulting from the financial conflict of interest.
 - 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).
 - Modification of the research plan.

- Severance of the relationships/activities that create an actual or potential FCOI.
- For research involving human subjects, disclosure of financial conflicts of interest directly to participants.

2. When an Investigator who is new to the project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest, the Institutional Official shall review the disclosure within 60 days and determine whether it is related to the PHS-funded research, determine whether an FCOI exists, and if so, implement, at a minimum, an interim action plan that shall specify the actions that have been, and will be, taken to manage the FCOI.
3. If a significant financial interest is not disclosed or reviewed in a timely manner, the Institutional Official will review the SFI within 60 days and determine if it is related to the PHS-funded research, determine whether an FCOI exists, and if so, implement, at minimum, an interim action plan that shall specify the actions that have been and will be taken to manage the FCOI going forward.
4. In addition, whenever an FCOI is not identified or managed in a timely manner—including where an FCOI is not disclosed or the Investigator fails to comply with the FCOI management plan, or the Institution fails to review or manage the FCOI—within 120 days of the determination of non-compliance, the Institutional Official will complete a Retrospective Review of the Investigator's activities and the PHS-funded project to determine whether any project activity, or a portion thereof, conducted during the time period of noncompliance, was biased in the purpose, design, conduct, or reporting of such project.
5. Retrospective Review: Tavo will document the retrospective review, and will produce a report that includes the following:
 - Project number;
 - Project title;
 - Project Director (PD)/Principal Investigator (PI) or contact PD/PI if a multiple PD/PI model is used;
 - Name of the Investigator with the FCOI;
 - Name of the entity with which the Investigator has a financial conflict of interest;
 - Reason(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
 - Conclusions of the review.

6. Based on the results of the Retrospective Review, Tavo will update its previously submitted FCOI report, where appropriate, identifying the actions that have been taken to manage the FCOI going forward.
7. Mitigation Report: If the Retrospective Review determines the FCOI biased the relevant project, Tavo will notify the PHS awarding component promptly and submit a Mitigation Report. The Mitigation Report must include, at a minimum:
 - The key elements documented in the Retrospective Review described above.
 - A description of the impact of the bias on the project.
 - Tavo's plan of action or actions to eliminate or mitigate the effect of the bias (e.g., impact on the project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the project is salvageable).
8. Tavo will monitor Investigator compliance with disclosure requirements and relevant management plans on an ongoing basis until completion of the DOE award.

Investigator Non-Compliance and Enforcement:

Failure on the part of an Investigator to comply with this Policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of employment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action mandated by the applicable funding agency or Tavo. The Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the Investigator.

In any case in which the HHS determines that a PHS-funded project of 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 as required, Tavo will 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.

Confidentiality:

Financial and other information disclosed in compliance with this Policy will be kept confidential and disclosed only on a need-to-know basis as required to perform appropriate review and evaluation required by the policy, except in the case of required public accessibility of identified financial conflicts of interest or as otherwise required by law.

Subrecipients:

For PHS-funded projects that involves contractors, subcontractors, subgrantees or subawardees (collectively "Subrecipients") that are other non-federal entities, Tavo requires a written agreement that includes terms that establish whether this Policy or the Subrecipient's FCOI

policy will apply to subrecipient Investigators.

If the parties determine that the Subrecipient's Investigators must comply with the Subrecipient's FCOI policy, the following will apply:

- The Subrecipient shall certify as part of the agreement referenced above that its FCOI policy complies with 42 C.F.R. Part 50, Subpart F. If the Subrecipient cannot provide such certification, the agreement shall state that Subrecipient Investigators are subject to Tavo's FCOI policy (this Policy) for disclosing financial conflicts of interest.
- The agreement referenced above shall specify time period(s) for the Subrecipient to report all identified financial conflicts of interest to Tavo. Such time period(s) shall be sufficient to enable Tavo to provide timely FCOI reports, as necessary, to PHS.
- The Subrecipient shall make its PHS-compliant FCOI policy available via a publicly accessible website. If the Subrecipient does not have any current presence on a publicly accessible website (and only in those cases), the Subrecipient shall make its written policy available to any requestor within five business days of a request.

Alternatively, if the Subrecipient's Investigators must comply with this Policy, the agreement referenced above shall specify time period(s) for the Subrecipient to submit all Investigator SFI disclosures to Tavo. Such time period(s) shall be sufficient to enable Tavo to comply timely with its review, management, and reporting obligations under PHS regulations and this Policy.

A Subrecipient's failure to promptly comply with this Policy will be considered grounds for immediate termination by Tavo of any applicable subcontract or subaward.

V. FCOI REPORTING REQUIREMENTS

Reporting:

1. Initial FCOI Report: Prior to the expenditure of any funds under a PHS-funded research project, Tavo will provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found to be an FCOI. Where Tavo identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, Tavo does not need to submit an FCOI report to the PHS Awarding Component.
2. Tavo will also provide an FCOI report within 60 calendar days from the date of any of the following: (1) when a new significant financial interest disclosure is determined to be an FCOI; (2) when a new Investigator with an identified FCOI becomes engaged on the project; or (3) when Tavo identifies an FCOI not previously disclosed.
 - a. As discussed above in Part IV of this Policy, where an FCOI is identified that was not timely disclosed, or not appropriately managed, Tavo will also complete a Retrospective Review to determine whether any PHS-funded research was biased in the design, conduct, or reporting of the research. If bias

is found, Tavo will promptly notify the PHS Awarding Component and submit a Mitigation Report.

3. The reports described above shall include:

- Project number;
- PI or Contact PI if a multiple PI model is used;
- Name of the Investigator with the financial conflict of interest;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Nature of any applicable financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium) and/or applicable external relationships or activities;
- Value of any applicable financial interest (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;
- A description of how the financial interest relates to the PHS-funded research and the basis for Tavo's determination that there is a conflict with such project; and
- A description of the key elements of the management plan for the FCOI, as required by PHS regulations.

4. For any FCOI previously reported, Tavo shall provide the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI previously reported, and if applicable, any changes to the management plan, for the duration of the award. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

VI. MISCELLANEOUS FCOI REQUIREMENTS

Training Requirements:

Investigators must complete FCOI training prior to engaging in research related to any PHS-funded project and at least every four years thereafter. Training must also be completed as soon as reasonably possible under the following circumstances:

- This Policy changes in a manner that affects Investigator requirements;
- An Investigator is new to Tavo and will be working on a PHS-funded project; or
- An Investigator is found to be noncompliant with this Policy or their approved FCOI management plan.

Following the completion of training, Investigators must acknowledge that they are in receipt of this Policy, and the PHS regulations on which it is based, and will abide by its terms.

Records:

Tavo will maintain all records of all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest), and all actions under the Institution's policy or retrospective review for at least three years from the date the final expenditure report is submitted to PHS or to the prime PHS awardee, or, where applicable, from other dates specified in 45 C.F.R. § 75.361.

Public Accessibility:

This policy will be posted on Tavo's public website.

In addition, prior to the expenditure of PHS funds, Tavo will publish on its website, or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- The Significant Financial Interest was disclosed and is still held by the Senior/Key Personnel;
- A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation. This information may be requested by emailing troy@tavobio.com.

Approved By: Gary Berman, CEO

Effective Date:

July 24, 2024