

Preservation Bio's Financial Conflict of Interest (FCOI) Policy

1. Purpose

The purpose of this Financial Conflict of Interest (FCOI) policy is to ensure that Preservation Bio's ("Company" or "Institution") research, teaching, service, and administrative activities are free from any actual or perceived bias caused by personal Financial Interest (defined below).

2. Scope

This policy applies to all Investigators (PD/PI, Co-PI, Co-I), employees, contractors, students, and other affiliated individuals of the Company responsible for the design, conduct, or reporting of research funded ("Individuals"), regardless of their role or position.

3. Definitions

1. Financial Conflict of Interest (FCOI): means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Public Health Service (PHS) funded research.
2. FCOI Committee: the Company's designated official(s) who review all disclosures by Individuals and determine whether any Significant Financial Interest is related to a NIH-funded research and a whether a FCOI exists
3. Financial Interest: means anything of monetary value, whether or not the value is readily ascertainable.
4. Investigator: means the Project Director or Principal Investigator (PD/PI) 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.
5. Senior/Key Personnel: means the PD/PI and any other person identified as senior/key personnel.
6. Significant Financial Interest (SFI): A Financial Interest consisting of one or more of the following interests of the Individual (and those of the Individual's spouse and dependent children) that reasonably appears to be related to the Individual's institutional responsibilities:
 - a. 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 Individual (or the Individual's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - b. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

The term significant Financial Interest does not include the following types of Financial Interests: salary, royalties, or other remuneration paid by the Institution to the Individual if the Individual 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 Individual, 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 Individual 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.

4. Policy

Individuals are required to disclose all relevant Financial Interests to the Company's designated FCOI Committee annually and within 30 days of acquiring a new Financial Interest. The FCOI Committee shall review all financial disclosures by Individuals and determine whether any SFI is related to a NIH-funded research and whether an FCOI exists by making a reasonable determination that the SFI could be affected by the NIH-funded research or is in an entity whose Financial Interest could be affected by the research. The Company may involve the Individual in the FCOI Committee's determination of whether a SFI is related to the PHS-funded research. A FCOI exists when the FCOI Committee reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

Any Individual who believes they may have a FCOI, or is unsure about the potential for a conflict, should seek advice from the FCOI Committee. When an FCOI is identified, the FCOI Committee will take appropriate steps to manage, reduce, or eliminate the conflict.

5. Procedures for Disclosure

Individuals must disclose their (and their spouse and dependent children's) domestic and foreign SFIs related to their institutional responsibilities. All foreign Financial Interests from foreign entities, including higher education institutions or foreign governments, must be disclosed if exceeding the \$5,000 threshold.

Individuals are expected to be transparent about income from seminars, lectures, teaching engagements, advisory committees, review panels, and travel reimbursements or sponsorships by foreign entities. The FCOI disclosure from all participating Individuals must be reviewed and approved by the FCOI Committee. Individuals must update their disclosures during the year if new Financial Interests are acquired.

6. Training and Compliance

All Individuals subject to this policy must complete Company-approved training on FCOI at the time of their association with the Company and at least once every four (4) years thereafter. Failure to comply with this policy may result in disciplinary action up to and including termination of employment or association with the Company.

Individuals must complete FCOI training:

1. Before engaging in NIH-supported research.
2. Every four (4) years thereafter.

Or immediately, if:

1. The institutional FCOI policies change, affecting Individual's requirements.
2. The Individual is new to the institution.
3. The Individual is found non-compliant with the institution's FCOI policy or management plan.

7. Management of FCOI

When a potential FCOI is disclosed, the FCOI Committee will review and determine whether an actual conflict exists and what actions should be taken to manage the conflict. Management strategies may include, but are not limited to:

1. Public disclosure of the FCOI
2. Monitoring of the research by independent reviewers
3. Modification of the research plan
4. Disqualification from participation in the portion of the funded research that would be affected by the FCOI
5. Divestiture of the Financial Interest

If the FCOI Committee identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Company during an ongoing research project (e.g., was not timely reviewed or reported by a subrecipient), the FCOI Committee shall, within sixty days: review the SFI; determine whether it is related to PHS-funded research; determine whether a FCOI exists; and, if so implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.

Whenever a FCOI is not identified or managed in a timely manner, including but limited to: failure by the Individual to disclose a SFI that is determined by the Company to constitute a FCOI; failure by the Company to review or manage such a FCOI; or failure by the Individual to comply with a FCOI management plan, the Company shall, within 120 days of the determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to 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.

The Institution shall document the retrospective review which shall include at least the following key elements: project number; project title; PD/PI or contact PD/PI if a multiple PD/PI model is used; name of the Individual 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, etc.); findings of the review; and conclusions of the review. If bias is found, the Institution shall notify NIH promptly and submit a mitigation report.

Where it is determined that an NIH-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 Individual with a conflicting interest that was not managed or reported by the Company as required by the regulation, the Company shall require the Individual(s) involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

8. Records Retention

Terms will be established in written agreements with subrecipients to determine whose FCOI policy will apply, including disclosure and/or FCOI reporting timeframes. All disclosure forms, conflict management plans, and related documents will be retained by The Company for a minimum of three (3) years from the date of the final payment on the associated project or longer if required by law or regulation.

9. Public Accessibility

The company will make information concerning identified FCOI held by Senior/Key Personnel publicly accessible, ensuring transparency to the public while respecting privacy regulations.

10. Reporting to Sponsors

If required, the Company will report FCOI to appropriate funding agencies or sponsors in compliance with applicable laws, regulations, and policies. For the NIH, FCOIs are reported to the awarding IC using the eRA Commons FCOI Module. This includes:

1. Initial FCOI report detailing grant number, Individual details, nature of the FCOI, value, how it relates to NIH-funded research, and key elements of the management plan.
2. Annual FCOI reports detailing the status of the FCOI and any changes to the management plan.

11. Amendments

This policy may be amended or revised as deemed necessary by the Company or in response to changes in relevant laws and regulations. This policy may be revised based on changes in the [Title 42 CFR Part 50 Subpart E](#) regulations or other relevant considerations.

Review Date: 8/23/23

Effective Date: 8/24/23

Compliance Officer: _____

DocuSigned by:

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