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Persista Bio Financial Conflict of Interest (FCOI) Policy

Version 1.0

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1. Introduction

The purpose of this policy is to ensure that research funded by the National Institutes of Health (NIH) is designed, conducted, and reported objectively and without bias resulting from Investigator financial conflicts of interest (FCOI). The regulations are 42 CFR Part 50 Subpart F and 45 CFR Part 94, which set requirements for promoting objectivity in Public Health Service (PHS)–funded research for grants, cooperative agreement, and research contracts, respectively. The regulations do not apply to Phase I SBIR or STTR applications or awards. This policy implements the regulatory requirements for PHS/NIH grants and cooperative agreements.

Persista Bio, Inc. ("Persista", "The Institution") adopts this policy for all Investigators (as defined below) engaged in PHS/NIH-funded research. It establishes processes to identify, disclose, and manage Investigator financial conflicts of interest to protect research integrity, ensure the safety of human and animal subjects, and maintain public trust in PHS/NIH-supported research.

2. Scope

This policy applies to all Investigators who are responsible for the design, conduct, or reporting of NIH-funded research at Persista. It also applies to "Investigators" who participate as employees, subcontractors, consultants, or collaborators on NIH-funded projects.

3. Definitions

For the purpose of these policies and procedures, the following definitions apply:

Financial conflict of interest (FCOI): A significant financial interest that is related to the PHS/NIH-funded research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial Interest: Anything of monetary value, whether or not its value is readily ascertainable.

Institutional Responsibilities: The professional activities an Investigator performs on behalf of Persista including: research; preclinical testing; product development and testing; publication and communication of research; consulting; interacting with vendors, collaborators, consultants and subcontractors; operations management; administration; administration of a quality management system (QMS); fundraising; and institutional committee memberships or panels (such as safety or QMS).

Designated Official (DO): The individual appointed by Persista to solicit and review disclosures of significant financial interests, determine FCOIs in accordance with 42 CFR 50.604(f) and this policy, and develop management plans for identified FCOI.

Institution: Any public or private organization, domestic or foreign (excluding a federal agency) that is applying for or receives PHS/NIH research funding.

Investigator: The Project Director (PD) or Principal Investigator (PI) and any individual, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded or proposed for funding. This may include, for example, collaborators or consultants. Persista determines who is responsible for the design, conduct, or reporting of PHS-funded research based on an individual's role and level of independence, not their title.

Manage: means 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, or experiment designed to develop or contribute to general knowledge relating broadly to public health, including biomedical research. This term includes both basic and applied research (e.g., published articles, books, or book chapters) and product development (e.g., implantable medical devices).

PHS-Funded Research: Any activity supported by a Public Health Service (PHS) Awarding Component through a grant, cooperative agreement, or contract, whether funded under the PHS Act or other statutory authority.

PHS: 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).

NIH: The biomedical research agency within the Public Health Service (PHS) that funds and conducts research to improve health and advance scientific knowledge.

Senior/Key Personnel: The PD/PI and any other individual identified as senior/key personnel by the Institution in a grant application, progress report, or other submission to PHS/NIH. For this policy, the term applies specifically to the public accessibility requirement, which mandates disclosure only of financial conflicts of interest held by these Senior/Key Personnel, as described in Section 9.

Significant Financial Interest (SFI):
A domestic or foreign financial interest of the Investigator, the Investigator's spouse, and dependent children that reasonably appears to relate to the Investigator's Institutional Responsibilities on behalf of Persista, and that consists of one or more of the following:

- **Publicly traded entity**: An SFI exists if the sum total of remuneration received from the entity in the previous 12 months and the value of any equity interest in the entity on the disclosure

date exceeds $5,000. Remuneration includes salary and payments for services (e.g., consulting fees, honoraria, paid authorship). Equity interest includes stock, stock options, or other ownership interests measured by public prices or other reasonable market value.

- **Non-publicly traded entity**: An SFI exists if the aggregated value of remuneration received from the entity in the 12 months preceding the disclosure exceeds $5,000, or if the Investigator (or their spouse or dependent children) holds any equity interest in the entity (e.g. stock, stock options, warrants, or other ownership interest).

- **Intellectual property:** An SFI exists if income related to intellectual property rights or interests (e.g., patents, copyrights) exceeds $5,000 during the 12 months preceding the disclosure.

Investigators must disclose any reimbursed or sponsored travel related to their Institutional responsibilities with a value exceeding $5,000. Such travel includes trips paid on behalf of the Investigator rather than being reimbursed directly, where the exact cost may not be known. The disclosure must cover the previous 12 months and include, at minimum, the purpose, sponsor or organizer, destination, and duration of each trip.

The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- a federal, state, or local government agency located in the United States,
- a United States Institution of higher education,
- an academic teaching hospital,
- a medical center, or
- a research institute affiliated with a United States Institution of Higher Education

The term “significant financial interest” does not include, and therefore investigators are not required to disclose, the following types of financial interests:

- Salary, royalties, or other remuneration paid by Persista to the Investigator if the Investigator is currently employed or otherwise appointed by Persista, including intellectual property rights assigned to Persista and any agreements to share royalties related to those rights.
- Any ownership interest in Persista held by the Investigator, since Persista is a commercial or for-profit organization. This exclusion applies only if the applicant or recipient (including a sub- recipient) is a for-profit or commercial institution.
- Income from investment vehicles such as mutual funds and retirement accounts, provided the Investigator does not directly control the investment decisions for those vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

- Income from service on advisory committees or review panels for a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

Foreign Financial Interests: Investigators must disclose all financial interests originating outside the United States, including income from seminars, lectures, teaching engagements, service on advisory committees or review panels, and reimbursed or sponsored travel, received from any foreign entity. This includes foreign institutions of higher education and foreign governments (including local or provincial governments). This is subject to the rules above for public, non-public and intellectual property financial interests.

4. Significant Financial Interest (SFI) Disclosure Requirements

Investigators are required to disclose Significant Financial Interests (SFIs) at the following times:

At the time of application: The PI and all other individuals who meet the definition of "Investigator" must disclose their SFIs to the DO(s). Any new Investigator who joins the project after the NIH application has been submitted or during the course of the research must also disclose their SFI(s) to the DO(s) promptly and before participating in the project, using the SFI Disclosure Form.

Annual Disclosure: Each Investigator participating in research under an NIH award must submit an updated SFI disclosure at least annually (on or before July 1) during the award period. The annual disclosure must include: (1) any new information that was not previously disclosed to Persista under this policy, including SFIs associated with NIH-funded projects transferred from another institution; and (2) updated details for any previously disclosed SFI, such as changes in the value of an equity interest.

New SFIs during the award: Each Investigator participating in PHS/NIH-funded research must submit an updated SFI disclosure within 30 days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Updated disclosure of reimbursed or sponsored travel must also be submitted within 30 days of each occurrence.

5. Review of SFI Disclosures

The Persista Designated Official (DO) identified in Section 18 is responsible for reviewing all SFI disclosures. Each SFI will be evaluated in relation to every PHS/NIH research application or award on which the Investigator is responsible for the design, conduct, or reporting of research, to determine whether

the SFI is related to the funded research and, if so, whether it constitutes a Financial Conflict of Interest (FCOI).

The SFI disclosures will be reviewed as described below:

- **Prior to the issuance of a new award:** The DO will review the Investigator's SFIs before NIH issues a new award, for example during the NIH Just-in-time (JIT) stage. If an FCOI is identified, an FCOI report will be submitted to NIH via the eRA Commons FCOI Module prior to any expenditure of funds.
- **Annual SFI disclosure:** As part of the annual disclosure process, Investigators must provide updated information on any previously disclosed SFIs (e.g., revised value of an equity interest). The DO will review these updates to determine whether changes to an existing management plan are needed. Any modifications will be reflected in the next Annual FCOI report submitted to NIH, if applicable.
- **During award period:** If a new Investigator joins a project or an existing Investigator acquires or discovers a new SFI during the project, the DO will, within 60 days: (1) review the disclosure; (2) determine whether the SFI is related to the PHS/NIH-funded research; (3) determine whether an FCOI exists; and, if so, (4) implement, on at least an interim basis, a management plan. The Institution may accelerate the process based on the nature of the SFI to implement an interim management plan. An FCOI report will be submitted to NIH within 60 days of identifying the FCOI.

6. Relatedness of SFI to PHS/NIH-Funded Research and FCOI

The DO is responsible for assessing the relatedness of SFIs to NIH-funded research and determining when they constitute a FCOI.

Relatedness Test: The DO determines whether an Investigator's SFI is related to research under an NIH award. An SFI is considered "related" when the DO reasonably determines that:

- The SFI could be affected by the PHS/NIH-funded research, or
- The SFI is in an entity whose financial interests could be affected by the PHS/NIH-funded research.

The DO may consult with the Investigator when assessing whether an SFI is related to the research.

Designated Official FCOI Determination: An FCOI exists when the DO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research ("significantly" meaning that the financial interest would have a material effect on the research).

7. Management of SFI that Pose a FCOI

When an FCOI is identified, the DO will determine and implement management strategies to ensure the research is conducted objectively. Examples of management conditions include:

1. Public disclosure of the FCOI (e.g., in publications or presentations, to study personnel, to the IRB, IACUC, or Data Safety Monitoring Board). While public posting of FCOIs is required only for senior/key personnel, the DO may require disclosure of any Investigator's FCOI as a condition of a management plan.
2. For human subjects research, disclosure of the FCOI to participants in the informed consent document
3. Appointment of an independent monitor to protect against bias in the design, conduct, and reporting of the research
4. Modification of the research plan
5. Change of personnel roles or removal from portions of the research
6. Reduction or elimination of the financial interest (e.g., divesting equity)
7. Severance of relationships creating the conflict

The DO will communicate the determination and the management plan in writing to the Investigator, the PI/PD, and the appropriate supervisor.

No expenditures on a new NIH award may occur until the Investigator has met all disclosure requirements and agreed in writing to comply with the management plan. For an ongoing award, see Section 5 above for the timeline to a management plan, and then the Investigator must meet all disclosure requirements and agree in writing to comply with the management plan to continue as an Investigator. The DO will submit an FCOI report to NIH via the eRA Commons FCOI Module.

8. Monitoring Investigator Compliance

Persista will monitor Investigator compliance with the management plan for the duration of the NIH award or until the FCOI no longer exists. Monitoring includes verifying that required public disclosures of FCOIs are made in publications, presentations, and other communications. Investigators must also disclose the FCOI in writing to study personnel and provide a copy of this disclosure to the DO for recordkeeping.

9. Public Access to the FCOI Policy and Related Information

FCOI Policy: A copy of this FCOI policy is available on Persista's public website, as required by Section 4.1.10 Financial Conflict of Interest of the NIH Grants Policy Statement.

Identified FCOIs held by Senior/key Personnel: Before any funds are spent under an NIH award, Persista will ensure public accessibility, either by posting on a publicly accessible website or by providing a written response, within five (5) business days to requests for information about any SFI that meets all three of the following criteria:

- The SFI was disclosed and is still held by Senior/Key Personnel (the PD/PI and any other individual identified by Persista as senior/key personnel in the application, progress report, or other NIH submission).
- Persista has determined that the SFI is related to the NIH-funded research.
- Persista has determined that the SFI constitutes an FCOI.

When applicable, Persista will make available at least the following information:

- Investigator's name
- Investigator's title and role with respect to the research project
- Name of the entity in which the SFI is held
- Nature of the SFI
- Approximate dollar value of the SFI in the following ranges: $0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000 and $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000; or a statement that the value cannot be readily determined by public prices or reasonable fair market value measures.

The written response will note that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of the Institution's identification of a new FCOI, which should be requested subsequently by the requestor.

If Persista uses a publicly accessible website to meet this requirement, the information will be updated at least annually and within 60 days of:

- Receiving or identifying an additional SFI of Senior/Key Personnel related to the NIH-funded research that was not previously disclosed, or
- A new SFI being disclosed by Senior/Key Personnel joining the project and determined by the DO to be related and an FCOI.

Information on SFIs subject to public accessibility will remain available for at least three years from the most recent update.

10. Reporting Financial Conflicts of Interest

Prior to spending any funds under an NIH-funded award, Persista will submit an FCOI report to NIH, in accordance with NIH regulations, for any Investigator's SFI determined to be an FCOI. Persista will also ensure that the Investigator has agreed to and begun implementing the associated management plan.

Persista will designate an Institutional official to act as the FCOI Signing Official (FCOI SO) in the eRA Commons FCOI Module. The FCOI SO is authorized to submit FCOI reports to NIH. FCOI reports are submitted only when an award is active and an FCOI has been identified (i.e., no award means no FCOI report, and no FCOI means no FCOI report).

The NIH eRA Commons FCOI Module User Guide, available at the following location provides instructions for preparing and submitting FCOI reports.
https://www.era.nih.gov/files/fcoi_user_guide.pdf

Initial (Original) FCOI Reports

- **Prior to the expenditure of funds:** If an FCOI is identified at the time a new NIH award is issued, the FCOI SO will submit an "Original" FCOI report (2011 FCOI) through the eRA Commons FCOI Module before any funds are spent. The report must include all information required under 42 CFR 50.605(b)(3) or as outlined in NIH FAQ H.5 https://grants.nih.gov/faqs#/financialconflict-of-interest.htm?anchor=52888.
- **Within 60 days during the award:** If an FCOI is identified during the award period (e.g., a new SFI is disclosed or a new Investigator joins the project), the Institution must submit an Original FCOI report within 60 days of identifying the FCOI.

Annual FCOI Reports: For the duration of an award, including any extensions with or without funds, the Institution must submit an annual FCOI report to NIH. This report will indicate whether each previously reported FCOI is still being managed or no longer exists and describe any changes to the management plan, if applicable.

- The annual report must be submitted at the same time as the Research Performance Progress Report (RPPR) or multi-year progress report, and at the time of any grant extension, following NIH guidance (see NIH FAQ H.2: https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52885).
- Annual FCOI reports are not required at grant closeout.

Revision (or Mitigation) FCOI Reports: After completing a retrospective review, the Institution will submit a Revision report to NIH if new information about the FCOI is discovered, or a Mitigation report if the review finds that bias has occurred.

Types of FCOI Reports Summary Chart for NIH:

Required FCOI Reports to NIH via eRA Commons FCOI Module		
REPORT	**CONTENT**	**REQUIRED WHEN**
New FCOI Report (Initial submission)	Grant number; PI; name of entity with FCOI; nature of FCOI; value of the financial interest (in required increments); description of how the financial interest relates to the research; key elements of the management plan.	Prior to the expenditure of funds on a new award; within 60 days of identifying any new FCOI during the award period.

Annual FCOI Report	Status of the FCOI (whether it is still being managed or no longer exists) and any changes to the management plan, if applicable.	Submitted annually at the same time as the annual progress report, multi-year progress report, or at the time of a grant extension.
Revised FCOI Report	If applicable, updates to a previously submitted FCOI report to describe actions that will be taken to manage the FCOI going forward or to revise the original report.	Following a retrospective review when noncompliance with the regulation is identified, if applicable.
Mitigation Report	Project number; project title; contact PI/PD; name of Investigator with FCOI; name of entity with FCOI; reason for review; detailed methodology, findings, and conclusions.	After a retrospective review when bias is found.

11. Training Requirements

Each Investigator will be informed of Persista 's FCOI Policy and trained on their responsibility to disclose foreign and domestic SFIs under this policy and the FCOI regulation at 42 CFR Part 50 Subpart F. Training must be completed before an Investigator engages in PHS/NIH-funded research, at least once every four years, and promptly (as described below) when any of the following occur:

- Persista revises this policy or related procedures in a way that affects Investigator requirements.
- An Investigator is new to Persista research under an NIH award (training must be completed before participating in the research).
- Persista determines that an Investigator has not complied with this policy or with a management plan issued under it. Then training must be completed within 30 days as directed by the DO.

To meet the NIH training requirement, Persista requires Investigators to complete at least one of the following NIH FCOI tutorials:

1) NIH FCOI tutorial from the following location, print and retain the completion certificate for audit purposes. https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html.

2) Virtual Seminar presentation on FCOI compliance and Investigator emails the DO that completed the viewing has been completed. https://www.youtube.com/watch?v=D292YZ6BX24.

12. Noncompliance With FCOI Policy And Corrective Actions

If Persista identifies an SFI that was not disclosed, reviewed, or managed in a timely manner, the DO will, within 60 days: review the SFI; determine whether it is related to NIH-funded research; determine whether it constitutes an FCOI; and, if so, implement an interim management plan describing actions that have been and will be taken to manage the FCOI going forward.

Persista will also submit an FCOI report to NIH via the eRA Commons FCOI Module.
In cases of noncompliance, including:

Failure by the Investigator to disclose an SFI that is later determined to constitute an FCOI

- Failure by the Institution to review or manage an FCOI
- Failure by the Investigator to comply with an established management plan

Persista will, within 120 days of identifying noncompliance:

- Conduct a retrospective review of the Investigator's activities and the NIH-funded research to determine whether the research, or any part of it, was biased in the design, conduct, or reporting.
- Document the retrospective review in accordance with 42 CFR 50.605(a)(3)(ii)(B) or NIH FAQ I.2 (https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52888).

If bias is found, Persista will promptly notify NIH and submit a mitigation report as required by 42 CFR 50.605(a)(3)(iii) or NIH FAQ I.3 (https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52896). The report will include:

- The impact of the bias on the research project, and
- The plan of action or corrective steps taken to eliminate or mitigate the effect of the bias.

Persista will thereafter submit FCOI reports annually to NIH as required by the regulations and the terms and conditions of the award. Depending on the circumstances, Persista may implement additional interim measures regarding the Investigator's participation in the research until the retrospective review is complete. If no bias is found, no further action is required.

13. Clinical Research Requirements

If HHS determines that a PHS-funded clinical research project evaluating the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with an unmanaged or unreported FCOI, Persista will require the Investigator to disclose the conflict in every public presentation of the research results and to request an addendum to previously published presentations.

14. Subrecipient Requirements

A subrecipient relationship exists when federal funds flow from or through Persista to another individual or entity that will carry out a substantive portion of a PHS-funded research project and is accountable to Persista for programmatic outcomes and compliance. Subrecipients (e.g. collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees) are subject to Persista's terms and conditions. Persista will take reasonable steps to ensure that all subrecipient Investigators comply with the federal FCOI regulations at 42 CFR Part 50 Subpart F. Persista will include in each written agreement with a subrecipient terms specifying whether Persista 's FCOI Policy or the subrecipient's own FCOI policy will apply to subrecipient Investigators (see NIH Grants Policy Statement Section 15.2.1 on Written Agreements:

https://grants.nih.gov/grants/policy/nihgps/html5/section_15/15.2_administrative_and_other_requirements.htm#Written).

- **If the subrecipient's FCOI policy applies:**
  The subrecipient institution must certify in the agreement that its policy complies with federal FCOI regulations. The agreement will specify the timeframe for the subrecipient to report identified FCOIs to Persista in time for Persista to meet NIH reporting deadlines (i.e., before funds are spent and within 60 days of the subrecipient identifying an FCOI). Typically, this means requiring subrecipients to report FCOIs to Persista within 50–55 days of identification. Persista 's DO will then submit the subrecipient FCOI report to NIH through the eRA Commons FCOI Module.
- **If the subrecipient cannot certify compliance:**
  The agreement will specify that Persista 's FCOI Policy applies. In this case, subrecipient Investigators must disclose their SFIs to Persista. The SFI disclosure must include SFIs that are directly related to the subrecipient's work for Persista. The agreement will allow suWicient time for Persista to review, manage, and report any resulting FCOIs. When an FCOI is identified, Persista will implement a management plan, monitor compliance by the subrecipient Investigator, and submit the required FCOI report to NIH via the eRA Commons FCOI Module.

15. Maintenance of Records

Persista will maintain records of all Investigator financial interest disclosures, Persista 's review and response to those disclosures (whether or not they resulted in a determination of an FCOI), and any actions taken under this policy or through retrospective review. These records will be retained for at least three years from the date of submission of the final expenditures report, or for longer periods as specified in 45 CFR 75.361 for specific situations. Persista will retain these records for each competitive segment as required by regulation.

16. Enforcement Actions for Investigator Noncompliance

Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Investigators who fail to comply may be subject to disciplinary action, which can include termination of employment or contract, formal warning letter or official notice of disciplinary action, restrictions on the use of research funds, and/or disqualification from further participation in any PHS/NIH-funded research, as deemed appropriate.

17. Useful FCOI AND NIH Resources

NIH e-mail address for FCOI-related inquiries
fcoicompliance@mail.nih.gov

FCOI Regulation 42 CFR Part 50 Subpart F-Promoting Objectivity in Research
https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F

Financial Conflict of Interest
https://grants.nih.gov/policy-and-compliance/policy- topics/fcoi

FCOI Training
https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi- training

FCOI Frequently Asked Questions (FAQs)
https://grants.nih.gov/policy-andcompliance/policy-topics/fcoi/fcoi-training

Information for Foreign Grants
https://grants.nih.gov/new-to-nih/information- for/foreigngrants

NIH "Welcome Wagon" Letter: Information for New Recipient Organizations
https://grants.nih.gov/policy-and-compliance/welcomewagon

18. Point Of Contact

If you have a question related to the FCOI Policy of Persista Bio, are required to disclose a financial interest, or would like to request a public disclosure per Section 9 above, contact us using the information below:

Contact:
The Designated Official (DO) and CFOI S0: Linda A. Tempelman, Ph.D. ltempelman@persistabio.com