BlueShield Therapeutics Financial Conflict of Interest (FCOI) Policy
Last updated December 18, 2024

FINANCIAL CONFLICT OF INTEREST POLICY

The Department of Health and Human Services (HHS) has established regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) aimed at ensuring objectivity in research. Initially developed in 1995 and revised in 2011, these regulations outline the responsibilities of individuals and institutions to maintain transparency and prevent bias in PHS-funded research. Applicable to all Public Health Service (PHS) funded grants, cooperative agreements, and research contracts—including those funded by the National Institutes of Health (NIH)—these regulations exclude Phase 1 Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) applications and awards. This policy is designed to ensure compliance with these federal requirements at BlueShield Therapeutics.

DEFINITIONS

- **Financial Conflict of Interest (FCOI)**
  A significant financial interest that could directly and significantly impact the design, conduct, or reporting of PHS-funded research.
- **Financial Interest**
  Any monetary value, regardless of whether its value is easily determined.
- **Institutional Responsibilities**
  Professional activities conducted by an investigator on behalf of BlueShield Therapeutics, such as administration, research, or consulting.
- **FCOI Official**
  The individual designated by BlueShield Therapeutics to oversee the financial conflicts of interest process, including the solicitation and review of disclosures of significant financial interests and identifying FCOIs in accordance with 42 CFR 50.604(f) and the policy outlined below. Currently, this role is held by Labed Sid Ahmed, CEO of BlueShield Therapeutics.
- **Investigator**
  The Project Director or Principal Investigator and any other individual, regardless of their title or position, who is responsible for the design, conduct, or reporting of research funded by an award or proposed for such funding. This definition includes collaborators or consultants. BlueShield Therapeutics' Principal Investigator/Project

Director, after considering the individual's role and level of independence in the research, will determine who is responsible for these aspects of the research.

- **Research**
  A systematic investigation, study, or experiment aimed at expanding generalizable knowledge in various fields, including public health, behavioral, and social sciences. This term includes both basic and applied research, such as published articles, books, or product development (e.g., diagnostic tests or drugs). For PHS-funded research, it encompasses any activity eligible for funding from a PHS awarding component through grants, cooperative agreements, or contracts authorized under the PHS Act or other statutory authorities.

- **Public Health Service (PHS)**
  A division of the U.S. Department of Health and Human Services that includes various agencies, such as the National Institutes of Health (NIH), tasked with protecting and advancing public health.

- **National Institutes of Health (NIH)**
  The primary biomedical research agency of the PHS, dedicated to conducting and supporting medical research.

- **Senior/Key Personnel**
  The Project Director/Principal Investigator (PD/PI) and any other individuals designated as senior/key personnel by BlueShield Therapeutics in grant applications, progress reports, or other submissions to the PHS/NIH. This designation relates specifically to the requirements for public accessibility of information regarding financial conflicts of interest.

Significant Financial Interest (SFI) Policy

(1) **Definition of Significant Financial Interest (SFI)**
A financial interest held by the Investigator, their spouse, or dependent children that reasonably appears to be related to the Investigator's institutional responsibilities at BlueShield Therapeutics includes the following:

- **Publicly Traded Entities:** An SFI exists if the combined value of any remuneration received from the entity in the 12 months preceding the disclosure and any equity interest in the entity exceeds $5,000. Remuneration includes salary and payments for services (e.g., consulting fees, honoraria, paid authorship), while equity interest includes any stock, stock options, or other ownership interests, determined through public prices or other fair market value measures.

- **Non-Publicly Traded Entities:** An SFI exists if the value of any 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, or other ownership interests).
- **Intellectual Property Rights and Interests:** An SFI exists upon receipt of income exceeding $5,000 related to such rights and interests (e.g., patents, copyrights).

(2) **Exclusions from Significant Financial Interest**
The term significant financial interest does not include the following types of financial interests:

- **Salary, Royalties, or Other Remuneration:** Paid by BlueShield Therapeutics to the Investigator if the Investigator is currently employed or otherwise appointed by BlueShield Therapeutics, including intellectual property rights assigned to BlueShield Therapeutics and agreements to share in royalties related to such rights.
- **Ownership Interest in BlueShield Therapeutics:** Any ownership interest held by the Investigator since BlueShield Therapeutics is a commercial or for-profit organization and such interest is excluded from the SFI definition per the regulation.
- **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 located in the United States, a US Institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a US Institution of higher education.
- **Income from Service on Advisory Committees or Review Panels:** For a federal, state, or local government agency located in the United States, a US Institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a US Institution of higher education.

(3) **Disclosure Requirements for Reimbursed or Sponsored Travel**
Investigators must disclose any reimbursed or sponsored travel exceeding $5,000 (i.e., travel paid on behalf of the Investigator and not reimbursed to the Investigator) that is related to their institutional responsibilities. The initial disclosure should include income received over the previous twelve months. The details of this disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

The disclosure requirement does not apply to travel 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
- A research institute affiliated with a United States Institution of higher education

Foreign Financial Interests
Investigators must disclose all foreign financial interests, which include income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel received from any foreign entity, including foreign institutions of higher education or a foreign government (including local, provincial, or equivalent governments of another country) when such income exceeds $5,000.

Financial Interest Reporting Disclosure Obligations
At the time of application, the Principal Investigator and all individuals who qualify as "Investigators" must disclose their Significant Financial Interests (SFIs) to the designated official at BlueShield Therapeutics.

Any new Investigator who joins the project after the initial application to NIH or during the course of the research must promptly disclose their SFIs to the FCOI Official before participating in the project.

Each Investigator involved in research funded by an NIH award must provide an updated disclosure of their SFIs at least once a year during the award period. This update should include any new information not previously disclosed to BlueShield Therapeutics according to this policy, or any subsequent SFI disclosures (e.g., financial conflicts of interest identified on an NIH-funded project directly as an NIH grantee or indirectly through a sub-award transferred from another institution). This update should also include revised details regarding any previously disclosed SFIs, such as the updated value of a previously disclosed equity interest.

Investigators participating in PHS/NIH-funded research must submit an updated disclosure of SFIs within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Additionally, Investigators must update their disclosures of reimbursed or sponsored travel within 30 days of each occurrence.

Evaluation of SFI Disclosures by BlueShield Therapeutics' Designated Official
At BlueShield Therapeutics, the designated official is tasked with reviewing all SFI disclosures. This involves examining each disclosed SFI and cross-referencing it with PHS/NIH research applications and awards where the Investigator is responsible for the design, conduct, or reporting of the research. The objective is to assess whether the disclosed SFI is related to the PHS/NIH-funded research and if it constitutes a Financial Conflict of Interest (FCOI).

Criteria for Assessing Relatedness of SFI to PHS/NIH-funded Research and Identifying FCOI
The designated official will evaluate whether an Investigator's SFI is related to the NIH-funded research. This evaluation considers whether the SFI could be affected by the research or if it is associated with an entity whose financial interests could be impacted by the research. The Investigator may be involved in this determination process.

A financial conflict of interest is established when the designated official concludes that the SFI could directly and significantly influence the design, conduct, or reporting of the PHS/NIH-funded research. "Significantly" in this context means that the financial interest would materially affect the research outcomes.

Management of Significant Financial Interests (SFIs)
When a financial conflict of interest (FCOI) is identified, BlueShield Therapeutics' designated official will establish appropriate management strategies to address and mitigate the conflict. The following are examples of measures that may be implemented to manage an FCOI:

1. **Public Disclosure:** Ensure transparency by publicly disclosing the financial conflict of interest. This includes sharing the information when presenting or publishing research, informing research personnel involved in the study, and notifying relevant institutional committees (e.g., Institutional Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board).
2. **Disclosure to Human Subjects:** For research involving human subjects, the conflict of interest must be disclosed directly to participants within the informed consent document.
3. **Independent Monitoring:** Appoint an independent monitor to oversee the research and ensure the integrity of its design, conduct, and reporting, thereby preventing bias due to the financial conflict.
4. **Research Plan Modification:** Adjust the research plan as necessary to address any potential biases introduced by the conflict of interest.

5. **Personnel Changes:** Modify the roles or responsibilities of involved personnel or, if necessary, disqualify certain personnel from participation in all or parts of the research to mitigate the conflict.
6. **Financial Interest Adjustment:** Reduce or eliminate the financial interest, for example, through the sale of equity interests, to minimize the impact on the research.
7. **Severance of Relationships:** End relationships or associations that create the financial conflict of interest.

If the designated official or committee determines that a conflict exists, the decision and the management plan developed to address the FCOI will be communicated in writing to the individual Investigator, the relevant Principal Investigator/Project Director, and the appropriate direct supervisor.

No funds from an NIH award will be utilized until the Investigator has met all disclosure requirements outlined in this policy and has agreed, in writing, to adhere to any management plans established by the designated official to address the Financial Conflict of Interest (FCOI). The designated FCOI official at BlueShield Therapeutics will then submit the FCOI report to the NIH through the eRA Commons FCOI Module.

Public Access to Financial Conflict of Interest Information
Before any funds from an NIH award are expended, BlueShield Therapeutics will ensure public access to information about disclosed Significant Financial Interests (SFIs) by responding in writing to any requestor within five business days. This response will provide information on any SFI that meets the following criteria:

1. **Active Disclosure:** The SFI was disclosed and is currently held by senior/key personnel. Senior/key personnel include the Principal Investigator/Project Director (PD/PI) and any other individuals identified as senior/key personnel by BlueShield Therapeutics in the award application, progress report, or other submissions to the NIH.
2. **Relevance to Research:** BlueShield Therapeutics has determined that the SFI is related to the research funded by an NIH award.
3. **Determination of Conflict:** BlueShield Therapeutics has determined that the SFI constitutes a financial conflict of interest.

The information made publicly accessible via BlueShield Therapeutics' website or in a written response to any requestor within five business days will include, at a minimum:

- **Investigator's Name:** The name of the Investigator.
- **Investigator's Role:** The title and role of the Investigator with respect to the research project.
- **Entity Name:** The name of the entity in which the Significant Financial Interest is held.
- **Nature of SFI:** A description of the Significant Financial Interest.
- **Value of SFI:** The approximate dollar value of the Significant Financial Interest in the following ranges: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 in increments of $20,000; amounts above $100,000 in increments of $50,000, or a statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

If BlueShield Therapeutics uses a publicly accessible website to meet the public disclosure requirements of NIH regulations, the information will be updated at least annually and within sixty days of receiving or identifying any additional Significant Financial Interests of the senior/key personnel for the NIH-funded research project that had not been previously disclosed. This also applies upon the disclosure of a new Significant Financial Interest of senior/key personnel for the NIH-funded research project if the designated official determines that the SFI is related to the research and constitutes a financial conflict of interest.

Information about an individual's SFI, as specified by this policy, will remain available for responses to written requests or for posting on BlueShield Therapeutics' publicly accessible website for at least three years from the date of the most recent update.

Reporting of Financial Conflicts of Interest: Before any NIH-funded award funds are spent, BlueShield Therapeutics will submit a Financial Conflict of Interest (FCOI) report to the NIH, as required by NIH regulations. This report will detail any Investigator's Significant Financial Interest (SFI) found to be conflicting, and will confirm that the Investigator has agreed to and implemented the necessary management plan.

BlueShield Therapeutics will designate an institutional official to serve as the FCOI Signing Official (SO) within the eRA Commons FCOI Module. This official will have the authority to submit FCOI reports to the NIH. The FCOI Module User Guide, which provides instructions on this process, is available at the NIH website.

Throughout the duration of the award, including any extensions (with or without additional funds), BlueShield Therapeutics will submit an annual FCOI report to the NIH. This report

will address the status of the FCOI, indicating whether it is still being managed or if it has been resolved, and will include any changes to the management plan if applicable.

If a new Significant Financial Interest is identified as conflicting after the initial FCOI report has been submitted during an ongoing NIH-funded research project (e.g., a new SFI is identified for an Investigator who is participating in the research, or a new Investigator joins the project), BlueShield Therapeutics will provide the NIH with an updated FCOI report within 60 days. This report will detail the financial conflict of interest and confirm that a management plan has been implemented and agreed upon by the Investigator.

The initial FCOI report will include all information required by the regulation at 42 CFR Part 50.605(b)(3) or as specified in the NIH's FAQs.

Training Requirements

Each Investigator will be informed about BlueShield Therapeutics' Financial Conflict of Interest (FCOI) Policy and trained on their responsibilities to disclose both foreign and domestic Significant Financial Interests (SFIs) as per this policy and the FCOI regulation outlined in 42 CFR Part 50 Subpart F. This FCOI training will be provided prior to an Investigator beginning any PHS/NIH-funded research, and it will be required at least every four years. Immediate training will be necessary under the following conditions:

1. BlueShield Therapeutics revises its FCOI policy or any related procedures that impact Investigator requirements.
2. A new Investigator joins BlueShield Therapeutics to participate in NIH-funded research (training must be completed before they engage in the research).
3. BlueShield Therapeutics determines that an Investigator is not in compliance with this policy or any management plan implemented under this policy (training must be completed within 30 days as specified by the designated official).

To meet the FCOI training requirements, BlueShield Therapeutics mandates that all Investigators complete the National Institutes of Health's Financial Conflict of Interest tutorial, available at the NIH FCOI Tutorial. Upon completion of the training, all Investigators must print a certification of completion and retain it for audit purposes.

Consequences of Non-Compliance with BlueShield Therapeutics' Conflict of Interest Policy for Public Health Service Funded Awards

In instances where a Financial Conflict of Interest (FCOI) is not identified or managed promptly—such as when an Investigator fails to disclose a significant financial interest, the Institution fails to review or manage such an FCOI, or an Investigator does not comply with

a management plan—BlueShield Therapeutics will take the following actions within 120 days:

1. **Retrospective Review:** Conduct a retrospective review of the Investigator's activities and the PHS/NIH-funded research project to determine if any portion of the NIH-funded research conducted during the period of noncompliance was biased in its design, conduct, or reporting.
2. **Documentation:** Document the retrospective review in accordance with the regulation at 42 CFR 50.605(a)(3)(ii)(B) or as described in NIH's FAQ I.2. at the NIH website.

If bias is found, BlueShield Therapeutics will:

- Notify NIH promptly and submit a mitigation report via the eRA Commons FCOI Module, which will address:
  ✓ The impact of the bias on the research project.
  ✓ The actions BlueShield Therapeutics has taken or will take to eliminate or mitigate the bias's effect.

Following this, BlueShield Therapeutics will submit annual FCOI reports to NIH in compliance with the regulations and the terms of the award agreement. Depending on the nature of the FCOI, BlueShield Therapeutics may determine that additional interim measures are necessary regarding the Investigator's participation in the research project between the date the FCOI is identified and the completion of the retrospective review. If no bias is found, no further action will be required.

Clinical Research Obligations

If the Department of Health and Human Services (HHS) finds that a funded clinical research project aimed at 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 Financial Conflict of Interest (FCOI), BlueShield Therapeutics will require the involved Investigator to disclose the FCOI in every public presentation of the research results and request an addendum to previously published presentations.

Subrecipient Requirements

A subrecipient relationship is formed when federal funds flow from or through BlueShield Therapeutics to another individual or entity responsible for conducting a significant portion of a PHS-funded research project, making them accountable to BlueShield Therapeutics for programmatic outcomes and compliance matters. Subrecipients, including collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, must adhere to BlueShield Therapeutics' terms and conditions. BlueShield

Therapeutics will ensure any subrecipient Investigator complies with federal FCOI regulations (42 CFR Part 50 Subpart F).

BlueShield Therapeutics will incorporate terms into a written agreement with the subrecipient to establish whether BlueShield Therapeutics' FCOI Policy or the subrecipient's institution's policy will apply to the subrecipient Investigator(s). Per the NIH Grants Policy Statement Section 15.2.1, if the subrecipient's FCOI policy applies, the subrecipient institution must certify compliance with federal FCOI regulations. The agreement will specify the timeline for the subrecipient to report identified FCOIs to BlueShield Therapeutics, ensuring timely submission of FCOI reports to PHS/NIH as required (i.e., before the subrecipient's expenditure of funds and within 60 days of FCOI identification during the award period). This may include a reporting requirement for FCOIs to be submitted within 50 or 55 days to allow BlueShield Therapeutics to meet the 60-day reporting deadline. The assigned FCOI Signing Official (SO) at BlueShield Therapeutics will submit the FCOI report to NIH via the eRA Commons FCOI Module.

If the subrecipient cannot certify compliance with the FCOI regulation, the agreement will state that the subrecipient Investigator is subject to BlueShield Therapeutics' FCOI Policy for disclosing SFIs directly related to the subrecipient's work for BlueShield Therapeutics. In such cases, BlueShield Therapeutics will require all Investigator disclosures of SFIs and include sufficient timelines to ensure compliance with review, management, and reporting obligations under the regulation. When an FCOI is identified, BlueShield Therapeutics will develop a management plan, monitor subrecipient Investigator compliance, and submit the necessary FCOI report to NIH through the eRA Commons FCOI Module.

Maintenance of Records

BlueShield Therapeutics will retain all records of Investigator disclosures of financial interests, as well as the Institution's review and response to these disclosures (regardless of whether a disclosure resulted in a determination of a Financial Conflict of Interest). This includes all actions taken under the Institution's policy or during any retrospective review, if applicable. Records of financial disclosures and any related actions will be maintained for a minimum of three years from the date the final expenditures report is submitted. In certain situations, records will be maintained for longer periods as specified in 45 CFR 75.361. BlueShield Therapeutics will ensure records are kept for each competitive segment as required by regulation.

Consequences for Non-Compliance

Adherence to this policy is a condition of employment and participation for all applicable Investigators at BlueShield Therapeutics. Investigators who fail to comply with this policy may face disciplinary actions. These actions can include but are not limited to letters of

reprimand, restrictions on the use of funds, termination of employment, or disqualification from participating in any PHS/NIH-funded research, as deemed appropriate by the Institution.

Updating and Reviewing the Policy

BlueShield Therapeutics will ensure regular updates to maintain compliance with federal regulations and internal best practices. A dedicated compliance officer will conduct annual reviews and immediate updates following regulatory changes or significant feedback. The process will involve evaluating the policy, analyzing compliance data, and benchmarking against industry standards. Draft revisions will be reviewed and approved by senior management. Updates will be communicated to all employees through training sessions and emails. Proper documentation will be maintained, and regular compliance audits will monitor adherence. This proactive approach will ensure the policy's ongoing integrity and effectiveness.