



Financial Conflicts of Interest (FCOI) Policy

PURPOSE

Eclipse Bioinnovations is committed to conducting objective research activities with integrity. The purpose of this policy is to ensure that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest (including Investigators and/or of the Investigator's spouse and/or dependent children). Eclipse Bioinnovations has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest. This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought

SCOPE

Company Wide. The Financial Conflicts of Interest Policy covers all Eclipse Bioinnovations projects funded by the Public Health Service (PHS) or National Institute of Health (NIH) and is applicable to all employees, sub-recipients, consultants, or any other covered organizations or persons involved in governmental awards.

DEFINITIONS

Investigator: Defined as the PD/PI and any other person, regardless of title or position who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding which may include, for example, collaborators or consultants.

Financial Interest: Anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children, regardless of whether the value is readily ascertainable.

Deciding Official: The individual designated by Eclipse Bioinnovations to oversee the financial conflicts of interest process, including solicitation and review of disclosure of significant financial interests.



Financial Conflict of Interest: A Significant Financial Interest (see below) related to a research program or project that could directly and significantly affect the design, conduct or reporting of research.

Significant Financial Interest (SFI): A financial interest consisting of one or more of the following interests of the 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. Regarding 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 includes 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.

For PHS-funded investigators, Significant Financial Interests also include 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 term Significant Financial Interest **does not include** the following types of financial interests:

- a. Salary or consulting fees paid by Eclipse Bioinnovations to the Investigator if the Investigator is currently employed or otherwise appointed by Eclipse Bioinnovations.
- b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.



- c. Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- d. Travel by a PHS-funded Investigator that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Financial Conflicts of Interest (FCOI): A significant financial interest that could directly and significantly affect the design, conduct or reporting of research. Examples include, but are not limited to, the following:

- Investigator (and/or an Investigator's spouse and/or dependent children) entering a paid consultancy with an outside entity that has an interest in the Investigator's (and/or an investigator's spouse and/or dependent children) receiving royalties or non-royalty payments related to ongoing research
- 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

Policy: Each year, any investigator who conducts research on any Eclipse Bioinnovations project must disclose via the electronic system all significant financial interests that are relevant to an investigator's institutional research responsibilities, or within 30 days after he/she becomes aware of new significant financial interests or after a financial conflict of interest has been eliminated.

Investigators are required to complete the annual Significant Financial Interest Disclosure (SFID) Form even if they have no financial interest to report. Transactional disclosure by the PI is also required at the time a research proposal is submitted to Eclipse Bioinnovations grants administrator to ensure compliance with federal disclosure and management requirements.

Procedure:

Investigator Responsibilities

- Disclosing all significant financial interests
- Providing updates to disclosed information as needed
- If acting as the PI/PD, providing a list of individuals who meet the definition of "investigator" within the required disclosure timeline
- Completing all required training and education



- Completing the annual disclosure form even if they have no financial interests to report.
- Ensuring that an updated FCOI in Research Disclosure is on file at the time of Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC) approval for any new research proposals.

Internal Reporting Requirements

- For PHS-funded research, as part of the funding application or proposal and prior to performing any work on the research, each Investigator who is planning to participate in the research is required by regulation to complete a Significant Financial Interest Disclosure (SFID) Form
- SFID Form must be submitted to the Eclipse Bioinnovations grant administrator
- This requirement also applies to Investigators who are or who work for subgrantees, subcontractors, or collaborators on PHS-funded research.
- SFID Forms will be made available, and the Eclipse Bioinnovations grant administrator will review SFID submissions.
- The information reported on SFID Forms includes a list of the Investigator's known significant financial interests and those of his/her immediate family that reasonably appear to be related to the research or that are in entities whose financial interest could be affected by the research.
- Eclipse Bioinnovations Investigators performing non-PHS funded research who have any significant financial interest that may reasonably appear to be affected by the research are also expected to complete the SFID Form and submit it to Eclipse Bioinnovations grant administrator.

Review of FCOIs

- Eclipse Bioinnovations FCOI administrator conducts an initial review of all disclosures.
- If necessary, the FCOI administrator obtains additional information from the investigator and other individuals to help determine whether the SFI disclosed is related to a proposed or existing sponsored project or program.
- The administrator then formally identifies cases that require further review by management.
- Eclipse Bioinnovations Management and the Deciding Official will review the collected information to determine whether a financial conflict of interest exists by considering the following:
 - Impact on integrity of research data
 - Risks to rights and safety of animal and/or human research subjects
 - Risks to the rights of students and trainees participating in research
 - Appearance of conflict of interest
- If a financial conflict of interest is identified, Eclipse Bioinnovations Management and the Deciding Official will determine whether the research can be undertaken.



Management of FCOIs

- For cases that require action, a FCOI management plan will be implemented and monitored on an ongoing basis.
- The management plan will include the appropriate steps to manage, reduce, or eliminate the conflict; the following are examples of conditions or restrictions that may be imposed:
 - Disclosure to research participants or the public of significant financial interests (e.g., when presenting or publishing)
 - Monitoring of research by independent reviewers
 - Modification of research plan
 - Disqualification of staff from participation in all or a portion of the research
 - Severance of relationships that create actual or potential conflicts
- The following are examples of conditions or restrictions that may be imposed:
 - Public disclosure of significant financial interests (e.g., when presenting or publishing the research), if appropriate
 - Disclosure of significant financial interests directly to subjects involved in human research
 - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research
 - Modification of research plans
 - Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research
 - Reduction or elimination of the financial interest (e.g., sale of an equity interest)
 - Severance of relationships that create the actual or potential conflict of interest
 - If it proves impossible to reach an acceptable plan of action, funds will be returned to the sponsor.
- A draft of the FCOI management plan will be provided to the Investigator for review and comment before it is finalized. The Investigator and their immediate supervisor must sign the approved plan to acknowledge their agreement to comply.
- If the Institution identifies an SFI that was not disclosed or reviewed in a timely manner it will initiate the review process and an interim plan of action will be implemented when necessary.

Monitoring

Investigator compliance with plans of action will be monitored by Eclipse Bioinnovations Management and the Deciding Official. The frequency of monitoring will be dictated by sponsor/agency requirements and action plan provisions.



External Reporting Requirements

- Eclipse Bioinnovations will disclose FCOI as required by applicable laws and regulations.
- Prior to expending any funds under a PHS award, Eclipse Bioinnovations will ensure public accessibility by posting FCOI information on a publicly available website.
- Eclipse Bioinnovations will report to the PHS Awarding Component, as detailed in the regulations, the existence of any FCOI that has not been eliminated and will ensure that a FCOI management plan has been implemented.

NIH Reporting

- If Eclipse Bioinnovations is unable to satisfactorily manage a conflict of interest involving NIH funding, it will appropriately notify NIH's Office of the General Counsel.
- Eclipse Bioinnovations will provide to the PHS Awarding Component a FCOI report as outlined in the regulations:
 - Initial Report: Prior to expenditure of any funds under the NIH-funded research project, the Institution will provide a FCOI report regarding any SFI found to be a FCOI. Eclipse Bioinnovations will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Institution identifies a FCOI not previously disclosed. This report will include the following information:
 - Grant/Contract Number
 - PD/PI
 - Name of Investigator with FCOI
 - Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement)
 - Value of the financial interest 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.
 - Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research.
 - Key elements of the FCOI action plan
 - Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:
 - Status of the FCOI
 - Changes to the action plan
 - Justification that an FCOI no longer exists



- If an FCOI is identified after its initial reporting and during ongoing research (e.g., through participation with another investigator) and has not been eliminated, Eclipse Bioinnovations will provide the PHS Awarding Component with an update within 60 days and ensure that it has implemented a plan to manage the conflict.
- If the FCOI report involves a significant financial interest that was not disclosed by an Investigator or not previously reviewed or managed by Eclipse Bioinnovations (e.g., not reviewed or reported by a subrecipient in a timely manner), Eclipse Bioinnovations will undertake a retrospective review to determine whether there was bias in the design, conduct or reporting of the PHS-funded research.

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
- The exception to this is in the case of required public accessibility of identified financial conflicts of interest held by senior/key personnel.

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 appointment 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 Eclipse Bioinnovations.

Appeals

- Investigators may appeal the Deciding Official decisions in writing within 15 days of receipt of the finalized action plan or other decision of the committee.
- The written appeal should include details regarding circumstances which support the request for a proposed revisions to the Deciding Official's decision.
- An Appeals Committee will be formed for the purposes of investigating the appeal and making a final decision.
- A meeting of the Appeals Committee will be convened to review the SFI information, the managements and monitoring plan, and previous meeting minutes, to decide.
- The Investigator may be invited to describe the reasons for the appeal and to address further questions.
- The appeal process will take no more than 60 days from the date requested by the Investigator.
- The decision of the Appeals Committee is final and binding.



Policy Revision

- Eclipse Bioinnovations may modify this policy to conform to organizational changes and circumstances including revisions to federal or state law or regulations. The Deciding Official will have 30 business days to review and comment on any proposed revisions.
- The Executive Committee of Eclipse Bioinnovations is responsible for granting final approval for these policy revisions. It will review all proposed revisions, in collaboration with management, and will consider the committee's feedback during the review process.
- When necessary, procedures will be developed or modified to implement this policy.

Additional Requirements

Public Accessibility

- This policy will be posted on the Eclipse Bioinnovations public website.
- Information concerning identified FCOIs held by senior/key personnel will be made available to requestors via an email response within five business days from when the Research Official receives the request.
- This information may be requested by emailing peter.chu@eclipsebio.com. The written response will include:
 - Senior/key personnel's role in the research project
 - Name of the entity in which the FCOI is held
 - Nature of the FCOI
 - Approximate dollar value of the FCOI or a statement that the value cannot be readily determined
- This information will remain available for three years from the date the information was most recently updated.

Training Requirements

- PHS-funded Investigators must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter.
- Training must 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 a subrecipient and will be working on PHS- funded research
 - An Investigator is found to be noncompliant with this policy or their approved action plan



Investigator/Institutional Non-Compliance

- If an SFI is not disclosed or reviewed in a timely manner, Eclipse Bioinnovations will review the Investigator's financial interest, and determine if it is related to PHS-funded research; determine whether an FCOI exists, and if so:
 - Implement an action plan for ongoing research, at a minimum implement an interim action plan
 - Complete a retrospective review of Investigator's activities and the PHS- funded research project within 120 days of a non-compliance finding to determine if bias was present in the design, conduct, or reporting of such research
 - If bias/non-compliance is found, the Institution will promptly inform the PHS Awarding Component by submitting a mitigation report
- If the retrospective review finds that the Investigator knew or should have known about the FCOI related to his/her institutional responsibilities, but failed to disclose in compliance with this policy, the costs associated with the retrospective review and mitigation report may be pulled from the subrecipient's Indirect Cost Allocation portion.
- If the Department of Health and Human Services determines that a PHS-funded clinical research project 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 a conflicting interest that was not managed or reported to Eclipse Bioinnovations, the Investigator must disclose the FCOI in each public presentation of the results of the research and must request an addendum to previously published presentations.

Responsibilities and Authorities:

- Investigators participating in, or planning to participate in the design, conduct, or reporting of research including Public Health Service (PHS) or National Institute of Health (NIH) funded research at Eclipse Bioinnovations have the authority and responsibility for the activities in this policy.
- Eclipse Bioinnovations will maintain all records related to the implementation of this policy for at least three years after:
 - the date of creation
 - the date of termination or completion of a research award or contract
 - the submission of the final expenditures report
 - the date of final resolution of any investigation, audit, or similar action involving the records