

FINANCIAL CONFLICT OF INTEREST POLICY

PhenoVista Biosciences, LLC

Purpose

These regulations describe the actions an individual/organization must take to promote objectivity in research, sponsored programs, and technology transfer activities at PhenoVista Biosciences, LLC to ensure that the funded activities are free from biases that result from financial conflicts of interest. The regulations apply to all Public Health Service (PHS)-funded grants, cooperative agreements, research contracts, except Phase 1 Small Business Innovation Research or Small Business Technology Transfer program grants (SBIR/STTR), and subawards, where the originating sponsor is an entity of PHS, including the National Institutes of Health (NIH). The regulations require that investigators submitting applications for funding disclose to PhenoVista Biosciences any significant financial interests related to their institutional responsibilities prior to the submission of the application. This policy was developed to comply with federal agency requirements defined in 42 CFR part 50, subpart F, providing the framework to identify, evaluate, and correct/remove real and potential conflicts of interest.

Definitions

- **Financial interest**: Anything of monetary value related to an investigator's institutional responsibilities, whether or not the value is readily ascertainable.
- **Financial conflict of interest (FCOI)**: A significant financial interest that could directly and significantly affect the design, conduct, or reporting of federally funded research.
- **FCOI report**: An institution's report of a financial conflict of interest to a PHS awarding component.
- **Institution**: Any domestic or foreign, public, or private, entity or organization (excluding a federal agency) applying for or receiving PHS research funding.
- **Institutional responsibilities**: An investigator's professional responsibilities on behalf of the institution, including but not limited to activities such as research and research consultation.
- **Investigator**: The project director (PD) or principal investigator (PI) and any other senior or key personnel, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of research funded by the NIH, which may include research assistants, post-doctoral researchers, collaborators, and consultants.
- **Manage**: 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 generalizable knowledge relating broadly to public health; encompasses basic and applied and product development and any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- **Significant financial interest (SFI)**:
 - (i) A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities: (i) 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 disclosure, when aggregated, exceeds \$5,000; (ii) 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 investigator (or the investigator's spouse or dependent children) holds any equity; or (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

- (ii) Investigators must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities; the investigator must disclose the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The appropriate official will determine if further information is needed, including a determination or disclosure of monetary value to determine whether the travel constitutes an FCOI with the PHS-funded research.
- Small Business Innovation Research (SBIR) Program: The extramural research program for small businesses established by the awarding components of certain federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the Small Business Technology Transfer (STTR) Program established by Public Law 102-564.

Policy Scope

This policy applies to all investigators and employees of PhenoVista Biosciences who participate in activities and research supported wholly or partially by PHS funding.

Subrecipients

Subrecipients will also follow PhenoVista's FCOI policy of the awardee institution or the FCOI policy of the subrecipient. In the latter, certification will be obtained from the subrecipient that its FCOI policy complies with the regulation. The FCOI policy to be followed will be confirmed via written agreement. The written agreement will include a requirement for the subrecipient to report identified FCOIs for its investigators in a time frame that allows the awardee institution to report identified FCOIs to the PHS grantee as required by regulation.

Policy

An up-to-date listing of any SFIs as defined above must be disclosed to respective supervisors and the Grants Coordinator at PhenoVista Biosciences no later than the time of application for PHS-funded research and at least annually during the period of the award. Any investigator who during the course of the research project or after submission of an application for funding from PHS acquires or discovers a SFI likewise must promptly disclose any new SFIs and/or provide updates to the disclosed SFIs. Any investigator who plans on participating in such research must disclose SFIs prior to participation in the project. The updates must include updated information regarding any previously disclosed SFIs, such as updated values of a previously disclosed interest. Each investigator participating in research under a PHS-funded project must submit an updated SFI within 30 days of discovering or acquiring a new SFI for review by PhenoVista's Grants Coordinator. These officials will review all SFIs that have been disclosed to determine whether the interest relates to a PHS award and whether it is a FCOI, as defined by this policy. Investigators must complete all required training and complete annual disclosure forms, even if they have no financial interests to report. The PI/PD is responsible for ensuring that annual updates and disclosures of new or increased financial interests are reported.

Guidelines for Determining Relatedness and Financial Conflict of Interest

The Grants Coordinator or CFO of PhenoVista Biosciences will determine whether an investigator's SFI is related to the research under an award from a PHS entity, and, if so, whether the SFI constitutes a FCOI. Before the institution's expenditure of funds, the Grants Coordinator or CFO must review all investigator SFI disclosures, determine if any SFIs relate to PHS-funded research, determine if an FCOI exists, and, if so, develop and implement management plans.

An SFI constitutes an FCOI when it is determined that the SFI could be affected by the research conducted under the PHS award or is an entity whose financial interest could be affected by the research conducted under the PHS award. The investigator may be involved in the determination if the SFI is related to a proposed or existing sponsored project or program.

An FCOI exists when it is determined that the SFI could directly and significantly impact the design, conduct, or reporting of the PHS-funded research. This determination includes:

- Consideration of the role of the investigator and the opportunity to bias research results;
- Whether the research is directed at understanding basic scientific processes, or whether the research results are such that immediate commercialization or clinical application is not likely;
- Whether the goal of the research is to evaluate an invention linked to the SFI, such as where the SFI is a patent or an interest in a company that has licensed the invention;
- Whether the goal of the research involves validating or invalidating a particular approach/methodology that could affect the value of the SFI
- Where the SFI is a privately held company, whether the SFI could result in the investigator having influence over company decisions or a significant impact on the company's business or financial outlook;
- Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the discloser's technology, the amount of commercialization payments received by the investigator from that technology, both currently and in the future;
- The value/magnitude of the SFI compared to the value of the entity;
- Where the SFI is an entity, the nature of the relationship an investigator has with the entity;
- Whether other scientific groups are independently pursuing similar questions;
- Whether sufficient external review of the research and the reporting of the research results exist to mitigate undue bias; and
- Whether the goal of the project is a comparative evaluation of a technology in which the investigator has an SFI.

If a financial conflict of interest is identified, the CFO or Grants Coordinator and corresponding PI/PD will determine whether the research can be undertaken with appropriate management.

Travel Disclosures

PHS-funded Investigators must disclose the occurrence of reimbursable or sponsored travel related to their institutional responsibilities, regardless of the value, within 30 days of the last day of the trip. The travel disclosure must include the purpose of the trip, the identity of the sponsor or organizer, the destination, the length, and the monetary value. Additional information may be requested at the time of review. The disclosure is not required for travel that is reimbursed or sponsored by any government agency, an institution of higher education, a medical center, or a research institute that is affiliated with an institute of higher education. Travel disclosures will be reviewed by the Grants Coordinator or CFO to determine whether the travel involves a FCOI with PHS-funded research or projects.

Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest

If it is determined that an FCOI exists, the Grants Coordinator or CFO and appropriate PI/PD will determine by what means the conflict should be avoided or managed to mitigate undue bias, such as the investigator's recusal from decisions affecting the conflict or monitoring of the activity. A management plan will be implemented within 60 days of when an SFI that was not timely disclosed by an investigator, or not previously reviewed by the institution, is identified. The investigator's role will be evaluated to determine whether it is necessary to continue advancing the research, based on factors such as the uniqueness of his/her expertise and qualifications. Conditions that might be imposed to manage an FCOI include, but are not limited to:

- Public disclosure of FCOI when presenting or publishing the research;
- Appointment of an independent subcommittee to evaluate and impose measures to protect the design, conduct, and reporting of research against bias resulting from the FCOI;
- Modification of the research plan or strategy;
- Change or disqualification of personnel or personnel responsibilities/participation in the research, wholly or partially;
- Reduction or elimination of the FCOI;
- Severance of the relationships that create FCOIs; and
- Written disclosure of the FCOI to all individuals participating in the research project.

The management plan will include:

- The role and principal duties of the conflicted investigator in the project;
- The conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the project;
- Confirmation of the investigator's, relevant PI/PD's, and relevant supervisor's agreement to the management plan; and
- How the management plan will be monitored to ensure compliance.

If an FCOI is determined to exist, the determination and means of managing the FCOI will be communicated in writing to the investigator, the relevant PI/PD, and the relevant supervisor for comment before it is finalized. The investigator, the relevant PI/PD, and relevant supervisor must sign the plan to acknowledge their agreement to comply. A record of the disclosure and any relevant information or updates will be kept for at least three years after the date of creation, the date of termination or completion of the corresponding PHS award, the submission of the final expenditures report, or the date of the final resolution of any investigation involving the records – whichever is later. No expenditures on an award supported by PHS will be permitted until the investigator has complied with the disclosure requirements of this policy and has agreed in writing to comply with any plans directed to managing the FCOI.

Public accessibility to information related to the determined FCOI prior to the expenditure of any funds under a PHS award will be granted by written response to any requestor of disclosed SFIs within five days of receipt of the request. Information that will be in the written response to the requestor will include the investigator's name, title, and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI, or a statement that the SFI is one whose value cannot be readily determined through reference to public prices or other measures of fair market value. The approximate dollar value under \$20,000 must be reported in intervals of \$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. The written response will state that the information is subject to updates on at least an annual basis and within 30 days of the identification of any new FCOI, which should be requested subsequently by the requestor.

Reporting of Financial Conflicts of Interest

Prior to the expenditure of any funds under a PHS award, PhenoVista Biosciences will provide to the PHS grantee a FCOI report compliant with PHS regulations regarding any investigator's SFI found to be conflicting and will ensure that the investigator has agreed to and implemented the corresponding management plan. FCOI reports will be submitted to the PHS grantee within 60 days of identification for an investigator who is newly participating in a PHS-funded project. For new or newly identified FCOIs for existing investigators during an ongoing PHS-funded project, the FCOI report will be submitted within 60 days, including confirmation that the management plan has been implemented and that the investigator has agreed to it. Reports will be submitted at least annually to provide the status of FCOIs and any changes to management plans, if applicable, until completion of the project.

Reports will contain a statement about how the SFI relates to the PHS-funded research and the basis for PhenoVista's determination that the SFI conflicts with such research. PhenoVista will not incur expenditures until it has received notification to do so from the PHS grantee. While the award is ongoing, including any extensions with or without funds, the PHS grantee will be provided an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.

If bias is found with the design, conduct, or reporting of PHS-funded research, the circumstances will be reported to the PHS grantee along with a mitigation report. If an investigator fails to comply with PhenoVista's FCOI policy or a FCOI management plan, resulting in bias of the design, conduct, or reporting of PHS-funded research, the PHS grantee will promptly be notified.

Training Requirements

Each investigator must read and sign PhenoVista Biosciences's Financial Conflict of Interest Policy prior to engaging in research related to any PHS-funded project and at least every 4 years, and immediately when any of the following circumstances apply:

- PhenoVista revises this policy or procedures related to this policy in any manner that affects the requirements of investigators;
- An investigator is new to PhenoVista research under an award issued by PHS. Training is to be completed prior to his/her participation in the research; or
- PhenoVista finds that an investigator is not in compliance with this policy or a management plan issued under this policy. Training is to be completed within 30 days.

In fulfillment of the training requirement, PhenoVista requires its investigators to complete the NIH's Financial Conflict of Interest tutorial located at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> in accordance with the requirements and expectations of this policy. A certification of completion at the end of training must be printed and submitted to the Grants Coordinator.

Consequences for Noncompliance

When a FCOI is not identified or managed in a timely manner, then PhenoVista will within 90 days:

- Complete a retrospective review of the investigator's activities and the research project to determine any bias in the design, conduct or reporting of research;
- Document the retrospective review consistent with the regulation;
- Document PhenoVista's determination as to whether any research, or portion thereof, conducted during the period of time of the investigator's non-compliance with this policy or FCOI management plan, was biased in the design, conduct, or reporting of such research; and
- Notify the PHS Grantee in writing.

If bias is found, PhenoVista will notify the PHS grantee promptly and submit a mitigation report to the PHS grantee that addresses the impact of the bias on the research project and PhenoVista's plan of action taken to eliminate or mitigate the effect of the bias. Thereafter, PhenoVista will submit FCOI reports annually to the PHS grantee, in accordance with the regulation and terms of the award agreement. Depending on the nature of the FCOI, PhenoVista may determine that additional interim measures are necessary with regard to the investigator's participation in the research project between the date that the FCOI is identified and the completion of PhenoVista's independent retrospective review. Non-disclosure of SFI or non-compliance with the FCOI management plan may subject the employee to employment discipline, including suspension or termination of employment. Retrospective reviews will be completed and documented within 120 days of the determination of noncompliance for SFIs not disclosed timely or previously reviewed.