

Virogenomics BioDevelopment, Inc.
Financial Conflict of Interest (FCOI) Policy
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Overview

Virogenomics BioDevelopment (VBD) shares the National Institutes of Health (NIH) commitment to conduct research objectively, without bias, and following the highest scientific and ethical standards. To address the increasing complexities related to financial interests held by biomedical and behavioral researchers, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) has published 42 CFR Part 50 Subpart F, which requires NIH grant recipients, such as VBD, to maintain an up-to-date, written, and enforced FCOI policy that complies with the regulation and to post the policy on the institution's publicly accessible website. [NIH FCOI Regulation](#)

Application

This policy applies to all employees of VBD. This policy also applies to subrecipients, subgrantees and collaborators of VBD who are responsible for the design, conduct, or reporting of research funded by the PHS that do not have their own FCOI policy and are abiding by VBD's conflict of interest policy.

Key Definitions

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to VBD.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Investigator refers to all persons for which this application applies including employees of VBD as well as subrecipients, subgrantees and collaborators of VBD who are responsible for the design, conduct, or reporting of research funded by the PHS that do not have their own FCOI policy and are abiding by VBD's conflict of interest policy.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of VBD, which includes but are not limited to activities such as research, research consultation and business transactions.

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 means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement.

Significant Financial Interest (SFI) means 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:

- (1) 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. 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 interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- (2) 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 interest (e.g., stock, stock option, or other ownership interest); or
- (3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (4) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities. Travel disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration and any other information as requested by the disclosure form or designated official. See exemptions in (6) below.

Exceptions: Significant Financial Interest does not include the following:

- (1) Salary, royalties, or other remuneration paid by VBD to the Investigator if the Investigator is currently employed or otherwise appointed by VBD, including intellectual property rights assigned to VBD and agreements to share in royalties related to such rights;
- (2) Ownership interest in VBD held by the Investigator;
- (3) 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;
- (4) Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;

- (5) Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
- (6) Travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Training Requirements

- (1) Training about VBD's FCOI must be completed by the Investigator:
 - a. Prior to engaging in research related to any PHS-funded grant;
 - b. At least every four (4) years;
 - c. Immediately, if:
 - i. VBD revises its FCOI policy that affects requirements of Investigators;
 - ii. Investigator is new to VBD; or
 - iii. Investigator is not in compliance with the policy.
- (2) Training includes:
 - a. Reading VBD's FCOI policy; and
 - b. Completing NIH's interactive training module. [Training Module](#)

Disclosure Requirements

- (1) Investigators must disclose all SFIs (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to their Institutional responsibilities;
 - a. No later than at the time of application for PHS-funded research;
 - b. At least annually during the period of award; and
 - c. Within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance).

Disclosure Review

- (1) The Designated Official shall solicit disclosures of SFIs from Investigators.
- (2) The VBD Board of Directors (BOD) will review all SFI disclosures to determine whether an Investigator's SFI is related to PHS-funded research, and if so related, whether the SFI is a FICO.
- (3) The VBD Board of Directors will determine whether to impose conditions to manage any FCOIs through the issuance of a management plan.

- a. Any Investigator who receives a management plan under this policy is required to abide by it.

Reporting Requirements to NIH

- (1) If a FCOI is identified, a FCOI report will be initiated through the eRA Commons FCOI module
 - a. Prior to expending any funds;
 - b. Within 60 days of identification for an Investigator who is newly participating in the project;
 - c. At least annually (e.g. same time as when VBD is required to submit the annual progress report, multi-year progress report, or at time of extension) to provide the status of the FCOI and any changes to the management plan until the completion of the project; or
 - d. Following a retrospective review to update a previously submitted report.
- (2) If VBD finds bias in the design, conduct or reporting of Research as a result of a Retrospective Review (see below), VBD shall submit a Mitigation Report to NIH through the eRA Commons FCOI module.
- (3) NIH will be notified if an Investigator fails to comply with VBD's FCOI policy or management plan.

Retrospective Reviews

- (1) VBD will conduct a retrospective review to determine whether any Research was biased in the design, conduct, or reporting of such Research, if:
 - a. If VBD determines that an Investigator is in noncompliance with VBD's FCOI policy, including a failure of the Investigator to disclose a SFI within 30 days of acquiring it or becoming aware of it and which is determined by VBD's BOD to be a FCOI;
 - b. Failure of VBD to review or manage a FCOI in a timely manner; or
 - c. Failure by the Investigator or VBD to comply with a conflict of interest management plan.
- (2) The retrospective review will occur within 120 days of the determination of noncompliance.
- (3) If VBD finds bias in the design, conduct or reporting of Research as a result of a Retrospective Review VBD shall prepare a Mitigation Report that describes the impact of the bias on the research project and VBD's plan of action to eliminate or mitigate the effect of the bias.

Maintenance of Records

- (1) Records of all financial disclosures and all actions taken by VBD will be maintained for at least three years from the date of submission of the final expenditures report.
- (2) Information regarding an Investigator's FCOIs will be made available within five (5) calendar days of a written request.

Enforcement Mechanisms and Remedies and Noncompliance

- (1) Repeated failure by the Investigator to comply with VBD's FCOI policy or management plan will result in the Investigator losing the right to work on the project and to apply for and receive PHS funding while affiliated with VBD.
- (2) If an Investigator's FCOI was not managed or reported by the Institution as required per regulation and the research project involves clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment then the Investigator involved must disclose the FCOI in each public presentation and request an addendum to previously published presentations.

Subrecipient Requirements

- (1) VBD will establish via written agreement whether a subrecipient on grant awarded to VBD will follow VBD's FCOI policy or the FCOI policy of the subrecipient.
- (2) Required in the subrecipient agreement is a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows VBD to report identified FCOIs to NIH as required by the regulation.

For questions concerning VBD's FCOI Policy or to inquire about identified FCOIs held by Investigators affiliated with VBD, contact Renee Shirley, Ph.D. at admin@virogenomics.com