

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 implements the regulatory requirements provided in 42 CFR Part 50 Subpart F for grants and cooperative agreements issued by the NIH. The policy also applies to individuals who meet the regulatory definition of "Investigator" (as defined below) who are planning to participate in, or who participate in NIH-funded research.

Key Definitions

Designated Official (DO) is the individual designated by VBD as an Officer to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests, identification of FCOIs per the regulatory criteria provided in 42 CFR 50.604(f), and monitoring staff FCOI training requirements. Renee Shirley is the designated official in charge.

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

Financial conflict of interest (FCOI) exists when the Institution, through its designated official(s), reasonably determines that an investigator's SFI is related to a NIH-funded research project and could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

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

Investigator refers to the Project Director or Principal Investigator and any other person, regardless of title or position and may be an employee, consultant or collaborator, who is responsible for the design, conduct or reporting of research funded by an award or proposed for funding 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 may include but are not limited to activities such as research, research consultation, fundraising, product or services development, 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 domestic or foreign 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 greater than \$5,000 related to such rights and interests received over the preceding twelve months.
- (4) Investigators also must disclose the occurrence of any reimbursed or sponsored travel that exceeds \$5,000 (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. The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months. 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 located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education;
- (5) Income from service on advisory committees or review panels for 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 that is affiliated with a U.S. Institution of higher education;
- (6) Travel that is reimbursed or sponsored by 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 that is affiliated with a U.S. Institution of higher education;
- (7) **NOTE:** Exclusions above do not apply to Foreign Financial Interests: Investigators must disclose all foreign financial interests (including 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 (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

Training Requirements

- (1) Training about VBD's FCOI must be completed by the Investigator:
 - a. Prior to engaging in research related to any PHS/NIH-funded grant;
 - b. At least every four (4) years;
 - c. Immediately (within 30 days), 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 by the Investigator includes:

- a. Reading VBD's FCOI policy and understanding their responsibility to disclose SFIs and when to disclose per the policy; and
- b. Completing NIH's interactive training module located here: [Training Module](#).
- c. Certificate of Completion of NIH's interactive training module should be sent to admin@virogenomics.com.

Disclosure Requirements

- (1) Investigators must disclose all SFIs (and those of the Investigator's spouse and dependent children) related to their Institutional responsibilities;
 - a. No later than at the time of application for NIH-funded research;
 - b. 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) during the period of award; and
 - c. Within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance). Investigators must also submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.
- (2) Note that the disclosure should include all SFIs related to their Institutional responsibilities, not just those they believe are related to the funded research. Determining whether an SFI is related to the NIH-funded research is the responsibility of the Designated Institutional Official as described below.

Disclosure Review

- (1) The Designated Institutional Official shall solicit disclosures of SFIs from Investigators.
- (2) The Designated Institutional Official initially review disclosures. If anything is disclosed, the VBD Board of Directors (BOD), along with the Designated Institutional Official, 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 FCOI. The "Relatedness Test" will be used to determine whether an Investigator's SFI is related to the research under an NIH award and, if so, whether the SFI is a financial conflict of interest using the following guidelines:
 - a. Relatedness Test: An Investigator's SFI is related to the research when the Designated Institutional Official reasonably determines the SFI:
 - i. Could be affected by the PHS/NIH-funded research; or
 - ii. Is in an entity whose financial interest could be affected by the PHS/NIH-funded research.
 - b. Investigator Involvement: The designated official(s) may involve the Investigator in determining whether an SFI is related to the NIH-funded research.

- c. FCOI Determination: A financial conflict of interest exists when the Designated Institutional Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. 'Significantly' means that the financial interest would have a material effect on the research.

Management of SFIs that pose FCOI

- (1) The VBD Board of Directors, along with the Designated Institutional Official, will determine whether to impose conditions to manage any FCOIs through the issuance of a management plan.
- (2) If determined to be required, the VBD Board of Directors will be responsible for writing and issuing the management plan. Examples of conditions that might be imposed to manage a FCOI include, but are not limited to:
 - a. Public disclosure of FCOI when presenting or publishing the research
 - b. For research projects involving human subjects research, disclosure of FCOIs directly to human participants in the informed consent document;
 - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
 - d. Modification of the research plan;
 - e. Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the research;
- (3) Any Investigator who receives a management plan under this policy is required to abide by it.

Monitoring Investigator Compliance

VBD will monitor Investigator compliance with the management plan for the duration of the PHS/NIH award or until the FCOI no longer exists. Monitoring of public disclosure requirements will include reviewing publications and presentations to confirm that the Investigator disclosed the FCOI in such communications. To facilitate additional monitoring, Investigators will be required to disclose the FCOI in writing to research personnel in the study and send a copy of the communication to the Designated Official which will serve as documentation for compliance with the management plan.

Public Accessibility of the FCOI Policy and FCOI Information Held by Senior/Key Personnel

- (1) VBD will ensure public accessibility of its policy by posting the FCOI policy on its publicly accessible website, and in compliance with the NIH requirements in the NIH Grants Policy Statement.

- (2) Prior to the expenditure of any funds under an NIH award, VBD will ensure public accessibility by providing a written response to any requestor within five business days of a request for information concerning any SFI disclosed that meets the following three criteria:
 - a. The SFI was disclosed and is still held by the senior/key personnel;
 - b. VBD has determined that the SFI is related to the research funded through an award; and
 - c. VBD has determined that the SFI is a financial conflict of interest.
- (3) The information made available via the public website or in a written response will include, at a minimum:
 - a. The Investigator's name;
 - b. The Investigator's title and role with respect to the research project;
 - c. The name of the entity in which the Significant Financial Interest is held;
 - d. The nature of the Significant Financial Interest; and
 - e. 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 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000, 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.

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 the VBD uses a publicly accessible website to meet this requirement, the information posted will be updated at least annually and within 60 days of receiving or identifying an additional SFI of Senior/Key personnel related to the PHS/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 Designated Institutional official to be related to the research and an FCOI.

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

Reporting Requirements to NIH

- (1) If a FCOI is identified, a FCOI report will be initiated through the eRA Commons FCOI module by the FCOI Signing Official (SO). The SO for VBD is Renee Shirley.
 - 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 because 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 whenever a FCOI is not identified or managed in a timely manner including:
- a. Failure by an Investigator to disclose a SFI that is determined by the Institution to constitute a FCOI;
 - b. Failure by the Institution to review or manage a FCOI;
 - c. Failure by the Investigator to comply with a FCOI management plan.
- (2) The retrospective review shall be conducted within 120 days of the Institution's determination of noncompliance to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.
- (3) Documenting the retrospective review must include the following key elements:
- a. Project number;
 - b. Project title;
 - c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - d. Name of the Investigator with the FCOI;
 - e. Name of the entity with which the Investigator has a FCOI;
 - f. Reason for the retrospective review;
 - g. Detailed methodology used for the retrospective review including methodology of the review process, composition of the review panel, documents reviewed, etc.);
 - h. Findings of the review; and
 - i. Conclusions of the review.

- (4) If VBD finds bias in the design, conduct or reporting of Research because 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) The Institution will maintain all records of all Investigator financial interest disclosures and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a FCOI), and all actions under the Institution's policy or retrospective review, if applicable, for at least three (3) years from the date the final expenditures report is submitted to the PHS/NIH or, where applicable, from other dates specified in [2 CFR 200.334](#) for different situations. The Institution will retain records for each competitive segment as provided in the regulation and this Policy.
- (3) Copies of Investigator management plans will be retained as part of the Institution's records and not submitted to the NIH per NIH's guidance. In addition, the PHS/NIH Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of an FCOI. The Institution will submit, or permit on site review of, all records pertinent to compliance with the regulation and this policy. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS/NIH Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS/NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the FCOI in accordance with the regulation or this policy. The PHS/NIH Awarding Component may determine that imposition of specific award conditions under [2 CFR 200.208](#), or suspension of funding or other enforcement action under [2 CFR 200.339](#) is necessary until the matter is resolved.

Enforcement Mechanisms and Remedies and Noncompliance

Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Investigators who fail to comply with this policy are subject to discipline, including letters of reprimand, restriction on the use of funds, termination of employment, or disqualification from further participation in any PHS/NIH-funded research, as deemed appropriate.

Clinical Research Requirements

If the Department of Health and Human Services determines that one of its funded clinical research projects, 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 FCOI that was not managed or reported by VBD, VBD shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Subrecipient Requirements

A subrecipient relationship is established when federal funds flow down from or through VBD to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to VBD for programmatic outcomes and compliance matters. Subrecipients, including but not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, are subject to VBD's terms and conditions.

- (1) VBD will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation at 42 CFR Part 50 Subpart F.
- (2) VBD will incorporate, as part of a written agreement with the subrecipient, terms that establish VBD's FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator(s).
 - a. If the subrecipient's FCOI policy applies: The subrecipient institution will certify as part of the agreement with VBD that its policy is in compliance with the federal FCOI regulation. 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. The VBD assigned FCOI SO will submit the FCOI report (subrecipient report) to the NIH via the eRA Commons FCOI Module.
 - b. If the subrecipient cannot provide certification: The agreement shall state that the subrecipient Investigator is subject to VBD's FCOI Policy for disclosing SFI(s) that are directly related to the subrecipient's work for VBD. VBD will require the submission of all Investigator disclosures of SFIs to VBD. The agreement will include sufficient time period(s) to enable VBD to comply timely with its review, management, and reporting obligations under the regulation. When an FCOI is identified, VBD will develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit an FCOI report (subrecipient report) to the NIH through the eRA Commons FCOI Module.

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