

**Financial Conflict of Interest (FCOI) Policy
for BIO Ventures for Global Health Investigators on Federal Grants**

Updated June 2021

This BIO Ventures for Global Health (BVGH) policy supports and describes required reporting for investigators of any financial conflicts of interest (FCOI) and ensures compliance with the FCOI policy of federal agencies, including the National Institutes of Health (NIH)¹.

A Financial Conflict of Interest (FCOI) means a circumstance in which an investigator's outside financial interest or obligation may have the potential to bias research or negatively impact the research.

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

The management of BVGH provides support and oversight for the process of disclosing significant financial interests, including the review of potential conflicts and management of identified conflicts. The policy applies to each investigator who is planning to participate in or is participating in federally-funded research. Each investigator is required to:

- 1) understand and comply with this policy;
- 2) complete FCOI training; and
- 3) submit all known Significant Financial Interests (SFIs), as well as those of their spouse and dependent children, that reasonably appear to be related to the investigator's institutional responsibilities, via BVGH's FCOI report form.

Investigator means the principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by federal agencies.

Significant financial interests (SFIs) means any and all significant financial interests, both foreign and domestic, that reasonably appear to be related to the investigator's institutional responsibilities. SFIs must be reported no later than at the time of application for federally funded research², within thirty days of discovering or acquiring – through marriage, inheritance, or purchase, for example – a new SFI, and/or annually during the period of the award.

This policy also details BVGH's administrative process to identify and manage FCOI; outlines how BVGH provides initial and ongoing FCOI reports, as warranted; and herein informs investigators of BVGH's commitment to make FCOI information related to NIH grants (including institutional reviews and determinations) available to HHS, promptly, upon request.

¹ NIH requires recipients and investigators (except Phase I SBIR/STTR applicants and recipients) to comply with the requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." See NIH GPS Section 4.1.10 Financial Conflict of Interest). See also National Science Foundation: Conflict of Interest Policies in PAPPG 20-1 Chapter IX-Grantee Standards.

² As long as an up-to-date disclosure is on file each time applicants apply, they do not have to submit a new disclosure for each application submission.

BVGH's FCOI policy requires each investigator to complete FCOI training prior to engaging in research related to any federally funded grant and at least every four years afterwards, whenever an FCOI policy revision requires additional training, whenever an investigator is new to BVGH, and/or whenever an investigator is not in compliance with the policy or management plan. In order to comply with NIH's training requirements, which include training on the regulation itself, BVGH requires any investigators involved in applying for NIH funding or conducting research funded by the NIH to also complete NIH's Office of Extramural Research's full FCOI course. Certificates of completion for the NIH course must be printed and submitted to jdent@BVGH.org prior to engaging in NIH-funded research.

In addition to all SFIs, BVGH also requires investigators to self-report on the form information regarding any "other support" from **both** domestic and foreign entities.

Other support means any and all resources and affiliations made available to an investigator in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at BVGH. This includes, but is not limited to:

- in-kind resources;
- financial support through grants, contracts, and other awards;
- positions and scientific appointments;
- selection to "talents" or similar-type programs; and
- "gifts" where items or funds are received with conditions attached or deliverables expected in return.

Foreign entities include governments, universities, and all companies that are non-U.S. based. As part of BVGH's FCOI training, all investigators must respond to questions about other support at the time of application, every four years during an award, and any time "other support" is acquired.

BVGH management reviews investigators' other support prior to submission to NIH to identify whether it may cause scientific, budgetary, or commitment overlap to investigators' research. Investigators may be asked to provide follow-up information about "other support," depending on the nature of the disclosure, and/or may be asked to provide BVGH with copies of contracts and agreements with outside entities.

Subrecipient Compliance

Subrecipients on federally-funded awards must certify in subaward agreements that their institutional policy complies with FCOI regulations. If the subrecipient cannot provide that certification, the subrecipient investigators are subject to BVGH's FCOI policy.

Institutional Process Related to Submitting FCOI Reports to NIH

If investigators disclose NIH-funded research-related SFIs, BVGH's President and CEO determines whether the SFI is an FCOI and takes necessary actions to manage FCOIs pursuant to the Code of Federal Regulations.

An SFI is related to NIH-funded research when BVGH reasonably determines that the SFI could be affected by the NIH-funded research and/or the SFI is in an entity whose financial interests could be affected by the research. BVGH may involve the investigator in the determination of whether an SFI is related to the NIH-funded research. *An FCOI exists when BVGH, through its process, reasonably*

determines that an SFI could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

As needed, and after the review of an SFI disclosure and determination of whether it is related to the research, the implementation of a management plan is undertaken, as warranted, by the President and CEO, who then provides initial and annual FCOI reports to the NIH through eRA Commons.

BVGH also makes information concerning identified FCOIs held by senior/key personnel publicly accessible for a period of three years, and maintains required records for a minimum of three years from the date the final expenditures report is submitted to the NIH. Upon request, BVGH agrees to make information promptly available to the NIH relating to any disclosure of FCOI and the institutional review of and response to such disclosure, whether or not it resulted in the determination of an FCOI.

Enforcement Mechanisms

In the event that investigators do not comply with the requirements of this policy and process, including failing to disclose SFIs or failing to comply with necessary management plans related to identified FCOIs, BVGH may implement sanctions or other administrative actions, where appropriate, such as requiring additional training or formally counseling investigators regarding the breach of policies, and may be required to take action up to and including suspending the investigator from participating in the research project, reporting the incident to NIH or another federal agency, and/or prohibiting the submission of future applications.

Other Elements of This FCOI Policy

Additional information about SFIs

A significant financial interest consists of interests that reasonably appear to be related to the investigator's institutional responsibilities with regard to:

- any publicly traded entity, an SFI exists if the remuneration received in the 12 months preceding the disclosure, and the value of any equity interest as of the date of disclosure, exceeds \$5,000. "Remuneration" includes (i) salary, and any payments for services such as consulting fees or honoraria, paid authorship, reimbursed or sponsored travel and (ii) equity interest includes any stock, stock option, or other ownership interest.
- any non-publicly traded entity, an SFI exists if the value of any remuneration received in the 12 months preceding the disclosure, and the value of any equity interest as of the date of disclosure, exceeds \$5,000, or when the investigator holds any equity interest.
- intellectual property rights and interests such as patents or copyrights, upon receipt of income related to such rights and interests.

An investigator must also disclose the occurrence of any **reimbursed or sponsored travel** (i.e., that which is paid on behalf of and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by certain *excluded sources* provided in regulation as follows:

- salary, royalties, or other remuneration paid by the institution to the investigator if the investigator is currently employed or appointed by the institution;
- intellectual property rights assigned to the institution and agreements to share in royalties related to such rights;

- income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a U.S.-based governmental agency, an institution of higher education (IHE), or a research institute affiliated with an IHE

Note that owning stock in a company does not by itself qualify as a significant financial interest, unless investigators receive more than \$5,000 in payments from that company or the company is not publicly traded. Income from investment vehicles, such as mutual funds and retirement accounts, is excluded as long as investigators do not directly control the investment decisions made in these vehicles.

Disclosure Process

The disclosure process is initiated by completing the FCOI Report Form, provided by the BVGH management, when applying for federal funding, annually during the project period, and/or within 30 days of any new SFI being acquired.

In line with federal regulations, BVGH management is responsible for the following institutional responsibilities related to FCOI:

- Providing public accessibility to BVGH's FCOI Policy.
- Informing investigators of regulation, institutional policy, SFI disclosure responsibility, and training requirements. BVGH management obtains and files signed FCOI forms upon proposal submission to NIH, NSF, and other federal agencies and emails annual reminders for investigators to update their FCOI status.
- Providing investigators with access to required FCOI training prior to engaging in research and at least every four years, and immediately when FCOI policies significantly change or when an investigator is new to BVGH or is found to be noncompliant. BVGH management tracks and verifies FCOI training of investigators.
- Incorporating language as part of subrecipient agreement contracts that establish FCOI policy (include terms that establish whether the FCOI policy of the awardee institution or that of the subrecipient will apply to the subrecipient investigators, and includes time periods to meet SFI disclosure, if applicable, and FCOI reporting requirements).
- Serving as the responsible office, with the institutional official being the President and CEO, to (a) solicit and review disclosure statements from each investigator planning to participate in federally funded research at time of application and annually, (b) oversee guidelines to identify conflicting interests, (c) develop and maintain management plans that specify the actions that have been, and shall be, taken to manage FCOI.
- Providing disclosure of FCOI to NIH, when FCOI is identified: prior to expenditure of funds, annually during the period of the award (at time of annual progress report or extension ask, via eRA Commons FCOI Module), and within 60 days of discovering or acquiring a new SFI.
- Maintaining records of all investigator disclosures of financial interests and of the institution's review of and response to such disclosures, for at least three years from submission of final expenditures report; providing initial and ongoing reports per NIH specifications through the eRA commons FCOI Module; and making information available upon federal agency request.
- Responding, within 120 days of determination, to noncompliance by completing and documenting a retrospective review of the investigator's activities and NIH-funded research project to determine if there was bias in design, conduct, or reporting.
- Addressing all required particulars if/when a management plan for FCOI Reporting is needed, including the role and principal duties of the conflicted investigator in the research project; the

conditions of the plan; how the management plan design will safeguard objectivity in the research project; confirmation of the investigator's agreement to the plan; and how the plan will be monitored to ensure investigator compliance.

Questions about the policy or form, or requests for additional information, should be directed to Jennifer Dent, President and CEO, at BVGH.