



FINANCIAL CONFLICT OF INTEREST POLICY

Financial Conflict of Interest Institutional Official: Anne Richie, Vice-President of Finance and Administration

Last Revision: 6/22/21

Purpose

To assure professional and commercial integrity in all matters, BioInVision maintains this policy that identifies and addresses financial conflicts of interest (“FCOI”). This policy applies to professional staff, employee or trainees participating in research and includes the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research performed by BioInVision, which may include outside collaborators and/or consultants.

Policy Statement

If an Investigator has a Significant Financial Interest (“SFI”) and that SFI is considered to be a conflict of interest (or a Public Health Service (“PHS”) Reportable Financial Conflict of Interest), the Investigator must obtain approval from the Institutional Officer to participate in the research.

Definitions

Institution: BioInVision, Inc.

Investigator: Any employee or trainee participating in research and includes the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research performed under the auspices of BioInVision, which may include non-BioInVision collaborators with, or non-BioInVision consultants to employees or trainees.

Institutional Official (“IO”): Named individual responsible for administering the FCOI policy

Conflict of Interest (“COI”): An interest—whether investment, compensation, or otherwise—in (including relationships with) a non-BioInVision entity that could be reasonably perceived as influencing his or her activities in working for BioInVision

Significant Financial Interest (“SFI”): A financial interest consisting of one or more 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, as further outlined below

Financial Conflict of Interest (“FCOI”): A financial interest or outside activity of an Investigator that could directly or significantly influence the Investigator’s performance of their institutional responsibilities

Fiduciary Service: An appointment as an officer, chief medical officer, director, trustee, partner, or governing board member, whether compensated or not (Fiduciary service as an officer or member of an external board of directors requires pre-approval of BioInVision)

Policy Implementation

An SFI in a non-BioInVision entity is one or more of the following financial interests of an Investigator (or immediate family member or entity controlled by an Investigator):

- Honoraria or consulting compensation exceeding \$5,000 in the previous 12 months, from a single non-BioInVision entity, including speaking, advising, other fees for services, paid authorship and other remuneration, whether cash or non-cash,
- Equity including stock, stock options, or other ownership interests of any amount,
- Royalty payments or the written contractual right to future royalties or other income related to intellectual property rights and interests, including licensing and option agreement fees,
- Payments not described in the research contract

The term SFI **does not** include income from seminars, lectures, teaching engagements or service on advisory committees or review panels sponsored by United States government agencies (for example, NIH Study Sections), United States institutions



of higher education as defined at 20 U.S.C. 1001(a), academic teaching hospitals, medical centers or research institutes that are affiliated with an institution of higher education. Income from these sources does not need to be disclosed to the IO. This exclusion does not apply to relationships with foreign governments or foreign institutions of higher education, academic teaching hospitals, medical centers or research institutes affiliated with an institution of higher education.

An FCOI exists when the Investigator has a SFI in the commercial sponsor of the research or any other financially interested company. (This includes the manufacturer of products under investigation or in use in the study); or the Investigator has a SFI that could be affected by the research.

A PHS-Reportable FCOI exists if the IO finds that the SFI could directly and significantly affect the design, conduct, or reporting of the research. Note that while the following situations could create a COI, they do not create a PHS-Reportable Financial Conflict of Interest:

- Royalties to be paid by BioInVision to the Investigator if the Investigator is employed by BioInVision
- Fiduciary Service
- Payments Not Described in the Research Contract
- For a publicly traded entity, if the sum of compensation received in the previous 12 months and the current value of any equity interest in the entity, as of the date of the disclosure, does not exceed \$5,000

When either a COI or a PHS-Reportable Financial COI exists, the Investigator's participation or continued participation in the research must be approved by the designated IO. Approval may be granted only if the FCOI Policy determines that a conflict management plan (or a PHS-Reportable Conflict Management Plan) will, to the extent possible, ensure that the design, conduct or reporting of the research will be free from bias that may result from the COI (or PHS- Reportable Conflict of Interest). The Investigator would be allowed to participate in the research only pursuant to a conflict management plan or a PHS-Reportable Conflict Management Plan, subject to modification by BioInVision's IO. The IO will monitor compliance with such Conflict Management Plans or PHS-Reportable Conflict Management Plans.

For Human Subjects Research, in addition to the approval and management requirements above, the FCOI program must find compelling circumstances to justify the Investigator's participation in the research when the COI or PHS-Reportable FCOI results from certain types of SFIs. Those SFIs are: equity, royalties, payments not described in the research contract, Fiduciary Service, or honoraria and consulting compensation exceeding \$30,000 in the previous 12 months from a single non-BioInVision Entity. Compelling circumstances are those facts that convince the IO that the Investigator may participate in the research despite the COI or PHS- Reportable Financial Conflict of Interest.

Training

Pursuant to federal conflict of interest regulations, the IO will provide FCOI training to Investigators on PHS- funded research projects. Investigators on PHS-funded research projects will undergo training prior to engaging in research and at least every four years thereafter, and immediately (at the next available training session) whenever (1) there are revisions to this policy, (2) the Investigator is new or 3) the Investigator is found to be not in compliance with this policy, a conflict management plan or PHS-Reportable Conflict Management Plan. FCOI training will be provided to other Investigators as deemed appropriate by the IO.

Disclosure, Review and Monitoring

Investigators participating in research must submit disclosures of all financial interests (whether SFI or not) in non-BioInVision entities annually and also within 30 days of a material change in any SFI. The initial disclosure must occur prior to participating in research. The IO will review all disclosures and, in consultation with the discloser, determine whether any of the financial interests that are SFIs constitute a Conflict of Interest.

Investigators are required to complete meeting attendance forms when traveling related to their BioInVision job responsibilities and the travel is reimbursed or sponsored by non-BioInVision entities, regardless of whether the Investigator



is using vacation or other personal time. These forms must specify the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. For PHS Investigators, travel sponsored or reimbursed by a non-BioInVision entity is considered an SFI.

Reporting

BioInVision will comply with federal regulations regarding reporting of FCOI's, e.g., by submitting FCOI reports to any awarding component, as required and with FCOI regulations regarding making publicly available information on identified FCOI's held by Investigators and key personnel.

Maintenance of Records

BioInVision will maintain all FCOI-related records relating to all Investigator disclosures of financial interests 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 or, where applicable, from other dates specified in 45 CFR 75.361 for different situations

Enforcement Mechanisms and Remedies

Whenever BioInVision's IO becomes aware of a FCOI or PHS- Reportable Financial Conflict of Interest that was not timely disclosed or was not timely identified while research is ongoing, the Investigator would be allowed to participate in the research only pursuant to a PHS-Reportable Conflict Management Plan. In the cases of such noncompliance involving PHS-funded research, the IO will have a PHS-Reportable Conflict Management Plan in place within 60 days of the disclosure or review of the SFI. In addition, within 120 days of the finding of such noncompliance, or a finding of noncompliance with a PHS-Reportable Conflict Management Plan, the Program will complete and document a retrospective review of the Investigator's activities and the PHS- funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research. If bias is found, the IO will provide the required notification and mitigation report to the PHS Awarding entity. In the cases of such noncompliance involving non-PHS-funded research, the parameters of the retrospective reviews will be determined on a case-by-case basis at the discretion of the IO.

Subrecipient Requirements

A subrecipient will follow the FCOI policy of the Institution of the subrecipient. BioInVision, Inc. will obtain a certification from the subrecipient that its FCOI policy complies with the regulation.

Public Accessibility

For PHS-funded research, the FCOI policy will be made available via a publicly accessible website or written policy will be provided within five business days of request. This information will be updated at least annually, and each time senior/key personnel disclose a relevant change. The information concerning the PHS-Reportable FCOI on this publicly accessible website or in response to written requests will remain available for at least three years from the date that the information was most recently updated.

Oversight and Responsibility

BioInVision's IO is responsible to review, revise, update, and operationalize this policy to maintain compliance with regulatory or other requirements. Principal Investigators share responsibility with the Program for ensuring compliance with this policy on their projects.

Any questions or comments related to this policy should be addressed to the Institutional Official.