

GenetiVision Corporation

Financial Conflict of Interest (FCOI) Policy

July 25, 2022

Introduction

This Financial Conflict of Interest Policy (this “**Policy**”) describes certain legal obligations applicable to Investigators’ disclosure of potential financial conflicts of interest (“**FCOI**”). The purpose of this policy is to comply with applicable law and to ensure the objectivity of the research conducted by *GenetiVision Corporation* (“**GV**”), its employees, contractors, and consultants.

Investigators applying for and working on Public Health Services (“**PHS**”), National Institutes of Health (“**NIH**”), or National Science Foundation (“**NSF**”) funded research must disclose significant financial interests that are related to the Investigator’s institutional responsibilities. Investigators are **all** persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research proposed for funding by the PHS, NIH, or NSF (the foregoing agencies, together with any other organizations providing funding through grant or contract to which the regulations contemplated herein apply, collectively, the “**Funding Agencies**”), including collaborators or consultants. This policy provides the framework to identify, evaluate and correct or remove real, apparent and potential conflicts of interest.

This policy requires that each investigator, subrecipient, subgrantee and collaborator affiliated with **GV** on a Funding Agency project be in compliance with 42 CFR Part 50, Subpart F for grants and cooperative agreements (and 45 CFR Part 94 for contracts). In addition, this legislation spells out NIH’s commitment to preserving the public’s trust that the research supported by them is conducted without bias and with the highest scientific and ethical standards. **GV** intends to use this same FCOI standard for all other Federal agency grant and contract efforts, as tailored or amended accordingly.

With respect to subrecipients, **GV** shall establish, via a written agreement, whether a subrecipient will follow the FCOI policy of **GV** or the FCOI policy of the subrecipient. If applicable, **GV** shall obtain a certification from a subrecipient that its FCOI policy complies with the applicable regulation. If applicable, **GV** shall include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows **GV** to report identified FCOIs to the applicable Funding Agencies as required by the regulation. Alternatively, if applicable, **GV** shall include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable **GV** to identify, manage and report identified FCOIs to the Funding Agency.

Definitions

The following definitions apply to this policy:

“**Funded Research**” means any research funded by a Funding Agency.

“**Investigator**” means any person (including subrecipients, subgrantees and collaborators) who is responsible for the design, conduct or reporting of research funded by a Funding Agency.

“**Training Requirement**” means training related to Financial Conflict of Interest (FCOI) and required under law. All **GV** Investigators are required to complete the Training Requirement. If any conflicts of interest are found or known, they must be disclosed. The training must be updated no less frequently than every four years or as designated based on grant or role circumstances. Information and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site: (grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html).

“Significant financial interest” means a financial interest consisting of one or more of the following interests of the investigator (including those of the investigator’s spouse and dependent children) that reasonable 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 the 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 in stock, stock options or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value;
2. With regard to any privately held entity, a significant financial interest exists if the value of any remunerations 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 interests (e.g. stock, stock options, 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.

With respect to Significant Financial Interest, Investigators also must disclose (and such disclosure shall constitute an SFI Disclosure, defined below) 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; provided, however, that this disclosure requirement does not apply to 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, medical center, or research institute that is affiliated with an institution of higher education. This disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Upon receipt of this disclosure, the Policy Coordinator will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the Funding Agency research.

The term Significant Financial Interest does not include the following types of financial interests: salaries, royalties or other remuneration paid by **GV** to the Investigator if the Investigator is currently employed or otherwise appointed by **GV**, including intellectual property rights assigned to **GV** and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the investigator; income from investment vehicles, such as mutual funds and retirements accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; 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, research institute that is affiliated with an institution of higher education; or 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.

A **“Financial Conflict of Interest”** or **“FCOI”** exists when **GV** reasonably determines that a significant financial interest could directly and significantly affect the design, conduct or reporting of Funded Research.

An **“SFI Disclosure”** is a report that each Investigator shall submit: (a) annually to the Policy Coordinator; (b) in the event of certain sponsored travel, as set forth in the definition of “significant financial interest,” above; (c) within thirty (30) days of an Investigator discovering or acquiring any significant financial interest; and (d) no later than at the time of application for PHS-funded research.

“Management” of an FCOI means taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of Funded Research will be free from bias.

An “**Awarding Component**” is the applicable sub-agency of a Funding Agency.

Disclosures/Reporting/Determination Process

Each Investigator shall submit SFI Disclosures (using the **GV** SFI Disclosure Form) to the Policy Coordinator as follows:

1. An updated general SFI Disclosure **annually**;
2. **Promptly** in the event of certain sponsored travel, as set forth in the definition of “significant financial interest,” above;
3. **Within thirty (30) days** of an Investigator discovering or acquiring any significant financial interest; and
4. No later than at the time of application for PHS-funded research.

Additionally, the Policy Coordinator shall solicit SFI Disclosures from each investigator, if applicable, during a reasonable period of time preceding the commencement of any research conducted hereunder.

Prior to the expenditure of funds, the Policy Coordinator, in consultation with **GV's** counsel, will review each SFI Disclosure and determine if any SFIs relate to funded research, determine if an FCOI exists, and develop and implement management plans as needed to manage FCOIs.

In determining whether an Investigator's SFI is related to funded research, and if so related, whether the SFI is an FCOI, the Policy Coordinator shall consider all available evidence in light of the following concepts, in addition to any other concepts the Policy Coordinator may reasonably consider:

Protected Interests

- Research integrity
- Safety of human subjects
- **GV's** reputation
- The Investigator's reputation

Relationship between the SFI and the Research

- Is the subject of the SFI or its products or services involved in the research, and how?
- Is the SFI in a diversified enterprise generally, or in a specific division or subsidiary more closely related to the research?

Nature of the SFI

- Equity, cash compensation, or in-kind compensation?
- Part of a diversified portfolio or a specific investment?
- Publicly-traded or private company?
- Does compensation exceed fair market value?

Likelihood of influence

- Role of the Investigator in the research

- Potential gain to Investigator if research yields particular results
- Safeguards built into design

If no FCOI is found, the SFI Disclosure will be filed with the Policy Coordinator's SFI Disclosure records. If a FCOI is identified it will be put on the FCOI report through the eRA Commons FCOI module (or, where **GV** is a subgrantee or subawardee, then **GV** will report the FCOI as required under the applicable subgrant or subaward agreement) prior to expending any Funding Agency funds. **GV** will then report any new FCOIs to the Awarding Component within 60 days. If an Investigator with an FCOI conducts a Funded Research, **GV** shall disclose the FCOI in each public presentation related to the results of the Funded Research.

GV shall make available information concerning identified FCOIs held by senior/key personnel publicly accessible prior to the expenditure of funds. The information will include the minimum elements as provided in the regulation, be posted on a public website or made available within five calendar days of a written request, be updated at least annually, be updated within 60 days of a newly identified FCOI, and remain available for three years from the date the information was most recently updated.

Records Management

GV will maintain records of all SFI disclosures, and records of resulting **GV** action, for at least three years from the date of submission of the final expenditures report for the applicable funding, or for such other periods of time as may be required under 45 CFR 75.361, if applicable.

Funded Research Exclusions

Funded Research is any project governed by Funding Agency regulations, but excluding applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Compliance and Penalties for Non-Performance

If an investigator fails to comply with the **GV** FCOI policy, within 120 days, **GV** shall complete a retrospective review of the Investigator's activities to determine bias. If as a result of that determination, or at any other time, any bias is found, **GV** shall submit a mitigation report to the applicable Funding Agency, in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias. **GV** will work with the Investigator to set up an FCOI management plan to mitigate the situation. Companywide, **GV** is required to mandate the Investigator disclose the FCOI in each public presentation with research results, and to request an addendum disclosing the FCOI in previously published presentations, if it was not reported up front. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future NIH funding.

Policy Coordinator

If you have a conflict of interest or if you have a question to discuss, contact the **GV** FCOI Policy Coordinator, Graeme Mardon, by email gmardon@genetivision.com