

vivoVerse, Inc. Policy	Reviewed by/Date: TPV/2022-11-18
SOP Number: VVS-PL-016-02 Financial Conflict of Interest	Reviewed by/Date: GL/2023-03-29
Effective Date: 2023-04-03 Previous Review Date: 2021-11-01 Next Review Date: 2025-01-01	Approved by/Date: Adela Ben-Yakar *Dated digital signature appears only on pg. 1 of PDF version



PURPOSE

This policy documents vivoVerse’s compliance with the NIH Grant Policy on Financial Conflict of Interest.

RESPONSIBILITY

It is the responsibility of vivoVerse Management to implement this policy.

It is the responsibility of all vivoVerse Employees to adhere to this policy.

ACRONYMS USED

- CFR – Code of Federal Regulations
- FCOI – Financial Conflict of Interest
- NIH – National Institutes of Health
- NSF – National Science Foundation
- PHS – Public Health Services
- SBIR – Small Business Innovation Research
- SFI – Significant Financial Interest
- STTR – Small Business Technology Transfer

1. PURPOSE OF THIS POLICY

- 1.1. 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 vivoVerse, LLC (“vivoVerse”), its employees, contractors, and consultants.
- 1.2. 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

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collaborators or consultants. This policy provides the framework to identify, evaluate and correct or remove real, apparent and potential conflicts of interest.

1.3. This policy requires that each Investigator, subrecipient, subgrantee and collaborator affiliated with vivoVerse 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. vivoVerse intends to use this same FCOI standard for all other Federal agency grant and contract efforts, as tailored or amended accordingly.

2. DEFINITIONS

The following definitions apply to this policy:

- 2.1 An “Awarding Component” is the applicable sub-agency of a Funding Agency.
- 2.2 A “Financial Conflict of Interest” or “FCOI” exists when vivoVerse reasonably determines that a significant financial interest could directly and significantly affect the design, conduct or reporting of Funded Research.
- 2.3 “Funded Research” means any research funded by a Funding Agency.
- 2.4 “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.
- 2.5 “Management” of an FCOI means taking action to address an 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.
- 2.6 “Significant Financial Interest” (SFI) means a financial interest consisting of one or more of the interests listed in Section 1-4 below 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.
- 2.7 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 “SFI” above; and (c) within thirty (30) days of an Investigator discovering or acquiring any SFI.

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2.8 “Training Requirement” means training related to Financial Conflict of Interest (FCOI) and required under law. All vivoVerse Investigators and all defined sub-level vendors 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: [https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html).

### 3 What *Is* An SFI And What Is *Not*

3.1 With regard to any publicly-traded entity, an SFI 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;

3.2 With regard to any privately held entity, a SFI 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

3.3 Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

3.4 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

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research.

3.5 The term SFI does not include the following types of financial interests: salaries, royalties, or other remuneration paid by vivoVerse to the Investigator if the Investigator is currently employed or otherwise appointed by vivoVerse, including intellectual property rights assigned to vivoVerse 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.

#### 4 Disclosures/Reporting Process

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

- 4.1.1 annually on or before the anniversary date of their initial disclosure;
- 4.1.2 promptly in the event of certain sponsored travel, as set forth in the definition of “SFI,” above; and
- 4.1.3 within thirty (30) days of an Investigator discovering or acquiring any SFI.

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

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5 Records Management

5.1 vivoVerse will maintain records of all SFI disclosures, and records of resulting vivoVerse action, for at least three years from the date of submission of the final expenditures report for the applicable funding.

6 Funded Research Exclusions

6.1 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.

7 Compliance and Penalties for Non-Performance

7.1 If an Investigator fails to comply with the vivoVerse’ FCOI policy, within 120 days, vivoVerse shall complete a retrospective review of the Investigator’s activities to determine bias. If a bias is found, vivoVerse 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. vivoVerse will work with the Investigator to set up an FCOI management plan to mitigate the situation. Companywide, vivoVerse is required to mandate the Investigator disclose the FCOI in each public presentation with research results 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.

8 Policy Coordinator

8.1 If you have a conflict of interest or if you have a question to discuss, contact the vivoVerse FCOI Policy Coordinator, Gina Lento, by email [gina.lento@newormics.com](mailto:gina.lento@newormics.com).

3. vivoVerse Compliance Measures

3.1. In order to convey this policy to staff, employees will:

3.1.1. Be given access to VVS-PL-016 (this document);

3.1.2. Be given access to tutorial website below;

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3.1.3. Be required to complete FCOI training within 10 business days of their start of employment; and,

3.1.4. Be required to submit a Certification of Completion of FCOI Training to the vivoVerse FCOI Policy Coordinator

APPENDICES

VVS-PL-016-F01: Downloadable SFI Disclosure Form (appended in pdf version)

REFERENCES

NIH FCOI Tutorial Web site: [https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html).

[Example of Certification of Completion for FCOI Training](#)

REVISION HISTORY

Original

Original reviewed on Nov 1, 2021, and unchanged.

Original Reviewed on March 29, 2023:

- Changed company name and logo from Newormics to vivoVerse, Inc.

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