



Conflict of interest Policy

Purpose

The National Institutes of Health (NIH) has adopted regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) on Promoting Objectivity in Research. These regulations describe the actions an individual and an organization must take to promote objectivity in research. The regulations apply to all NIH funded grants, cooperative agreements, research contracts (but not Phase 1 Small Business Innovations Research or Small Business Technology Transfer program grants), and subawards where the originating sponsor is NIH.

The purpose of this document is to describe the measures implemented in accordance with such regulations, allowing OSIVAX to ensure the absence of conflict of interest within the framework of the programs of research carried out, between funding organizations and operational teams.

Definition

Institutional responsibilities: means an Investigator's professional activities on behalf of OSIVAX ("OVX") (e.g., administration, research or consulting).

Investigator : means the project director or principal Investigator and any other person, regardless of title or position, whether an employee of Osivax or of a subgrantee, who is responsible for the design, conduct, or reporting of research funded by the PHS award, or proposed for such funding, which may include, for example, collaborators or consultants. OVX's Principal Investigator/Project Director, upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

PHS : means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Significant Financial Interest: means "(1) A 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 on behalf of OVX:

(i) 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 for the investigator (and its spouse and dependent children), 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;

(ii) 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

(iii) With regards to intellectual property rights and interests (e.g., patents, copyrights), a significant financial interest exists upon receipt of income related to such rights and interests in excess of \$5,000.

(2) 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 must be disclosed to OVX (; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency located in the United States, an United States 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 United States Institution of higher education). The details of this disclosure will include Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does not include the following types of financial interests:

(i) salary, royalties, or other remuneration paid by the Institution (OVX) to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution (OVX), including intellectual property rights assigned to the Institution (OVX) and agreements to share in royalties related to such rights;

(ii) any ownership interest in the Institution (OVX) held by the Investigator;; if the Institution is a commercial or for-profit organization;

(iii) 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;

(iv) 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education;

(v) or 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education."

Policy Scope

The conflict-of-interest policy that is the subject of this document is applicable to all research programs for which American Public Health Service ("PHS") funding is sought.



Procedure

1/ Disclosure

Prior to the submission of an application to the NIH Grantee for funding, the Principal Investigator and all other Investigators at OVX must have disclosed to OVX's designated official an up-to-date listing of their foreign and domestic Significant Financial Interests [SFIs] (and those of their spouse and dependent children), as defined above. Any new Investigator, who, subsequent to the submission of an application to NIH for funding from NIH, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to the designated official promptly and prior to participation in the project.

Each Investigator who is participating in research under an award from NIH must submit an updated disclosure of SFI at least annually on January 1st, during the period of the award. Such disclosure must include any information that was not disclosed initially to OVX pursuant to this Policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on a NIH- funded project directly as a NIH Grantee and/or indirectly through a subaward) that was transferred from another Institution, and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in research under an award from NIH must submit an updated disclosure of SFI (including reimbursed travel) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

2/ Review by OVX's Designated Official

The designated official will conduct reviews of disclosures. The designated official will review any SFI that has been identified in a disclosure; these interests will be compared to each research award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award.

When an Investigator is new to participating in the research project or when an existing Investigator discloses a new SFI, OVX's designated official shall within sixty days review disclosures of SFIs, determine whether the SFI is related to PHS funded research, determine whether an FCOI exists, and if so, implement a management plan that specify the actions that have been taken to manage such FCOI.

Whenever OVX identifies an SFI that was not disclosed timely by an Investigator, or was not previously reviewed during an ongoing PHS funded research project, the designated official shall within sixty days review disclosures of SFIs, determine whether the SFI is related to PHS funded research, determine whether an FCOI exists, and if so, implement a management plan that specify the actions that have been taken to manage such FCOI.

The designated official has been initially designated as OVX VP Finance Florian Sourd.



3/ Guidelines for Determining “Relatedness” and Financial Conflict of Interest

The designated official will determine whether an Investigator’s SFI is related to the research under a NIH award and, if so, whether the SFI is a financial conflict of interest. An Investigator’s SFI is related to the research under the award when the designated official reasonably determines that the SFI: could be affected by the research conducted under the award; or is in an entity whose financial interest could be affected by the research.

The designated official may involve the Investigator in the determination of whether a SFI is related to the research supported by the award. A financial conflict of interest exists when the designated official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. In determining if an Investigator’s SFI is related to the research under a NIH award, and if so, whether the relationship creates a FCOI, the designated official considers the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the designated official may also consider the following factors:

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
4. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher’s SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company’s business or financial outlook (excluding Phase I SBIRs and STTRs); or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser’s technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future; or
8. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
10. Whether other scientific groups are independently pursuing similar questions; or
11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
12. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI; or



13. Whether the project involves a subaward to an entity in which the Investigator has a SFI.

4/ Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest

If a conflict of interest exists, the designated official will determine by what means – such as the individual’s recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the designated official will be guided by the principles discussed in this Policy the designated official will also take into consideration whether the Investigator’s ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- a). Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, the Institution Review Board, Institutional Animal Care and Use Committee, etc.);
- b). For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- 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 financial conflict of interest;
- 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;
- f). Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- g). Severance of relationships that create financial conflicts;
- h). For research projects involving human subjects research, use of a data and safety monitoring board;
- i). Double-blind conditions;
- j). Provisions to conduct the work simultaneously at multiple sites;
- k). Written disclosure of the conflict to all individuals working on the research project;
- l). Annual reports on the research progress to the designated official.
- m). Disclosure at any presentation of information related to the FCOI.

If the designated official determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor. The designated official will keep a record of the disclosure and other relevant information for at least three years. If the designated official prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

No expenditures on a NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the designated official necessary to manage the Conflict of Interest. The designated official will communicate, in writing, with the NIH Grantee to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated. No expenditures can be incurred until the NIH Grantee has reported the FCOI to NIH via the eRA Commons FCOI Module.



The designated official will keep a record of Investigator disclosures of financial interests and the designated official's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three years from the date the final expenditures report is submitted and in accordance with the terms and conditions of the award and relevant NIH Regulations.

A retrospective review will be conducted within 120 days of determining noncompliance when there is an untimely or unmanaged FCOI, including:

- A failure by the Investigator to disclose a Significant Financial Interest that is determined by the Designated Research Official to constitute a Financial Conflict of Interest
- A failure by the Designated Research Official to review or manage such a Financial Conflict of Interest
- A failure by the Investigator to comply with a Financial Conflict of Interest management plan

The retrospective review must include the following:

- Project number
- Project title
- PD/PI or contact PD/PI if a multiple PD/PI model is used
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has a financial conflict of interest
 - Reason(s) for the retrospective review
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.)
- Findings of the review
- Conclusions of the review

5/ Public Accessibility to information related to Financial Conflicts of Interest

This policy will be publicly available via the OVX website.

In addition to this policy, upon receipt of a written request for information concerning identified FCOI's held by senior/key personnel and related to the funded research, OVX will make that information available within five (5) business days of the request. The information shall include all elements required by 42 CFR Part 50, updated through the date of the response:

- Investigator's name
- Investigator's title and role with respect to the research project
- Name of the entity in which the Significant Financial Interest is held
- Nature of the Significant Financial Interest
- Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$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
- Name and address of contact person for obtaining written requests

If OVX responds to written requests, OVX will note in its written response 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 OSIVAX's identification of a new Financial Conflict of Interest, which should be requested subsequently by the requestor

Information concerning the Significant Financial Interests of an individual, as limited by this Policy, will remain available, for responses to written requests for at least three years from the date that the information was most recently updated.

6/ Reporting of Financial Conflicts of Interest

Prior to the expenditure of any funds under an award funded by NIH, OVX will provide to NIH a FCOI report compliant with NIH regulations regarding any Investigator's Significant Financial Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan.

While the award is ongoing (including any extensions with or without funds), OVX will provide to NIH an annual FCOI report that addresses the status of the FCOI and any changes in the management plan. For any Significant Financial Interest that is identified as conflicting subsequent to an initial FCOI report during an ongoing NIH-funded research project (e.g., upon the participation of an Investigator who is new to the research project or for a newly identified FCOI for existing investigators), OVX will provide to NIH, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that OVX has implemented a management plan and the Investigator has agreed to the relevant management plan.

OVX will also provide to NIH an FCOI report regarding the financial conflict of interest after a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.

OVX will promptly notify the NIH if bias is found with the design, conduct or reporting of PHS funded research and include the requirement to submit a Mitigation report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation.

OVX will promptly notify the NIH if an Investigator fails to comply with OVX's FCOI policy or a FCOI management plan appears to have biased the design, conduct or reporting of the PHS funded research.

7/ Training Requirements

Each Investigator must complete training on OVX's Conflict of Interest Policy Applicable to an Award Issued by Public Health Services prior to engaging in research related to any NIH-funded award and at least every four years, and immediately (as defined below) when any of the following circumstances apply:

- 1). OVX revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators (training is to be completed within the timeframe specified in communications announcing such changes);



- 2). An Investigator is new to OVX research under a NIH award (training is to be completed prior to his/her participation in the research); or
- 3). OVX finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within 30 days in the manner specified by the designated official).

Each investigator must be informed of its disclosure responsibilities of all foreign and domestic significant financial interests (SFI) per the SFI definition and NIH's FAQs E.9 and E.20.

In fulfillment of the training requirement, OVX requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> in accordance with the requirements and expectations of this Policy. All investigators must print a certification of completion at the end of training and retain it for audit purposes

8/ Failure to Comply with OVX's Conflict of Interest Policy Applicable to Public Health Service Funded Award

When a FCOI is not identified or managed in a timely manner, including, for example, because the underlying Significant Financial Interest is not disclosed timely by an Investigator or, because a FCOI was not timely reviewed or reported by OVX; or because an investigator failed to comply with a management plan; then OVX will within 90 days:

- a) Complete a retrospective review of the Investigator's activities and the research project to determine any bias in the design, conduct or reporting of research;
- b) Document the retrospective review consistent with the regulation at 42 CFR 50.605(a)(3)(ii)(B);
- c) Document OVX's determination as to whether any research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with this Policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research;

If bias is found, OVX shall notify NIH promptly and submit a mitigation report to NIH that shall address the following:

- Impact of the bias on the research project and
- OVX's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, OVX shall submit FCOI reports annually to NIH, in accordance with the regulation and terms and conditions of the award agreement. Depending on the nature of the Financial Conflict of Interest,

OVX may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of OVX's independent retrospective review.

9/ Clinical Research

If OVX 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 Financial Conflict of Interest that was not managed or reported by OVX, OVX shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published



presentations.

10/ Subrecipient FCOI Compliance

A subrecipient relationship is established when federal funds flow down from or through the OVX to another individual or entity and the subrecipient will be conducting a substantive portion of a PHS funded research project and is accountable to the OVX for programmatic outcomes and compliance matters. Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors and subawardees, are subject to the OVX's terms and conditions, and as such, OVX will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation.

OVX will incorporate, as part of a written agreement with the subrecipient, terms that establish whether the OVX's Investigator FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with OVX that it is in compliance with the federal FCOI regulation and that the institution's portion of the project is in compliance with the federal conflict of interest policy.

If the subrecipient cannot provide the certification, the agreement shall state that the subrecipient Investigator is subject to OVX's Investigator FCOI Policy for disclosing Significant Financial Interests that are directly related to the subrecipient's work for OVX. OVX will, if applicable, submit a FCOI report to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to OVX. Such time period must be sufficient to enable OVX to provide timely FCOI reports to the NIH as necessary, through the eRA Commons FCOI Module.

If the subrecipient Investigator is subject to the OVX's Investigator FCOI Policy, the agreement shall specify the time period for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to OVX. Such time period shall be sufficient to enable OVX to comply with its review, management, and reporting obligations under the regulation. OVX will submit any NIH FCOI reports for a subrecipient Investigator through the eRA Commons FCOI Module.

11/ Maintenance of Records

Records relating to conflict of interest matters covered under this Investigator FCOI Policy for PHS funded research must be maintained for a minimum of three years after any applicable research project's final financial report is submitted to the funding agency, or until three years after the final action has been taken on any audit, litigation or claim, whichever is longer. Records for conflict of interest matters relating to other funded research will be maintained in accordance with OVX's Record Retention Policy.



12/ Failure to Comply with This Policy

No expenditures of funds on an award supported by NIH will be permitted unless the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any designated official-approved FCOI management plan.

In Lyon, France,

June 30th, 2023

Alexandre Le Vert

CEO and cofounder