



## **Policies and Procedures on Financial Conflicts of Interests**

### Introduction

This document has been generated to ensure that OneVax is in compliance with the Code of Federal Regulations Section 42, Part 50, Subpart F: "Responsibility of Applicants for Promoting Objectivity in Research", the purpose of which is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

### Significant Financial Interest (SFI)

- 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:
  - o OneVax is a non-publicly traded, for profit entity, but a SFI exists if the value of any remuneration received from OneVax in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000
  - o Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Investigators also must disclose 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 excluded sources provided in regulation.

NOTE: Salary and income from retirement accounts are exempt from these requirements as the Investigator does not directly control the investment decisions made in these vehicles. Income from service on advisory committees or review panels or 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, or a research institute that is affiliated with an Institution of higher education are also exempt.



### Basic Principles of Financial Conflicts of Interests (FCOI)

- A "conflict of interest" occurs in any situation in which a person serves or represents two distinct entities (or persons) or must choose between two conflicting interests.
- A FCOI is an SFI that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.
- FCOI must be reported by all senior/key personnel (the principle investigator and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation).

### OneVax's Policies

- Employees listed as principle investigator or senior/key personnel are required to:
  - o Complete the online training listed here and provide a certificate of completion:  
[https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)
  - o At the times listed below, report any and all SFI to Greg Marshall, Designated Institutional Official to help determine if a FCOI exists:
    - At time of application for new award
    - Annually
    - Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI
- OneVax is required to:
  - o Establish standards that provide a reasonable expectation that the design, conduct, and reporting of NIH-funded research will be free from bias resulting from Investigator financial conflicts of interest.
  - o Develop an administrative process to identify and manage FCOIs related to all PHS research projects.
  - o Promote and enforce Investigator compliance with the regulation pertaining to disclosure of SFIs.



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- Manage FCOIs and provide initial and ongoing FCOI reports to PHS/NIH:
  - Prior to expenditure of funds
  - Within 60 days of identifying a FCOI
  - Annually
- Maintain an up-to-date, written, enforced policy that complies with the FCOI regulation and make available via a publicly accessible Web site ([www.onevax.com](http://www.onevax.com))
- Maintain records of 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 FCOI) and all actions under the Institution's policy or retrospective review, if applicable for at least three years from the date of submission of the final expenditures report.
- Subcontracts established with the University of Florida are subject to the University of Florida's policies on FCOI which can be found here: <http://generalcounsel.ufl.edu/media/generalcounselufledu/documents/COI.pdf>
- Failure to disclose SFI with OneVax may be grounds for termination