

ProtonVDA LLC Financial Conflict of Interest Policies

ProtonVDA is committed to conducting research without bias and with the highest scientific and ethical standards. We have established the following policies in order to ensure compliance with NIH standards for objectivity in research according to the requirements of the Financial Conflict of Interest (FCOI) regulation 42 CFR Part 50 Subpart F.

Subrecipient Requirements

In order to ensure compliance of subrecipient activities, ProtonVDA will:

- Incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet SFI disclosure, if applicable, and FCOI reporting requirements.
- Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS/NIH Awarding Component (i.e., to NIH through the eRA Commons FCOI Module) to meet FCOI reporting obligations.

ProtonVDA Investigators

For the purposes of these policies, an investigator is any person (including subrecipients, subgrantees and collaborators) who is responsible for the design, conduct or reporting of research funded by NIH awards to ProtonVDA.

Training Requirements

Investigators are required to complete training related to Financial Conflict of Interest (FCOI). Information and other resources developed by NIH can be accessed through the NIH Web site.

<https://grants.nih.gov/grants/policy/coi/>

Training is required at the following times:

- Prior to engaging in research related to any NIH funded project;
- At least every four years, and
- Immediately when any of the following circumstances apply:
 - Institution revises its policy in a manner that affects the investigator;
 - When an investigator is new to the institution; or
 - When the institution finds an Investigator is not in compliance with the Institution's policy or management plan.

Significant Financial Interests

Investigators are required to disclose any Significant Financial Interest (SFI), defined by the regulations as:

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 reasonable appears to be related to the Investigators institutional responsibilities:
 - a. With regard to any publically 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;
 - b. With regard to any non-publicly traded 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

- c. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
2. 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 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. The 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 a FCOI with the PHS-funded research.
3. The term significant financial interest does not include the following types of financial interests: salaries, royalties or other remuneration paid by the institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the investigator, if the Institution is a commercial or for profit organization; 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.

The following are SFI exclusions from disclosure requirements:

1. Salary royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
2. Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights;
3. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
4. 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;
5. 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, or a research institute that is affiliated with an Institution of higher education; or
6. Income from service on advisory committees or review panels for a federal, state or local government agency, 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.

Financial Conflict of Interest (FCOI)

A Financial conflict of interest exists when ProtonVDA reasonably determines that a Significant Financial Interest (defined above) could directly and significantly affect the design, conduct or reporting of NIH-funded research.

Management of a 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 research will be free from bias. ProtonVDA will develop a management plan for each FCOI and monitor compliance. Key elements of a management plan include:

- Role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

If ProtonVDA identifies an SFI that was not disclosed or reviewed in a timely manner, the designated official(s) shall within sixty (60) days review the SFI, determine if an FCOI exists and implement an interim management plan, if needed.

In cases of non compliance, ProtonVDA will notify NIH and complete, within 120 of determination, a retrospective review of the investigator's activities and the project to determine bias, and submit a Mitigation Report if bias is found.

Disclosures/Reporting Process

ProtonVDA's designated official(s) will review all disclosures and evaluate whether they contain any FCOI. Investigators are required to disclose known SFI at the following times:

- At time of Application
- Annually in accordance with the specific time period prescribed by the Institution, during the period of the award.
- Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Reporting Requirements to NIH

ProtonVDA will provide initial and ongoing FCOI reports to NIH:

- Prior to the expenditure of funds
- During the period of award
- Within 60 days of identifying a new FCOI
- Annually
 - Report on the status of FCOI and any changes in management plan
 - Due at same time as when grantee submits annual progress report, including multi-year progress report, or at time of extension

All FCOI reports are submitted to NIH through the eRA Commons FCOI Module.

Maintenance of Records

ProtonVDA will 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 or, where applicable,
- from other dates specified in 45 C.F.R. 74.53(b) and 92.42 (b) for different situations.

Public Accessibility

This policy document will be posted on the ProtonVDA web site: <https://protonvda.com/>

Information concerning FCOIs held by investigators will also be posted on the ProtonVDA web site, and ProtonVDA will:

- Update the website annually and within 60 days of identifying any new FCOIs when posting FCOIs to website

- Retain information for three years
- FCOIs will be disclosed in each public presentation of the research

Point of Contact

If you have a conflict of interest or if you have a question to discuss, contact the ProtonVDA Signing Official, Don F. DeJongh

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