

VeraChem LLC

Financial Conflict of Interest Policy and Procedure

The Public Health Service (PHS), and the Office of the Secretary, HHS, have issued regulations (42 CFR Part 50; Subpart F) and established standards and procedures to be followed by institutions that apply for research funding from the National Institutes of Health (NIH) to ensure that the design, conduct, or reporting of research funded under NIH grants, cooperative agreements or contracts will not be biased by any conflicting financial interest of those investigators responsible for the research. This policy has been developed to address and comply with these requirements. VeraChem LLC believes this policy to fully addresses these requirements and we will continue to update it as necessary.

Definitions

Investigator here means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the NIH. For purposes of determining Significant Financial Interest, it includes the Investigator's spouse and dependent children.

Senior / Key Personnel the PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the NIH.

Institution VeraChem LLC

Significant Financial Interests (SFI) here 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:
 - 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, exceeds \$5,000
 - 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. Upon receipt of income related to intellectual property rights and interests (e.g. patents, copyrights)
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 excluded sources provided in regulation. For example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by the Company directly (i.e. the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Company relating to the trip, such as purpose of the trip,

identify of the payer/sponsor, destination and duration. The Company is required to determine if additional information is required (e.g. monetary value) and whether the travel constitutes a FCOI with NIH-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 to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
 - ii. intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
 - iii. any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
 - iv. 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;
 - v. 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
 - vi. 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.

Training

All Investigators shall be required review this policy document and provide a signed acknowledgment of having done so to VeraChem's Chief Executive Officer (CEO) or such person or persons designated for this purpose by the CEO.

Investigators as shall also complete the NIH provided Financial Conflict of Interest (FCOI) Tutorial, accessible at <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training> On completion of this training Investigators will receive a certificate of completion. This certificate shall be provided to VeraChem's Chief Executive Officer (CEO) or such person or persons designated for this purpose by the CEO.

Policy review and tutorial completion shall be repeated should changes be made to the policy, or if an Investigator is found to not be in compliance with the policy or at an interval of four years.

Procedures

The Owner / Members of VeraChem LLC, or other company personnel designated by these members, will constitute a Committee to review financial disclosures and determine whether any of the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research. In cases in which the person under consideration is a member of the Committee, they shall recuse themselves.

Every investigator applying to NIH or NSF for a research grant and having a potential SFI shall submit to the Committee a Financial Conflict of Interest (FCOI) Disclosure Form (below) listing these interests. This form will be provided along with instructions to all prospective investigators. Investigators must provide updated FCOI disclosure forms annually or more frequently if required by a FCOI management plan. In addition, any Investigator who discovers or acquires a new SFI shall file an updated FCOI disclosure form within 30 days of such acquisition or discovery.

The existence of any financial interests reported on this form shall be kept confidential to the extent permitted by law and by the need to manage, reduce or eliminate significant conflicts of interest.

The Committee will determine whether each reported financial interest constitutes a SFI that would reasonably appear to be affected by the research and/or is in entities whose financial interests would reasonably appear to be affected by the research and whether the SFI could directly and significantly affect the design, conduct, or reporting of the research. If necessary, the Committee may consult with person(s) with expertise in relevant areas, such as law or finance, in making its determination.

If a conflict of interest is determined to exist, steps shall be taken to manage, reduce, or eliminate the conflict to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias. Examples of conditions or restrictions that might be imposed include, but are not limited to: public disclosure of SFIs; monitoring of research by independent reviewers; modification of the research plan; disqualification from participation in all or a portion of the research funded; divestiture of SFIs; or severance of relationships that create actual or potential conflicts. The Committee will also report the existence of such conflicting interests to the NIH (see reporting details below)

Investigators must comply with any conditions or restrictions imposed by the Committee before beginning the research for SFIs existent prior the the start of the project. In the case of SFIs acquired or discovered during ongoing research the committee will conduct it's review and, if applicable determine a management plan within 60 days. If an investigator is found by the Committee to have not complied with this FCOI policy or the Committee's recommendations, or to have misrepresented his/her financial interests, the matter will be addressed through administrative and/or peer review with loss of the right to work on the project and/or apply for NIH funding in the future possible in extreme cases.

In cases of noncompliance the Committee will within 120 days of the the determination of noncompliance, complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. If bias is determined the Committee will also submit a mitigation report to the NIH (see below).

In all cases in which the Committee finds that a FCOI has not been reported or managed as required by regulation the Investigator shall be disclose the FCOI in all public presentations of results of the research and to request an addendum to previously published presentations.

Records of all financial disclosures and actions taken with respect to each conflicting interest shall be retained by VeraChem LLC as required by 42 CFR 50.604(i) for at least three years from the date of submission on the final expenditures report, or where applicable, from other dates specified in 45 CFR 75.361 Such records shall be made available to NIH upon their request.

Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. If a SFI is identified by the sub-award recipient, they are required to notify the VeraChem of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with federal regulations.

The Committee is responsible for the reporting matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the NIH:

1. Initial report – prior to the Company's expenditure of any funds under a NIH-funded research project, the Company must provide to the NIH an FCOI report regarding any Investigator SFI found by the Company to be a financial conflict of interest in accordance with the regulation.
2. During on-going NIH-funded research projects – the Company shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed in a timely manner, the Company shall submit a FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.
3. Annual FCOI report – For any FCOI previously reported to the NIH, the Company shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.
4. Mitigation reports and Investigator noncompliance - In any case in which bias is found in the design, conduct, or reporting of NIH funded research, or in cases of an Investigator's failure to comply with this FCOI policy of management plans imposed by the Committee an appropriate report will be submitted. This report will comply with the requirements of 42 CFR 50.605(a)(3) and 42 CFR 50.606(a) as applicable.

Public Accessibility

This policy shall be made available to the public at <https://www.verachem.com/fcoi>

In addition, the Committee will maintain information concerning identified FCOIs held by Senior / Key Personnel and will make such information available within 5 days of a written request. This information will comply with the requirements of 42 CFR 50.605(a)(5)(i)-(iv) This information will be updated within 60 days following identification of a new FCOI and will be maintained for three years from the date it was last updated.