

The following is Voxeleron's FCOI policy extracted from our quality management system SOP, VOX-SOP-000002 (Voxeleron QMS overview)-1.0.2.

6 Financial Conflicts of Interest Policy

It is required that, for National Institute of Health (NIH) grant awards, the applicant must submit a copy of the institution's financial conflict of interest (FCOI) policy to the eRA Commons Institution Profile. To do this it is required that:

- "There is in effect at the Institution an up-to-date, written and enforced administrative process to identify and manage Financial Conflicts of Interest (FCOI) with respect to all research projects for which NIH funding is sought or received;
- The Institution shall promote and enforce Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests (SFIs);
- The Institution shall identify and manage FCOIs and provide initial and ongoing FCOI reports to the NIH consistent with this subpart;
- When requested, the Institution will promptly make information available to the NIH/HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI;
- The Institution shall fully comply with the requirements of the regulation."

Specifically, the NIH requires recipients and investigators to comply with the requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which public health service (PHS) Funding is Sought." Phase I SBIR/STTR applicants and recipients are exempt.

6.1 FCOI Procedure

From the [compliance document](#), we define a significant financial interest to mean:

anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

- (1) Salary, royalties, or other remuneration from the applicant institution;
- (2) Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;
- (3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (4) Income from service on advisory committees or review panels for public or nonprofit entities;
- (5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or
- (6) Salary, royalties or other payments that when aggregated for the

Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

At Voxeleron, it is required that:

1. Voxeleron maintains an appropriate written, enforced policy on conflict of interest that complies with this subpart and inform each Investigator of that policy, the Investigator's reporting responsibilities, and of these regulations. If the Institution carries out the PHS-funded research through subgrantees, contractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with this subpart, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this subpart.
2. Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.
3. Require that by the time an application is submitted to PHS each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):
 - a. That would reasonably appear to be affected by the research for which PHS funding is sought; and
4. In entities whose financial interests would reasonably appear to be affected by the research.
5. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
6. Provide guidelines consistent with this subpart for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
7. Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.
8. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
9. Certify, in each application for the funding to which this subpart applies, that:
 - a. There is an effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS,
 - b. Prior to the Institution's expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the institution and assure that the interest has been managed, reduced or eliminated in accordance with this subpart; and, for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting

interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification;

- c. The Institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and
- d. The Institution will otherwise comply with this subpart.

For NIH funding applications, it is required, therefore, that all members of staff complete a FCOI form that covers questions relating to the specific project. A single form is required for each project and all members of staff must complete it. It must then be signed off by senior management as well as the designated official. The form template is "VOX-FCOI-000ABC- template (ABC).docx". This requires that, for each possible Significant Financial Interest (SFI), the document details what that is. The official then reviews these to determine if that constitutes a conflict or not. Should a conflict occur, then it must be appropriately managed.

It is also required that this information be made public.

6.2 Management of Conflicting Interests

The designated official(s) must:

- Review all financial disclosures; and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:
 - Public disclosure of significant financial interests;
 - Monitoring of research by independent reviewers;
 - Modification of the research plan;
 - Disqualification from participation in all or a portion of the research funded by the PHS;
 - Divestiture of significant financial interests; or
 - Severance of relationships that create actual or potential conflicts.
- In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

6.3 Remedies for Identified Conflicting Interests

In the case where conflicts are found, it is required that the designated officer ensures compliance or that the investigator is removed from the project. Specifically:

- If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The

PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

- The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that suspension of funding under 45 CFR 74.62 is necessary until the matter is resolved.
- In any case in which the HHS determines that a PHS-funded project of clinical research 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 conflicting interest that was not disclosed or managed as required by this subpart, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.