

Savara Inc. Company Policy - Financial Conflict of Interest (FCOI) Policy

Effective January 1st, 2013

Overview

Objective research is of paramount importance to Savara and our subgrantees and defined vendors herein, to ensure public trust and meet scientific, program and ethical goals of our National Institutes Health (NIH) grant efforts. To address the increasing complexities related to financial interests held by researchers, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) has published their final rules. Savara believes we have fully addressed the requirements (including those of our defined sub-level vendors) of this ruling although we will continue to update this policy as needed, particularly related to any changes in personnel FCOI issues or upon further DHHS guidance.

Effective January 1st, 2013, Savara's policy requires that each investigator, subrecipients, subgrantees and collaborators affiliated with Savara, by NIH or any other applicable grant or contract, be in compliance with 42 CFR Part 50, Subpart F for PHS grants and cooperative agreements (and 45 CFR Part 94 for contracts). In addition, this legislation spells out NIH's commitment to preserving the public's trust that the research supported by them is conducted without bias and with the highest scientific and ethical standards. Savara intends to use this same FCOI standard for all other Federal agency grant and contract efforts, as tailored or amended accordingly.

The following are key term definitions and Savara's policy guidance for principal or program investigators, subrecipients, subgrantees and collaborators affiliated with Savara.

Funded Research

Funded Research is a project governed by PHS regulations including NIH Small Business Innovation Research (SBIR) grants. Excluded are applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Investigator

An Investigator is any person (including subrecipients, subgrantees and collaborators) who is responsible for the design, conduct or reporting of Funded Research.

Training Requirement

Savara Investigators and all applicable sub-level vendors are required to complete training related to FCOI. If any conflicts of interest are found or known, they must be disclosed. The training must be updated no-less than every four years or as designated based on grant or role circumstances. Information and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>).

PHS Awarding Component

The PHS awarding component is any sub-agency of the Public Health Service or Department of Health and Human Services.

Significant Financial Interest (SFI)

Significant Financial Interest is 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:

(i) 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;

(ii) 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

(iii) 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 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.

Financial Conflict of Interest (FCOI)

A Financial conflict of interest exists when Savara reasonably determines that a Significant Financial Interest (defined above) could directly and significantly affect the design, conduct or reporting of Funded Research.

Disclosures/Reporting Process

Savara's designated official(s) will review all "disclosure" and evaluate whether they contain any FCOI. If no FCOI is found the "disclosure form" will be filed. If a FCOI is identified it will be put on the FCOI report through the eRA Commons FCOI module prior to expending any funds. If any interests are identified as conflicting subsequent to the initial report they must be reported to Savara within 30 days. Savara will then report it to the PHS awarding component that has issued the award within 60 days. If a PHS-funded project is conducted by an investigator or SO with a conflict that was not disclosed or managed, Savara is required to disclose the conflict in each public presentation related to the results of the 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.

Compliance and Penalties for Non-Performance

If an investigator fails to comply with Savara's FCOI policy, within 120 days, Savara shall complete a retrospective review of the Investigator's activities to determine bias. If a bias is found, Savara shall submit a mitigation report to the NIH, in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias. Savara will work with the Investigator to set up an FCOI management plan to mitigate the situation. Companywide, Savara is required to mandate the Investigator disclose the FCOI in each public presentation with research results if it was not reported up front. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future NIH funding.

Records Management

The records of all financial disclosures and all actions taken by Savara will be maintained for at least three years from the date of submission of the final expenditures report.

Savara Inc. – Financial Conflict of Interest Disclosure Form

Persons completing this form are expected to have read and understood the Savara Financial Conflict of Interest Policy (FCOI) on Federal Grants and Contracts. If you have any questions regarding that policy contact the Savara’s Head of Business Operations prior to signing this document.

The period covered by this disclosure is January 1st, 2012 to date of signature below. Any conflict that occurs following signature, must be disclosed per the FCOI policy.

1. Do you, your spouse, or dependent children have a “significant financial interest (SFI)” (as defined on the FCOI Policy) that would reasonably appear to be affected by your above-described covered “Research”?

Yes No

If yes, please describe on a separate page the nature and extent of your/their affiliation.

2. Do you, your spouse or dependent children have a “significant financial interest” in any business or legal entity whose financial interests would reasonably appear to be affected by this covered “Research”?

Yes No

If yes, please describe on a separate page the nature and extent of your/their affiliation.

I certify that:

I have read Savara Inc. Policy on Financial Conflict of Interest on Federal Grants and Contracts.

I have made all required financial disclosures.

(If the program leader, principal investigator or project director) I have made every effort to ensure that all Investigators (see policy for definition) responsible for the design, conduct or reporting of the research have submitted required disclosures.

Signature _____ Date: _____

Name: _____