



Saavsus, Inc. Conflict of Interest Policy

The National Institutes of Health (NIH) has adopted regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) on Promoting Objectivity in Research. Saavsus complies fully in implementing this policy regarding the promotion of objectivity in research. The policy applies to all NIH funded grants and subawards where the originating sponsor is NIH.

The policy applies to all grant related activities performed by Saavsus and subaward Investigator's professional activities including administration, research, and consulting.

Investigator is defined to include the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research related to NIH awards, or proposals. It applies to advisors or consultants.

Significant Financial Interest means: (1) A financial interest consisting of one or more of the following interests of the Investigator, Investigator's spouse, and dependent children that reasonably appear to be related to the Investigator's NIH funded activities.

1. **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 for the investigator, investigator's spouse and dependent children, exceeds \$5,000. For 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 includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
2. **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
3. **Intellectual property rights and interests** (e.g., patents, copyrights), a significant financial interest exists upon receipt of income of greater than \$5,000 related to such rights and interests.
4. **Third party reimbursed or sponsored travel**, which is paid on behalf of the Investigator, the Investigator's spouse, or dependent children that is greater than \$5,000 and related to the Investigator's administrative, research, or consulting activities must be disclosed to Saavsus. Disclosure requirement does not apply to travel paid for by Saavsus and does not apply to travel that is reimbursed or sponsored by an U.S. federal, state, or local government agency, an U.S. 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.

Significant financial interest does not include the following types of financial interests:

1. **Salary, royalties, or other remuneration** paid by Saavsus to the Investigator if the Investigator is currently employed or otherwise affiliated with Saavsus, including intellectual property rights assigned to Saavsus and agreements to share in royalties related to such rights.
2. **Income from investments**, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these investments.
3. **Income from seminars, lectures, or teaching engagements** sponsored by an U.S. 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.
4. **Income from service on advisory committees or review panels** for an U.S. 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.

Investigator requirement to disclose

Principal Investigators and all other Investigators affiliated with Saavsus must disclose to Saavsus' President or Science Director, the designated officials, a listing of their **Significant Financial Interests** (and those of their spouse and dependent children), as defined above. This disclosure must take place prior to commencing development of any NIH proposal or their participation in any NIH grant award project. Each Investigator who is participating in research under an award from NIH must inform and disclose any **Significant Financial Interests** as soon as they become aware of the existence of such interests.

Saavsus review of disclosures

Saavsus' President and/or Science Director, the company's designated officials, will conduct reviews of disclosures. They will review any **Significant Financial Interest** that has been identified in a disclosure and will compare it to relevant projects that the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the **Significant Financial Interest** is related to the award and constitute a Financial Conflict of Interest (FCOI) related to that research award.

Determining Financial Conflict of Interest

Investigator's **Significant Financial Interest** is related to the research under the award when the designated official reasonably determines that the **Significant Financial Interest** could be affected by the research conducted under the award; or are in an entity whose financial interest could be affected by the research.

The designated officials may discuss with the Investigator to assess whether a **Significant Financial Interest** is related to the research supported by the award. A financial conflict of interest exists when the designated official reasonably determines that the **Significant Financial Interest** could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. The role of the Investigator and the potential to bias the results along with the value of the **Significant Financial Interest** in relation to the size and value of the entity are considered. In addition, the designated officials may also consider the following factors:

1. Whether the goal of the research is to evaluate an invention linked to the **Significant Financial Interest** (such as where the **Significant Financial Interest** is a patent, or an interest in a company that has licensed the invention).
2. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board.
3. Where the **Significant Financial Interest** is in a privately held company, whether the researcher's **Significant Financial Interest** could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs).
4. The magnitude of the **Significant Financial Interest** and the amount of commercialization payments received by the Investigator from that technology, both currently and in the future.
5. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts.
6. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the **Significant Financial Interest**.
7. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a **Significant Financial Interest**.
8. Whether the project involves a subaward to an entity in which the Investigator has **Significant Financial Interests**.

Response to and Management of Financial Conflict(s) of Interest

Should a conflict of interest be identified, the designated officials will determine ways to mitigate the conflict. This might include the Investigator's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee. In making those determinations, the designated official will be guided by the principles discussed in this Policy. The designated officials will also take into consideration whether the Investigator's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include:

1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing research).
2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants.
3. Modification of the research plan.
4. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
5. Reduction or elimination of the financial interest (e.g., sale of an equity interest).
6. Severance of any relationships that create financial conflicts.
7. Written disclosure of the conflict to all individuals working on the research project.
8. Periodic reporting on the research progress to the designated officials.
9. Disclosure at any presentation of information related to the FCOI.

If the designated official determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, using the "Management Plan Response

to COI Incident” form included as an attachment to this policy to the Investigator, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor. The designated officials will keep a record of the disclosure and other relevant information for at least three years. No expenditures on a NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with the “Management Plan Response to COI Incident”.

The designated officials will communicate, in writing, with the NIH Grantee to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated. No expenditures can be incurred until the NIH Grantee has reported the FCOI to NIH. The NIH Grantee will notify Saavsus when it may incur expenditures. The designated officials will keep a record of Investigator disclosures of financial interests and the designated official’s review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three years from the date the final expenditures report is submitted and in accordance with the terms and conditions of the award and relevant NIH Regulations.

Public Accessibility to Information Related to Financial Conflicts of Interest

Prior to the expenditure of any funds under a NIH award, Saavsus will ensure public accessibility via a publicly accessible website or by written response to any requestor within five business days of a request of information concerning any **Significant Financial Interest** disclosed that meets the following three criteria:

1. The **Significant Financial Interest** was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by Saavsus in the award application, progress report or any other report submitted to the NIH Grantee;
2. Saavsus has determined that the **Significant Financial Interest** is related to the research funded through an award; and
3. Saavsus has determined that the **Significant Financial Interest** is a financial conflict of interest.

The information that Saavsus will make available via a publicly accessible website or in a written response to any requestor within five days of request will include, at a minimum, the following:

1. The Investigator’s name, title and role with respect to the research project.
2. The name of the entity in which the **Significant Financial Interest** is held.
3. The nature of the **Significant Financial Interest**.
4. The approximate dollar value of the **Significant Financial Interest** in the following ranges: \$0-\$4,999; \$5,000-9,999; \$10,000 - \$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

If Saavsus uses a publicly accessible website to comply with the public disclosure requirements of the NIH regulations, the information posted will be updated at least annually, and within thirty days of receipt or identification of information concerning any additional **Significant Financial Interest** of the senior/key personnel for the NIH-funded research project that had not been previously disclosed, or upon the disclosure of a **Significant Financial Interest** of senior/key personnel new to the NIH-funded

research project, if it is determined by the designated officials that the **Significant Financial Interest** is related to the research and is a financial conflict of interest.

If Saavsus responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within 30 days of Saavsus' identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the **Significant Financial Interest** of an Investigator, as limited by this Policy, will remain available, for responses to written requests or for posting via Saavsus' publicly accessible website for at least three years from the date that the information was most recently updated.

Reporting of Financial Conflicts of Interest

Prior to the expenditure of any funds under an award funded by NIH, Saavsus will provide to NIH an FCOI report compliant with NIH regulations regarding any Investigator's **Significant Financial Interest** found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. While the award is ongoing (including any extensions with or without funds), Saavsus will provide to NIH an annual FCOI report that addresses the status of the FCOI and any changes in the management plan. For any **Significant Financial Interest** that is identified as conflicting subsequent to an initial FCOI report during an ongoing NIH-funded research project (e.g., upon the participation of an Investigator who is new to the research project), Saavsus will provide to NIH, within thirty days, an FCOI report regarding the financial conflict of interest and ensure that Saavsus has implemented a management plan and the Investigator has agreed to the relevant management plan.

Training Requirements

Each Investigator will receive a copy of the Saavsus Conflict of Interest Policy as a component of the Saavsus Employee Manual and they must complete training on the policy applicable to an Award Issued by NIH at least every four years, or when any of the following circumstances apply:

1. Saavsus revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators (training is to be completed within the timeframe specified in communications announcing such changes).
2. An Investigator is new to Saavsus research under a NIH award (training is to be completed prior to his/her participation in the research).
3. Saavsus finds that an Investigator is not in compliance with this Policy or a Management Plan issued under this Policy (training is to be completed within 30 days in the manner specified by the designated officials).

In fulfillment of the training requirement, Saavsus requires its Investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html. All investigators must print a certification of completion at the end of training and retain it for audit purposes.

Failure to Comply with this Policy

When a FCOI is not identified or managed in a timely manner, for any reason, Saavsus will, within 60 days:

1. Complete a retrospective review of the Investigator's activities and the research project to determine any bias in the design, conduct or reporting of research.
2. Document the retrospective review consistent with the regulation.
3. Document Saavsus' determination as to whether any research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with this Policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research.

If bias is found, Saavsus shall notify NIH promptly and report on the impact of the bias on the research project and Saavsus' plan of action or actions taken to eliminate or mitigate the effect of the bias. Thereafter, Saavsus shall submit FCOI reports annually to NIH, in accordance with the regulation and terms and conditions of the award agreement. Depending on the nature of the Financial Conflict of Interest, Saavsus may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of Saavsus' independent retrospective review.

Clinical Research

If Saavsus determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of an intervention or training program has been designed, conducted or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by Saavsus, the Investigator involved shall be required to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Subrecipient Conflict of Interest Compliance

Subrecipients, who include, but are not limited to collaborators, consortium members, consultants, contractors, subcontractors and sub awardees, are subject to Saavsus' terms and conditions. Saavsus will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation. Saavsus will incorporate, as part of a written agreement with the subrecipient, terms that establish whether Saavsus' Investigator FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator. If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with Saavsus that it is in compliance with the federal FCOI regulation, and that the institution's portion of the project is in compliance with the federal conflict of interest policy. If the subrecipient cannot provide the certification, the agreement shall state that the subrecipient Investigator is subject to Saavsus' Investigator FCOI Policy for disclosing **Significant Financial Interests** that are directly related to the subrecipient's work for Saavsus. Saavsus will, if applicable, submit a FCOI report to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to Saavsus. Subrecipient response time period must be sufficient to enable Saavsus to provide timely FCOI reports to the NIH as necessary, through the eRA Commons FCOI Module. If the subrecipient Investigator is subject to Saavsus' Investigator FCOI Policy, the agreement shall specify the time period for the subrecipient to submit all Investigator disclosures of **Significant Financial Interest** to Saavsus. The specified time period shall be sufficient to enable Saavsus to comply with its review, management, and reporting obligations under the

regulation. Saavsus will submit any NIH FCOI reports for a subrecipient Investigator through the eRA Commons FCOI Module.

Maintenance of Records

Records relating to compliance with this policy must be maintained for a minimum of three years after any applicable research project's final financial report is submitted to the funding agency, or until three years after the final action has been taken on any audit, litigation or claim, whichever is longer. No expenditures of funds on an award supported by NIH will be permitted unless the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any designated official-approved FCOI management plan.