

SACNAS
Financial Conflict of Interest Policy

Effective Date: August 1, 2020

The purpose of this Financial Conflict of Interest Policy (“FCOI Policy”) is to foster public confidence in the integrity of SACNAS and our research-related activities funded by the Public Health Service (“PHS”) of the U.S. Department of Health and Human Services (“HHS”). SACNAS has implemented this FCOI to comply with the requirements of the PHS-funded research regulations contained in 42 C.F.R. Part 50, Subpart F (“FCOI Regulations”).

I. Purpose and Applicability

The FCOI Regulations were established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest. The FCOI Regulations are applicable to institutions that apply for or receive PHS grants or cooperative agreements for research and to each Investigator (as defined below) planning to participate in or participating in such research.

SACNAS is required to create and maintain an up-to-date written and enforced policy stating the procedures for implementing the FCOI Regulations, as well as to inform each Investigator of the FCOI Regulations, of this FCOI Policy, and of the Investigator's disclosure responsibilities under the FCOI Regulations and this FCOI Policy.

This policy applies to all National Institute of Health (“NIH”) funded research activities with an award issue date of July 31, 2020 or later, and to proposals for research activities submitted to PHS on or after January 23, 2019. To the extent that other funding agencies or organizations (whether governmental or private) have adopted financial conflict of interest policies and procedures, SACNAS will comply with such policies and procedures when applicable.

II. Definitions

- *Disclosure of significant financial interests* means an Investigator's disclosure of significant financial interests to SACNAS.
- *Financial conflict of interest or FCOI* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- *FCOI report* means SACNAS’ report of a financial conflict of interest to a PHS Awarding Component, such as NIH.
- *Financial interest* means anything of monetary value, whether or not the value is readily ascertainable.

- *Institutional responsibilities* means an Investigator's professional responsibilities on behalf of SACNAS, and as defined by SACNAS in this FCOI Policy.
- *Investigator* means the project director (“PD”) or principal Investigator (“PI”) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research PHS-funded, or proposed for such funding, which may include, for example, collaborators or consultants.
- *Manage* means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the NIH.
- *PHS Awarding Component* means the organizational unit of the PHS that funds the research that is subject to the FCOI Regulations.
- *Research* means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). As used in the FCOI Regulations, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- *Senior/key personnel* means the project director or principal Investigator and any other person identified as senior/key personnel by SACNAS in the grant application, progress report, or any other report submitted to the PHS by SACNAS under the FCOI Regulations.
- *Significant financial interest* means 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. 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. 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.

- ii. 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. Intellectual property: Intellectual property rights and interests (e.g., patents, copyrights) must be disclosed upon receipt of income related to such rights and interests.
- iv. Travel Expenses: 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 in the twelve months preceding the disclosure if the value of such travel, when aggregated from all sources, exceeds \$5,000; 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, a medical center or a research institute that is affiliated with an institution of higher education.
Disclosures relating to travel expenses must specify at a minimum the purpose and duration of the trip, the identity of the sponsor/organizer and the destination.

- The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by SACNAS to the Investigator if the Investigator is currently employed or otherwise appointed by SACNAS, including intellectual property rights assigned to SACNAS and agreements to share in royalties related to such rights; any ownership interest in SACNAS held by the Investigator, if SACNAS is a commercial or for-profit organization; 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; 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 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.

III. Investigator Training Requirements

Each Investigator, including subrecipient Investigator(s), must complete FCOI training before engaging in research related to any PHS-funded grant or contract, and at least every four (4) years thereafter, on the following: (i) this FCOI Policy, (ii) the Investigator's responsibilities

regarding disclosure of significant financial interests relating to the Investigator's institutional responsibilities, (iii) and the FCOI Regulations.

Investigators are required to complete FCOI training immediately under the following circumstances: (i) SACNAS' FCOI policies change in a manner that affects Investigator requirements, (ii) an Investigator is new to SACNAS, or (iii) SACNAS finds an Investigator noncompliant with SACNAS' FCOI policy or a management plan.

IV. Disclosure Requirements

SACNAS will identify an official to solicit and review disclosures of Significant Financial Interests from each Investigator or key personnel who is planning to participate in, or is participating in, PHS-funded research. This official will serve as the SACNAS-FCOI Officer ("FCOI Officer").

Each Investigator, who is planning to participate in or is participating in PHS-funded research is required to disclose to SACNAS his/her known Significant Financial Interests (and those of his/her spouse and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities. Such disclosures are required: (i) at the time of application for PHS-funded research, (ii) no later than thirty (30) days from the date of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI; and (iii) at least annually during the period of award.

Prior to SACNAS' expenditure of any funds under a PHS-funded research project, the FCOI Officer will review all Investigator disclosures of Significant Financial Interests, determine whether any Significant Financial Interests relate to PHS-funded research; determine whether a FCOI exists; and, if so, develop a management plan that specifies the actions that have been and will be taken to manage the financial conflict of interest. The key elements of the management plan include:

- i. The role and principal duties of the conflicted Investigator in the research project;
- ii. Conditions of the management plan;
- iii. How the management plan is designed to safeguard objectivity in the research project;
- iv. Confirmation of the Investigator's agreement to the management plan; and
- v. How the management plan will be monitored to ensure Investigator compliance.

Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- i. Public disclosure of financial conflicts of interest (e.g, when presenting or publishing research);
- ii. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the financial conflict of interest;
- iv. Modification of the research plan;

- v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- vi. Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
- vii. Severance of relationships that create financial conflicts.

Updated or annual FCOI reports must include the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted to NIH.

V. Subrecipient Requirements

If SACNAS subcontracts elements of the PHS-funded research to an outside entity, each subrecipient investigator or their key personnel shall be required to comply with this policy or provide documentation that the subrecipient institution complies with the FCOI Regulations. SACNAS will incorporate in a written agreement with any subrecipient terms that establish whether this FCOI Policy or the subrecipient's FCOI policy will apply to subrecipient investigators and will include time periods to meet disclosure and/or FCOI reporting requirements. If the subrecipient's Investigators must comply with the subrecipient's own FCOI policy, the subrecipient must certify as part of the agreement with SACNAS that its FCOI policy complies with the FCOI Regulations. If the subrecipient cannot provide such a certification, the agreement between SACNAS and the subrecipient will state that subrecipient Investigators are subject to this FCOI Policy for disclosing significant financial interests that are directly related to the subrecipient's work for SACNAS.

VI. SACNAS Review and Monitoring Requirements

The FCOI Officer will be responsible for reviewing all disclosures of Significant Financial Interests, making the requisite determinations, and taking any subsequent action. Prior to the expenditure of funds or, with respect to an ongoing PHS-funded project, within sixty (60) days of the disclosure or discovery of a Significant Financial Interests, the FCOI Officer will:

- i. review all disclosure forms and determine whether (a) an Investigator's significant financial interest is related to PHS-funded research and (b) if so related, whether the significant financial interest is a financial conflict of interest (FCOI); and
- ii. in the case of a FCOI, develop and implement a management plan specifying actions that have been and shall be taken to manage the FCOI; and
- iii. submit initial and ongoing FCOI reports to NIH as required under the FCOI Regulations.

SACNAS will provide guidelines to the designated FCOI Officer to determine whether an Investigator's Significant Financial Interest is related to PHS-funded research and, if so related, whether the Significant Financial Interest is a FCOI. An Investigator's Significant Financial Interest is related to PHS-funded research when the FCOI Officer reasonably determines that the Significant Financial Interest could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. In making this determination, the

FCOI Officer will consider all relevant factors and information, including but not limited to the nature of the research, the magnitude of the financial interest and degree to which it is related to the research, the extent to which the interest could be directly and substantially impacted by the research, and the degree of risk to the human subjects, if any, that is inherent in the research protocol.

Prior to making the decision whether a FCOI exists, the FCOI Officer may impose interim measures, may ask the Investigator to submit additional information and may meet or communicate with the Investigator. The Investigator may be encouraged to suggest procedures, protocols, or other measures designed to manage the FCOI.

Whenever a FCOI is not identified or managed in a timely manner due to failure by the Investigator to disclose a Significant Financial Interest that is determined by SACNAS to constitute a Financial Conflict of Interest, failure by SACNAS to review or manage such a Financial Conflict of Interest, or failure by the Investigator to comply with a Financial Conflict of Interest management plan, SACNAS will, within one-hundred and twenty (120) days of SACNAS' determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

SACNAS will document the retrospective review, which will include at least the following key elements:

- i. Project number;
- ii. Project title;
- iii. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- iv. Name of the Investigator with the FCOI;
- v. Name of the entity with which the Investigator has a financial conflict of interest
- vi. Reason(s) for the retrospective review;
- vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- viii. Findings of the review; and
- ix. Conclusions of the review.

If bias is found, SACNAS will notify NIH promptly and submit a mitigation report to NIH. The mitigation report will include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of the bias on the research project, and SACNAS' plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, SACNAS will submit FCOI reports annually as prescribed by the regulation and this FCOI Policy.

VII. Reporting Financial Conflict of Interests to NIH

For PHS awarded grants and cooperative agreements, SACNAS will submit all initial, annual, and revised FCOI reports to NIH through a method designated by NIH.

- **Initial FCOI Reports:** Before SACNAS' expenditure of any funds under a PHS-funded research project, SACNAS will provide NIH with a FCOI report and ensure that SACNAS has implemented a management plan for any FCOI. If SACNAS identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, SACNAS is not required to submit a FCOI report to NIH.
- **FCOI Reports during ongoing PHS-funded Research:** For any FCOI that SACNAS identifies during an ongoing PHS-funded research project (such as, upon participation of an Investigator who is new to the project, or for newly identified FCOIs for existing Investigators), SACNAS will provide NIH, within sixty (60) days, a FCOI report regarding the FCOI and ensure that a management plan has been implemented.
- **Annual FCOI report:** For any FCOI previously reported by SACNAS, SACNAS will provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Annual FCOI reports must be submitted to NIH for the duration of the project period (including extensions with or without funds) at the same time as when SACNAS is required to submit the annual progress report, including a multi-year funded progress report, or at the time of the extension. The annual FCOI report is not to be submitted as part of the annual progress report. The annual FCOI report is submitted separately through the submission method designated by NIH.

All FCOI reports must include the following information:

- i. Project number;
- ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- iii. Name of the Investigator with the financial conflict of interest;
- iv. Name of the entity with which the Investigator has a financial conflict of interest;
- v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- vi. Value of the financial interest, 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;
- vii. A description of how the financial interest relates to the PHS-funded research and the basis for SACNAS' determination that the financial interest conflicts with such research; and
- viii. A description of the key elements of SACNAS' management plan.

VIII. Record Maintenance

All records relating to disclosures of financial interest, including any review and actions taken by SACNAS, will be maintained by the FCOI Officer or designee for a period of five (5) years from the date the final grant expenditure report is submitted to NIH.

The FCOI Officer shall maintain all disclosure forms and related records of determinations made and actions taken for a period of three (3) years from the date of submission of the final expenditures report to NIH (or, where applicable, from other dates specified in 45 CFR 74.53(b)).

IX. Enforcement Mechanisms and Remedies for Noncompliance

All researchers to whom this FCOI Policy applies are expected to fully and promptly comply with it. If an Investigator fails to comply with this FCOI Policy, or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, SACNAS shall promptly notify NIH of the corrective action taken or to be taken. NIH will consider the information submitted and may require or recommend additional action.

SACNAS shall submit, or permit on site review of, all records pertinent to compliance with the FCOI Regulations. On the basis of its review of records or other information that may be available, NIH may decide that a particular financial conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that SACNAS has not managed the financial conflict of interest in accordance with the FCOI Regulations. NIH may determine that imposition of specific award conditions under 45 CFR 75.207, or suspension of funding or other enforcement action under 45 CFR 75.371, is necessary until the matter is resolved.

Failure by an individual to comply with the terms of this FCOI Policy, to file a complete and truthful financial disclosure for pending proposals, or when a new financial interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed project monitoring bodies, will be grounds for discipline. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated. Similarly, agreements with subrecipient organizations may be terminated if that organization fails to comply with its obligations under the FCOI Regulations.

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 financial conflict of interest that was not managed or reported by SACNAS as required by the FCOI Regulations, SACNAS shall require the Investigator involved 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.

X. Public Accessibility of FCOI Policy and FCOI Information

This FCOI Policy will be posted on the SACNAS publicly accessible website, as required by the FCOI Regulations.

Prior to SACNAS' expenditure of any funds under a PHS-funded research project, SACNAS shall ensure public accessibility of information concerning any significant financial interest disclosed to SACNAS that meets the following three criteria: (i) the significant financial interest was disclosed and is still held by the senior/key personnel, (ii) SACNAS determines that the significant financial interest is related to the PHS-funded research; and (iii) SACNAS determines that the significant financial interest is a financial conflict of interest.

SACNAS will make such information available by a written response to any requestor within five (5) business days of a request made to info@sacnas.org. SACNAS will update such information as specified by the FCOI Regulations and information will be available for three (3) year from the date it was last updated. This information will include:

- i. The name of the Investigator,
- ii. The Investigator's title and role with respect to the research project,
- iii. The name of the entity in which the Significant Financial Interest is held,
- iv. The nature of the Significant Financial Interest, and
- v. The approximate dollar value of the Significant Financial Interest or a statement that the interest is one whose value cannot be readily determined through reference to public process or other reasonable measures of fair market value.

In situations where SACNAS is working with a subrecipient, it is SACNAS' responsibility to make FCOI information publicly accessible. However, when the subrecipient investigator is required to comply with the subrecipient's own FCOI policy, the subrecipient Institution will also make FCOI information publicly accessible. In these situations, SACNAS can consider including the requirement for the subrecipient Institution to make FCOI information publicly available as part of the subaward agreement.