



SARC's Financial Conflict of Interest

Policy Statement

SARC is committed to protecting the integrity and objectivity of its research activities by ensuring that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest. SARC has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest. The procedures described in this policy were created and designed primarily to comply with the specific regulatory requirements for U.S. Public Health Service (PHS)-sponsored research, but are also intended to provide basic frameworks and standards for identifying, evaluating, and managing potential financial conflicts of interest related to SARC's other research activities. For non-PHS research, the steps, timing, determinations, documentation, and notification may be tailored as appropriate but will remain focused on maintaining SARC's standards for research integrity and effectively eliminating or managing actual or potential financial conflicts of interest.

Reason for Policy

This policy and related procedures have been developed to identify, manage, and mitigate any potential financial conflicts of interest. The policy was written to be in conformance with the Code of Federal Regulations (CF) 42, Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research.

Definitions

For purposes of this policy, the following definitions shall apply:

Designated Official is the individual designation by SARC to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests.

Financial conflict of interest means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research as determined by SARC through the Designated Official.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Immediate family refers to an Investigator's spouse and dependent children.

Investigator means the project direct/principal investigator and any other person who is responsible for the design, conduct, or reporting of the research or proposed research.



PHS means the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50, Subpart F, and 45 CFR Part 94.

PHS-funded Research means research funded under PHS grants, cooperative agreements, or contracts.

Remuneration includes, for example, salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship).

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 also includes all work involving human subjects requiring Institutional Review Board approval. For purposes of this policy, *Research* additionally regards any activity for which funding is sought and/or received through an extramurally sponsored project.

Significant Financial Interest means a financial interest consisting of one or more of the following interests of the investigator and/or his/her immediate family that reasonably appear to be related to the investigator's SARC project responsibilities, including:

- With regard to interests in any publicly traded entity, a significant financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure and any equity interest (e.g., stock, stock option, or other ownership interest) in the entity as of the date of disclosure, in which the value when aggregated exceeds \$5,000;
- With regard to interests in any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, in which the value when aggregated exceeds \$5,000, or when the Investigator or his/her immediate family holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

Examples of *financial interests* that must be disclosed to the SARC Designated Individual include, but are not limited to:

- remuneration for participation in *external activities* (e.g., salary (not from advisory committees or review panels, seminars or lectures), consulting and other fees, gifts, honoraria, etc.);
- acquisition or ownership of (or an option to acquire or own) stock, shares, or other types of equity interests;



- income arising from stock, shares, and/or other types of equity interests;
- income received from royalties (e.g., for sale by volume of products, textbooks, etc.);
- income received from commercialization of intellectual property (e.g., for licenses, options, or other revenue generating activity); or
- sponsored or reimbursed travel.

Significant Financial interest does not include the following:

- Salary, income from seminars, lectures, or income from service on advisory committees or review panels.

Procedures

Responsibilities of SARC's Designated Official

The Designated Official or his/her designee shall be responsible for the following:

- Obtain a completed Financial Disclosure Form from all Investigators prior to engaging in work;
- Obtain an institutional signature on the Statement of Intent to Establish a Consortium, which certifies institution has an implemented and enforced written policy of conflicts of interest consistent with the provision of 42 CFR Part 50, Subpart F & 45 CFR Subtitle A, Part 94. If a conflict occurs, the Cooperating Institution will report to the SARC the existence of the conflict, including the project number, project title, PI (if different from the investigator with the financial interest), name of investigator with the FCOI, name of the entity with which the Investigator has an FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, findings of the review; and conclusions of the review, and specific method the Cooperating Institution adopts for addressing the conflict (managing, reducing, or eliminating it). SARC would then notify the NIH of the conflict of interest.
- Reviewing disclosures of significant financial interest with SARC's President to determine whether they are related to the subject research and, if so, whether they constitute financial conflicts of interest. In the event, the President cannot make this determination, it will be reviewed by the Board of Directors.
- Screening and managing potential financial conflict of interest.
- Maintaining all records relating to disclosures of financial interests, SARC's review of and response to such disclosures, and any related actions under this policy;
- Ensuring inclusion of any required certifications in application for funding or contract proposals; and
- Reporting and disclosure as required under this policy and applicable regulations.



For PHS-funded research, the Designated Official shall also have the following responsibility:

- Taking reasonable steps to ensure that Investigators for subrecipients (e.g., subcontractors, or collaborators) fully comply with this policy or provide SARC will sufficient assurances to enable SARC's compliance with all applicable laws or regulations.
- The Designated Official will retain financial conflicts of interest disclosure forms and other supporting information consistent with SARC Record Retention policy. For PHS-funded research, records of all financial disclosures will be retained for at least 3 years from the date of submission of the final expenditures report or final payment on the contract [42 CFR 50.604\(i\)](#).
- Investigators are expected to submit an updated Financial Conflict of Interest form during the period of the award as necessary (at least annually for PHS-funded research).

Determination and Management of Financial Conflict of Interest

If SARC determines that a financial conflict of interest exists, a financial conflict of interest management plan will be implemented and monitored on an ongoing basis. The management plan would include appropriate steps to manage, reduce, or eliminate the conflict.

Public Accessibility Requirements

- SARC's FCOI policy will be made publicly available on our public website [sarctrials.org](#)
- SARC will make publicly available any FCOI's on our public website [sarctrials.org](#)

External Reporting Requirements

SARC will disclose financial conflicts of interest as required by applicable laws or regulations as soon as they are made aware of a conflict. Within 60 days of notification of the conflict of interest SARC's Designated Official will provide an additional update to ensure that the management plan has been followed.

SARC will notify NIH promptly if there is any bias found with the design/conduct or reporting of PHS/NIH-funded research and include the requirements to submit a mitigation report to explain what actions have been or will be taken to mitigate the effects.

Confidentiality

SARC, to the extent possible, will protect the confidentiality of disclosures. Disclosures will be available to SARC staff only on a need-to-know basis and will not be disclosed outside of SARC unless necessary to comply with contractual, legal, or regulatory requirements.



Investigator Noncompliance

If an Investigator knowingly fails to comply with this policy (e.g., fails to identify an actual or potential conflict of interest), SARC may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research. In addition, for PHS-funded research, failure to comply with this policy or the applicable regulations shall result in the following:

- If the Investigator's failure to comply with this policy or financial conflicts of interest management plan has biased the design, conduct, or reporting of the PHS-funded research, SARC shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;
- SARC will make available to HHS all records pertinent to financial conflicts of interest and the management of those conflicts; and
- If HHS determines that a clinical PHS-funded research project 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 neither disclosed nor managed, SARC shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

Training and Education

Investigators and SARC staff receive training to promote objectivity in research and to ensure compliance with regard to the applicable regulations and significant financial interest disclosure obligations [42 CFR 50.604\(b\)](#). SARC requires Investigators to complete such training annually, and when any of the following occurs:

- SARC revises its financial conflicts of interest policy or procedures in any manner that affects the Investigator's obligations;
- An Investigator is new to SARC; or
- SARC finds that an Investigator is not in compliance with this policy or a financial conflict of interest management plan.

Point of Contact

If you have a conflict of interest or if you have a question to discuss, contact the SARC FCOI Designated Official.