



SRI INTERNATIONAL POLICIES, PROCEDURES AND GUIDELINES

Policy #: Ethics - 02

Policy Title: Investigator Financial Conflicts of Interest

Executive Owner: General Counsel

Policy Owner: Ethics Officer

REVISION CONTROL

By printing this document, it becomes a “Reference” copy. Users are responsible for verifying that they are using the latest revision available. An Index of Policies listing current revision number and date is available from the SRI Corporate Policies Page on the Insider through SharePoint.

When any part of this document requires amendment, the document shall be reissued in its entirety. Requests for change shall be addressed to the Document Owner.



1.0 Overview

This policy augments SRI’s general conflict of interest policy, adding specific rules to address disclosure and management of any financial conflicts of interest (“FCOIs”) of investigators performing projects funded by federal agencies requiring disclosure and management of conflicting financial interests (the “FCOI Agencies”). These include the National Science Foundation (NSF) [NSF PAPAG Chapter IX.A], the Public Health Service (PHS) (which includes the National Institutes of Health) [42 CFR Part 50, Subpart F], and the Department of Energy (DOE) [DOE FAL 2022-02].

2.0 Policy Statement

SRI’s policy is to comply with all applicable agency regulations and award conditions regarding disclosure of financial interests and management of FCOIs.

Persons identified in a FCOI Agency proposal or award as having the role of principal investigator (“PI”), project director (“PD”), co-PI, co-PD, and any other person (regardless of title or position) who is responsible for the design, conduct, or reporting of the funded research or educational activities (collectively, the “Investigators”) must disclose to SRI for review and appropriate action all “Significant Financial Interests” of the Investigator and the Investigator’s spouse and dependent children.

The PI or PD (with the guidance of the ethics officer, if needed) shall determine if any project members (other than the PI, PD, co-PI, and co-PDs) are also considered “responsible” for the design, conduct, or reporting of the research, such that they qualify as an Investigator under this policy. Agencies do not provide guidance on exactly who qualifies – the PI/PD’s reasonable judgment should be used based on the circumstances.

Significant Financial Interests are defined differently for each agency. For the purposes of simplifying reporting financial interests under this policy, SRI uses a definition that covers all reportable interests (attached as Exhibit A to this policy). However, in determining whether a Significant Financial Interest constitutes a financial conflict of interest with respect to a specific proposal or award, the ethics officer may use the specific-agency’s definition.

If an FCOI Agency-funded project uses collaborators (e.g., subrecipients, subcontractors, and consultants), SRI will take reasonable steps to ensure that the collaborator has a compliant policy in place to meet the funding agency’s requirements. If the collaborator does not have a policy, SRI will require the third party’s Investigators to follow this policy.

The SRI ethics officer is designated at SRI’s institutional official for the purposes of this policy, responsible to solicit and review disclosures of Significant Financial Interests of Investigators (and their spouses and dependent children) for determination of any FCOIs.

3.0 Responsibilities

Investigators

- If you don’t already have a financial disclosure statement on file, submit one to SRI before submitting a new proposal or joining an ongoing project that is funded by a FCOI Agency.



- Update your financial disclosure statement: (a) annually, by March 1st of each calendar year; and (b) within 30 days of obtaining a new Significant Financial Interest.
- The PI of each proposal to a FCOI Agency must review the proposed staffing plan to determine if any other persons are Investigators and identify such persons to the Contract Administrator.
- If, after award, a new person that meets the definition of Investigator is added to the project team, the PI must notify the Contract Administrator.
- Each Investigator must complete training on this policy, the Investigator's disclosure responsibilities, and the Federal regulations: (a) before engaging in FCOI Agency-funded research; (b) at least every 4 years thereafter; and (c) immediately whenever: (1) this policy is changed in a manner that impacts the requirements of Investigators; (2) the Investigator is new to SRI; or (3) SRI finds that the Investigator is not in compliance with this policy or any conflict management plan.

Contract Administrator

- For each proposal, determine (with assistance from the ethics officer, if required) if Investigator financial disclosures are required by the applicable agency rules or award conditions. If so: (a) notify the PI that they must identify to you any individuals that will be Investigators on that proposal; and (b) notify the Subcontracts Administrator.
- Before submitting a proposal to a FCOI Agency, or if notified that a new Investigator is joining an ongoing project, ensure that each Investigator has: (a) a financial disclosure form on file dated within the past 12 months; and (b) has taken FCOI training within the last 4 years. If either or both are untrue, ensure the Investigator files the required disclosure or takes the training, as necessary.
- If any Investigator's disclosure form includes a Significant Financial Interest, send the form to the Ethics Officer for review. This is required even if the same form has been reviewed in the past, because whether a Significant Financial Interest is a FCOI can depend on the specific work being proposed.
- Provide all financial conflict of interest reports and certifications as required by the client.

Contracts Strategic Services

- Obtain annual updates for each Investigator's disclosure form each year before March 1st. Report to the ethics officer any Investigators who have not timely updated their form.

Subcontract Administrator

- Obtain written assurance from each collaborator on FCOI Agency-funded proposals (i.e., subrecipients, subcontractors, and consultants) that it has in place a financial conflict of interest policy that meets the funding agency's requirements.



- If the collaborator (whether entity or individual) does not certify that it has a compliant policy: (a) provide a copy of this policy to the collaborator; (b) obtain written confirmation that the third party's investigators will follow SRI's policy; and (c) inform the Ethics Officer.

Institutional Official (Ethics Officer)

- Create training that informs each Investigator of this policy, the Investigator's disclosure responsibilities for all foreign and domestic Significant Financial Interests, and the applicable federal regulations.
- Review any Investigator's disclosure of Significant Financial Interests to determine if the interest relates to FCOI Agency research and if any financial conflict of interest exists, using the guidelines on Exhibit B. If so, develop and implement a management plan detailing what conditions or restrictions, if any, SRI should impose to manage, reduce, or eliminate such conflict of interest (e.g., requiring full public disclosure, appointment of an independent monitor, modification of the research plan, etc.). Any Significant Financial Interests disclosed at proposal time must be reviewed before proposal submission and expenditure of funds; subsequent statements (e.g., from a new Investigator to the research project, or a new SFI of an existing Investigator) must be reviewed and any required plan created within 60 days.
- Take appropriate action as necessary to manage FCOIs, including those of subrecipient Investigators, if applicable.
- Monitor compliance with conflict management plans until completion of the affected project.
- Review all Investigator disclosures of reimbursed or sponsored travel, determine if additional information is needed (including the monetary value of the travel), and determine if the travel constitutes a financial conflict of interest.
- For PHS-funded projects if an FCOI is determined to exist, submit initial, annual (i.e., ongoing), and revised FCOI reports including all required information defined in the regulation and/or NIH's FAQ H.5, through eRA Commons FCOI Module: until the end of the award or until the FCOI no longer exists: (a) prior to the expenditure of Funds; (b) within 60 days of identification for an Investigator who is newly participating in the project; (c) within 60 days for new, or newly identified, FCOIs for existing Investigators; (d) at least annually at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension), such annual report to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and (e) after a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.
- Promptly notify PHS/NIH if bias is found within the design, conduct, or reporting of PHS/NIH-funded research, including submission of a mitigation report explaining what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation. Such notification must include all of the



- reporting elements required by the regulation (e.g, entity name, name of the investigator with the FCOI, nature of SFI(s), value of the SFI(s), etc.).
- Notify NIH promptly if an Investigator fails to comply with SRI's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research, and promptly take corrective action for noncompliance with SRI's policy or the management plan.
 - For NSF-funded projects, keep the NSF Office of the General Counsel appropriately informed if: (a) a conflict of interest cannot be satisfactorily managed; and (b) if SRI finds that research will proceed without the imposition of conditions or restrictions when a conflict of interest exists.
 - Maintain all FCOI-related records relating to all Investigator disclosures of Significant Financial Interests, SRI's review of and response to such disclosures (whether or not a disclosure resulted in SRI's determination of a financial conflict of interest), and all actions taken under SRI's policy or retrospective review, for at least 3 years from submission of the final expenditure report / closeout of the project to which they relate, or until final resolution of litigation, audit, or similar action involving those records, if longer.
 - Ensure that this policy is posted on a publicly accessible SRI web site, and within SRI's Institutional Profile Module within eRA Commons. Ensure that the policy is promptly updated upon change of applicable regulations.
 - For PHS projects, make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation, not the NIH Grants Policy Statement), publicly accessible prior to the expenditure of funds. This information will: (a) include the minimum elements as provided in the regulation; (b) be made available within 5 business days of any written request; (c) include any information from annual updates; (d) include any information regarding newly identified FCOIs; and (e) remain available for 3 years from the date the information was most recently updated.
 - If a Significant Financial Interest was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed during an ongoing research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official shall, within 60 days: review the Significant Financial Interest; determine whether it is related to the funded research; and determine whether a financial conflict of interest exists. If so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward. In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by SRI to constitute a financial conflict of interest; failure by SRI 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, SRI shall, within 120 days of SRI's 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. SRI shall document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements: (1) Project number; (2) Project title; (3) PD/PI or contact PD/PI if a multiple PD/PI model is used; (4) Name of the Investigator with the FCOI; (5) Name of the entity with which the Investigator has a financial conflict of interest; (6) Reason(s) for the retrospective review; (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (8) Findings of the review; and (9) Conclusions of the review. Based on the results of the retrospective review, if appropriate, SRI shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, SRI shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and SRI's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., 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, SRI will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, SRI may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of SRI's retrospective review.

- 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 SRI as required under the regulations, 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.

4.0 Enforcement

Violations of the policy must be reported to the SRI Ethics Officer, and may be made via SRI's ethics hotline. Non-compliance may result in disciplinary action, up to and including termination.

5.0 Exceptions

No exceptions to this policy are permitted.

6.0 Policy Review

This Policy will be reviewed periodically and updated as appropriate.



Exhibit A: Definition of “Significant Financial Interest”

Significant Financial Interest means anything of monetary value, whether or not the value is readily ascertainable, consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that either:

- (a) reasonably appears to be related to the Investigator's SRI responsibilities; or
- (b) reasonably appear to be affected by the research or educational activities funded or proposed for funding or are in entities whose financial interests would reasonably appear to be affected by such activities.

The term Significant Financial Interest includes:

- (a) With regard to any foreign or domestic 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;
- (b) With regard to any foreign or domestic 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); and
- (c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

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 of the U.S., a domestic (U.S.) Institution of higher education as defined at 20 U.S.C. 1001(a), or a domestic (U.S.) research institute that is affiliated with a domestic Institution of higher education. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

The term Significant Financial Interest does not include the following types of financial interests:

- (a) salary, royalties, or other remuneration paid by SRI to the Investigator if the Investigator is currently employed or otherwise appointed by SRI, including



- intellectual property rights assigned to SRI and agreements to share in royalties related to such rights;
- (b) 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 of the U.S., a domestic (U.S.) Institution of higher education as defined at 20 U.S.C. 1001(a), or a domestic (U.S.) research institute that is affiliated with a domestic (U.S.) Institution of higher education; and
 - (c) income from service on advisory committees or review panels for a Federal, state, or local government agency of the U.S., a domestic (U.S.) Institution of higher education as defined at 20 U.S.C. 1001(a), or a domestic (U.S.) research institute that is affiliated with a domestic (U.S.) Institution of higher education.



Exhibit B: Guidelines for Determinations

The following guidelines are for use of the designated institutional official(s) to determine whether an Investigator's SFI is related to FCOI-agency funded research and, if so related, whether the SFI is an FCOI.

An SFI is related to funded research when SRI, through its designated official(s), reasonably determines that the SFI:

- could be affected by the funded research; or
- is in an entity whose financial interest could be affected by the research.

The Investigator may be involved in making the determination of whether the SFI is related to the research.

An FCOI exists when SRI, through its designated official(s), reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the funded research. The following (non-exhaustive) list of factors may be considered in making that determination:

- What is the value of the SFI?
 - Equity or cash interests?
 - Consistent or fluctuating over time?
 - Comparison of the value of the SFI to the Investigator's compensation from SRI
- Likelihood of Influence
 - What is the Investigator's role in the project?
 - Is the project one part of a larger study or research endeavor?
 - Are there already safeguards in the project design to mitigate any influence?
- Relationship between the SFI and the Research
 - How could the SFI or the entity's financial interests be impacted by or influence the design, conduct, or reporting of the research?
 - Is the entity in which the SFI is held involved in the research itself (e.g., as a collaborator, subcontractor, or vendor)
 - Is the entity a funder of other research at SRI, a donor to SRI, or have any other relationship with SRI, independent of this research project?