SRNT
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1.13 Policy on Financial COI as related to NIH R13 Grants

SRNT promotes objectivity in the presentation of research at its Annual Meeting by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research presented will be free from bias by any conflicting financial interest of the PD/PI and any other person, regardless of title or position, who is responsible for the design of the conference program and selection of content to be presented.

In addition to the development of the program on the part of the PI and co-investigators, all lead authors of accepted abstracts must complete conflict of interest disclosures as part of SRNT's CME process.

The design of the program and selection of content to be presented will not be biased by any conflicting financial interest of those investigators responsible for the research. This policy applies to the project director or principal investigator and any other person, regardless of title or position, the institution determines is responsible for the design of the conference program and selection of content to be presented.

SRNT has in effect an up to date, written and enforced administrative process and policy to identify and manage FCOI.

SRNT's Financial COI Policy is available at www.srnt.org and will be submitted as part of any NIH grant application through the eRA Commons.

SRNT will educate the grant investigators about the FCOI regulation, the Institution's policy, and the Investigator's responsibility to fully disclose all domestic and foreign SFIs (and those of their spouse and dependent children) that are related to their responsibilities as an R13 grant investigator for SRNT.

Investigators must disclose all domestic and foreign SFIs that are related to their responsibilities as an R13 grant investigator for SRNT. Disclosure of foreign financial interests differs from disclosure of domestic financial interests. Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000).

SRNT will review each Investigator SFI disclosure to determine if a SFI is:

- related to the Investigator's NIH-funded research, and
- a FCOI. An SFI is considered a FCOI when the SFI could directly and significantly (i.e., have a material effect) affect the design, conduct, or reporting of the NIH-funded conference grant.

If SRNT determines that an FCOI exits, SRNT will report to the NIH awarding Institute or Center through the submission of an initial (Original) and annual FCOI report through the eRA Commons. SRNT will also manage any identified FCOI by removing the individual from their role as an R13 Investigator.

SRNT will maintain records of and, when requested, will promptly make available to the NIH relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in SRNT's determination of an FCOI.

1.13A SRNT policy and process to identify and manage FCOIs

SRNT requires Program Committee Co-Chairs/R13 Grant Administrators to declare any and all domestic (US) or foreign financial conflicts of interest.

SRNT will review any such conflicts to determine if they have an impact on the Investigator's ability to contribute to the design of the SRNT program content. If SRNT determines that an FCOI exits, SRNT will report to the NIH awarding Institute or Center through the submission of an initial (Original) and annual FCOI report through the eRA Commons. SRNT will also manage any identified FCOI by removing the individual from their role as an R13 Investigator.

SRNT will maintain records of and, when requested, will promptly make available to the NIH relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in SRNT's determination of an FCOI.

1.13B Policy for reporting SRNT R13 Investigator COIs

SRNT will report to NIH the names of all Investigators and any/all financial COIs, including the name of the entity with which the investigator has an FCOI; the nature of the Significant Financial Interest (SFI); the value of the financial interest; a description of how the financial interest relates to the NIH-funded research and why SRNT determined that the financial interest conflicts with designing the SRNT conference program, and a description of the key elements of the institution's management plan, including other required information.

If no financial COI exists, SRNT will so report.

1.13C SRNT R13 Investigator FCOI Report, to be completed by all R13 Investigators

SRNT will develop a financial disclosure form for use in FCOI disclosure requirements. The financial disclosure form will be used by "Investigators" to disclose their SFIs (i.e., domestic and foreign) to the Institution's designated official(s) typically to determine if the SFI is related to an Investigator's NIH-funded research and if there is an FCOI. The following will be included

• Investigator's name

• Entity name in which the Investigator (and spouse and dependent children) has an SFI

• Disclosure requirement that is consistent with the institution's definition of SFI

• Disclosure of financial interests in the 12 months preceding the disclosure and value of each equity interest as of the date of disclosure

• Disclosure of intellectual property (IP) rights and interests (e.g., patents, copyrights), upon the receipt of income related to such rights and interests.

• Disclosure of reimbursed or sponsored travel. The policy will specify the details of such disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

• Clarify that disclosure is required for all financial interests received from foreign institutions of higher education or the government of another country when such income meets the threshold for disclosure (e.g., income in excess of $5,000)

• The value of the SFI.

• Indicate whether the SFI is from a publicly traded or non-publicly traded entity. Also note that disclosure requirements for equity interest differ for each.

• Describe the nature of the SFI (e.g., salary, royalties, consulting fees, honoraria, paid authorship, reimbursed or sponsored travel).

• Indicate whether the SFI is related to any NIH application or NIH-funded project and an explanation for the relatedness to assist with the institution's designated official(s) review.

SRNT's designated official will make the determination whether the SFI is an FCOI (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research). Per the preamble in the Final Rule (page 53261), "significantly" means "…the financial interest would have a 'material effect on the research'…".

1.13D SRNT will:

- Solicit and review financial disclosures of Investigators that are reasonably related to an Investigator's responsibilities to SRNT performed on behalf of SRNT;
- Provide FCOI training to Investigators about the FCOI regulation, the institution's FCOI policy and the Investigator disclosure requirements per the institution's FCOI policy;
- Determine whether an Investigator's SFI is related to the NIH-funded research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest can be affected by the research) and, if so related, whether the SFI is a FCOI (i.e., an SFI that could directly and significantly affect the design, conduct or reporting of the PHS/NIH-funded research);

- Develop and implement management plans, as needed to manage FCOIs for awardee Investigators and subrecipient Investigators, if applicable, and monitor Investigator compliance with the plan;
- Submit Original and annual FCOI reports to the NIH via the eRA Commons FCOI Module;
- Complete retrospective reviews when there is noncompliance with SRNT's policy or the FCOI regulation and update any previously submitted FCOI report, if required, after the retrospective review is complete;
- Submit mitigation reports when bias is found in NIH-supported research following the completion of the retrospective review;
- Maintain FCOI-related records and for 10 years per the FCOI regulation and grant regulation

1.13D Training Process:

1. SRNT will inform investigators of: SRNT's FCOI policy; Investigator's disclosure responsibilities of all foreign and domestic significant financial interests (SFI) per the SFI definition and NIH's FAQs E.9. and E.20. or the institution's disclosure requirements if more restrictive; Federal regulation, "FCOI Training" tutorial and other training resources on NIH's FCOI Training website
2. SRNT will require each NIH-supported Investigator to complete FCOI training: Prior to engaging in research related to any NIH-funded grant; At least every four (4) years; Immediately, if: SRNT revises its FCOI policy that affects requirements of Investigators or an Investigator is new to SRNT or an Investigator is not in compliance with the policy or management plan.

1.13E Disclosure, Review and Monitoring

1. Each Investigator is required to disclose their foreign and domestic Significant Financial Interests (SFIs) (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities2 (e.g., research, research consultation, teaching, professional practice, etc.) that meet the regulatory definition of SFI: No later than at the time of application for NIH-funded research or at least annually during the period of the award or within thirty (30) days of discovering or acquiring a new SFI.
2. SRNT will designate an official to: Solicit and review Investigator SFI disclosures (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities for a determination of FCOI.
3. SRNT will provide adequate guidelines consistent with the regulation for the designated institutional official to determine whether an Investigator's SFI is related to PHS/NIH-funded research and, if so related, whether the SFI is an FCOI. *NOTE*: *An SFI is related to PHS/NIH-funded research when the Institution through its designated official(s), reasonably determines that the SFI could be affected by the PHS/NIH-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 PHS/NIH-funded research. An FCOI exists when the Institution, through its designated official(s), reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.

4. SRNT will include the examples of conditions or restrictions that might be imposed to manage conflicts of interest (e.g., full public disclosure, appointment of an independent monitor, modification of the research plan, etc.). Adding additional conditions to manage an FCOI is at SRNT's discretion.
5. SRNT will require the designated official(s), prior to Institution's expenditure of funds, to: Review all Investigator SFI disclosures; Determine if any SFIs relate to the Investigator's NIH-funded research; Determine if an FCOI exists (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research); Develop and implement a management plan to manage the FCOI(s).
6. SRNT will require when an Investigator who is new to participating in the research project or when an existing Investigator discloses a new SFI, the institution's designated official to review within sixty (60) days disclosures of SFIs, determine whether the SFI is related to the Investigator's NIH-funded research; determine whether an FCOI exists; and, 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 the FCOI.
7. Whenever SRNT identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official will review within sixty (60) days disclosures of SFIs, determine whether the SFI is related to the Investigator's NIH-funded research; determine whether an FCOI exists; and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage the FCOI going forward.
8. SRNT will take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.

1.13F Reporting to NIH

1. SRNT will send initial, annual and revised FCOI reports for the Institution's Investigators and those of its subrecipients, if applicable, including all required information defined in the regulation and in NIH's FAQ H.5, to the NIH via the eRA Commons FCOI Module, as required by the regulation and as stated below: Prior to the expenditure of funds; Within sixty (60) days of identification for an Investigator who is newly participating in the project; Within sixty (60) days for new, or newly identified, FCOIs for existing Investigators; 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). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; After a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.
2. Based on the results of a retrospective review, SRNT will notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and submit the required Mitigation Report. The Mitigation report includes the key elements of the Retrospective review plus information to explain what action(s) have been or will be taken to mitigate the effects of the bias (i.e., a description of the impact of the bias on the research

project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.

3. SRNT will notify NIH promptly if an Investigator (or subrecipient Investigator) fails to comply with the Institution's FCOI policy or noncompliance with a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research. SRNT will promptly notify NIH and take corrective action for noncompliance with the policy or the management plan.
4. SRNT will maintain all FCOI-related records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under SRNT's policy or retrospective review, if applicable: for at least three (3) years from the date the final expenditures report (Final Federal Financial Report) is submitted. or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

1.13G Enforcement Mechanisms and Remedies and Noncompliance

1. SRNT will establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance (e.g., letters of reprimand, restriction on the use of funds, etc.).
2. SRNT will complete a retrospective review (see FAQs in Section I) within 120 days of the Institution's determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including: Failure by the Investigator to disclose an SFI that is determined by the Institution to constitute a financial conflict of interest; Failure by the Institution to review or manage such a financial conflict of interest; Failure by the Investigator to comply with the financial conflict of interest management plan.
3. SRNT will document the retrospective review which shall include at a minimum the following key elements: Project Number Project Title PD/PI or contact PD/PI if multiple PD/PI model is used; Name of the Investigator with the FCOI; Name of the entity with which the Investigator has an FCOI; Reasons for the retrospective review; Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed); Findings of the review; and Conclusions of the review.
4. SRNT will ensure that in any case in which the Department of Health and Human Services determines that an NIH-funded research 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 an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to: Disclose the FCOI in each public presentation of the results of the research, and Request an addendum to previously published presentations.

1.13H Subrecipient Requirements

SRNT does not generally have subrecipients. However, if it does, SRNT will

1. Address FCOI subrecipient requirements including compliance with NIH subaward/consortium written agreement requirements provided in the NIH Grants Policy Statement Section;
2. Establish, via a written agreement, whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient. Obtain a certification from

the subrecipient that its FCOI policy complies with the regulation. Include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the awardee Institution to report identified FCOIs to the NIH as required by the regulation. Alternatively, SRNT will include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee Institution to identify, manage and report identified FCOIs to the NIH.

1.13I Public Accessibility

1. SRNT's FCOI policy will be publicly accessible on the SRNT's public Web site.
2. SRNT will 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. The publicly accessible information will: Include the minimum elements as provided in the regulation Be posted on SRNT's Public Website or made available within five (5) business days of a written request. Be updated, at least annually. Be updated, within sixty (60) days of a newly identified FCOI. Remain available for three (3) years from the date the information was most recently updated.

Additional information about the CHECKLIST FOR POLICY DEVELOPMENT RELATED TO THE 2011 FINANCIAL CONFLICT OF INTEREST (FCOI) REGULATION, PROMOTING OBJECTIVITY IN RESEARCH can be found at https://grants.nih.gov/grants/policy/coi/FCOI-Policy-Development-Checklist.pdf