RESEARCH FINANCIAL CONFLICT OF INTEREST (FCOI) PROCEDURE

I. PURPOSE

To establish standards to promote objectivity in research and to ensure the design, conduct, or reporting of research will be free from bias resulting from a FCOI.

II. SCOPE

This applies to all investigators, grant project Directors, contractors, subrecipient grantees, collaborators, Board of Directors, vendors, contractual partners, direct hire employees, civil service, and Commissioned Corps officers working under contractual agreements with SCF who participate in, or planning to participate in, cooperative agreements or grants for research.

III. DEFINITIONS

A. Awarding entity: An organization that provides grant funding for research or other projects or initiatives and specifies the conditions for receiving the funding.

   1. Awarding entities include but are not limited to Public Health Service (PHS) agencies or components.

B. Cooperative agreements: A financial assistance mechanism similar to a grant but involves substantial and active involvement of the funder during the performance of the project.

   1. The nature of that involvement will always be specified in the offering or application guidance materials.

C. Equity interest: A proportion of ownership, typically via investment in a business.

   1. Stocks are also known as equities.

D. Financial conflict of interest (FCOI): For purposes of this procedure, means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

E. FCOI management plan: A plan taking action to address a FCOI which can include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct, and reporting of research is free from bias.

F. FCOI report: An institution's report of a FCOI to a PHS awarding agency including, the Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institute of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMHSA).

G. Financial interest: Anything of monetary value, whether or not the value is readily ascertainable.

H. Honoraria: A payment or fee rendered in recognition of SCF employee services made prior to the institution of salaries and does not have a predetermined value.

I. Institution: Any domestic, foreign, public, or private entity or organization that is applying for or receives PHS research funding.

    1. For purposes of this procedure, SCF is the institution.

J. Investigator: The project director or principal investigator (PD/PI) and any other individual, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

K. Investigator's institutional responsibilities: An investigator's professional responsibilities on behalf of the institution, which may include, for example, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

L. Public Health Service (PHS): The PHS of the U.S. Department of Health and Human Services (DHHS)), and any components of the PHS to which DHHS authority may be delegated, including HRSA, IHS, NIH, and SAMHSA.

M. Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

    1. Activities that meet this definition constitute research for purposes of this procedure whether or not they are conducted or supported under a program that is considered research for other purposes.

a. For example, some demonstration and service programs may include research activities and, for purposes of this part, the following activities are deemed not to be research:

i. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.

ii. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority including activities such as:

1) Activities that are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products).

2) Include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

N. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

O. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

P. Research Integrity Officer (RIO): Designated institutional official responsible for ensuring SCF has policies and procedures for inquiring into and investigating allegations of research misconduct and responsible conduct of research as described in 42 CFR Part §93.301(b).

1. The designated RIO at SCF is the Director of Corporate Compliance.

Q. Senior/key personnel: For the purpose of this procedure, is the PD/PI and any other individual identified as senior/key personnel by SCF in the grant application, progress report, or any other report submitted to the PHS by SCF.

R. Significant financial interest (SFI): A financial interest consisting of one (1) or more of the following interests of the investigator, the investigator's spouse, or the investigator's dependent children, that reasonably appear to be related to the investigator's SCF responsibilities:

1. With regard to any publicly traded entity, an SFI exists:

    a. If the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds five thousand dollars ($5,000).

    b. 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 include any stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value.

2. With regard to any non-publicly traded entity, an SFI exists:

    a. If the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds five thousand dollars ($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).

3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

4. Any reimbursed or sponsored travel, 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, and is related to the Investigator's institutional responsibilities; provided, however, it does not include travel that is reimbursed or sponsored by a local, state, or federal government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

    a. Such disclosures will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

b. SCF will determine if further information is needed, including a determination or disclosure of monetary value in order to determine whether the travel constitutes a FCOI.

5. An SFI does not include the following types of financial interests:

a. Salary, royalties, or other remuneration paid by SCF to the investigator as a current member of its workforce, including intellectual property rights assigned to SCF and related royalty sharing.

b. Income from investments in mutual funds, retirement accounts, or similar accounts as long as the investigator does not control the investment decisions made for these accounts.

c. Income from seminars, lectures, or teaching engagements sponsored by a local, state, or federal government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institute of higher education.

d. Income from service on advisory committees or review panels for local, state, or federal government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

S. Sub-recipient: A non-federal entity that receives a sub-award from a pass-through entity to carry out part of a federal program; but does not include an individual that is a beneficiary of such program.

1. A sub-recipient may also be a recipient of other federal awards directly from a federal awarding agency.

T. Workforce: Includes all direct hire employees, civil service, and Commissioned Corps officers working under contractual agreements with SCF, volunteers, trainees, residents, interns, students, and other individuals whose conduct, in the performance of work for SCF is under the direct control of SCF, whether or not they are compensated by SCF.

IV. PROCEDURE

A. Training Requirements

1. The SCF Research department will inform investigators of the SCF *Research Financial Conflict of Interest (FCOI) Procedure* which includes the

investigator's institutional responsibilities regarding disclosure of SFI, the applicable regulations, and Research FCOI training requirements:

a. Prior to engaging in research related to any PHS-funded grant.

b. During Annual Reorientation.

c. Immediately when any of the following occurs:

i. SCF revises its Research FCOI Procedure.

ii. An investigator is new to SCF.

iii. SCF finds that an investigator is not in compliance with SCF's *Research Financial Conflict of Interest (FCOI) Procedure* or a FCOI management plan.

B. FCOI Disclosure Responsibilities

1. Investigators have an ongoing obligation and are required to disclose SFI, and those of the investigator's spouse and dependent children, who reasonably appear to be related to the investigator's institutional responsibilities throughout the awarded project period:

a. No later than at the time of application for PHS-funded research.

b. Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

c. At least annually, or in accordance with a time period prescribed by SCF during the period of award.

2. Disclosures may be made on a form provided by SCF or comparable FCOI disclosure form.

a. Disclosure forms will include at a minimum:

i. The investigator's name and role

ii. Project number, e.g., grant number or number specific to funding source.

iii. Project title

iv. Description of the SFI, if any

v. Name of the entity or entities with which the investigator has an SFI.

3. If SCF is not the main recipient of the funding grant, SCF will use the form provided by the external partner and follow their process on disclosures to their institution.

C. Review and Monitoring

1. The SCF Director of Research, Data, and Evaluation Services, or their designee, is the institutional official designated to solicit and review all investigator disclosures to determine if:

   a. An SFI is disclosed.

   b. The SFI relates to PHS-funded research.

   c. A potential FCOI exists.

2. Any disclosure with a potential FCOI will be referred to the RIO.

3. The RIO, or their designee, will review the disclosure of the SFI and make a determination of a FCOI.

4. Where a FCOI exists, the RIO will notify the Director of Research, Data, and Evaluation Services and the Director Grants of the FCOI, and when possible, prior to any expenditure of PHS awards/funds.

5. The RIO will work with the investigator (including a sub-recipient investigator) who has the FCOI to manage, reduce, or eliminatethe FCOI by developing a FCOI management plan.

   a. FCOI management plans may include but is not limited to:

      i. Public disclosure of the SFI

      ii. Disclosure of the FCOI directly to participants for research projects involving human subjects.

      iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from a FCOI.

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. The conflicted investigator may be required to reduce or divest themselves of the SFI.

vii. Sever the relationships that create the FCOI.

viii. Actions taken will be commensurate with the severity and impact of the identified conflict.

6. Where an investigator discloses a new SFI during a research project, where an investigator who is new to an ongoing research project discloses a SFI, or the SFI was not previously reviewed, the RIO will implement an interim management plan to take appropriate interim measures with regard to the investigator's project participation until the RIO makes a determination of a FCOI.

7. Whenever a FCOI management plan is implemented, the RIO, Director of Research, Data, and Evaluation Services and Director Grants will monitor investigator compliance with the management plan on an ongoing basis until the completion of the project.

   a. If a FCOI is not identified or managed in a timely manner, or an investigator fails to comply with a FCOI management plan, SCF will complete a retrospective review of the investigator's activities within one hundred and twenty (120) days of the determination of non-compliance.

   b. If the identified FCOI is found to have biased the results of a research project, it will be investigated as research misconduct in accordance with SCF's *Allegations of Research and/or Scientific Misconduct Procedure*.

D. Reporting Requirements

1. The RIO will prepare a report documenting the FCOI and the FCOI management plan.

2. The report will include sufficient information about SCF and any sub-recipient investigators to allow the awarding entity to understand the nature and extent of the FCOI and to assess the appropriateness of SCF's FCOI management plan.

3. Reports will include at least the following:

    a. Project number

    b. PD/PI or contact PD/PI if multiple PD/PI

    c. Name of the investigator with the FCOI

    d. Name of the entity with which the investigator has a FCOI.

    e. Nature of the SFI (e.g., equity, consulting fee, travel reimbursement, honorarium)

    f. The value of the SFI or a statement that the interest is one whose value cannot be readily determined.

    g. A description of how the SFI relates to the PHS-funded research and basis for SCF's determination that a FCOI exists.

    h. A description of the key elements of SCF's FCOI management plan to include:

        i. Role and principal duties of the conflicted investigator in the project.

        ii. Conditions of the FCOI management plan.

        iii. How the FCOI management plan is designed to safeguard objectivity in the research project.

        iv. Confirmation of the conflicted investigator's agreement with the FCOI management plan.

        v. How the FCOI management plan will be monitored.

        vi. Other information as needed.

4. For retrospective reviews, the report will also include:

    a. Reason for the retrospective review

    b. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)

c. Findings of the review

d. Conclusions of the review

5. Additional reporting requirements may be required by a particular awarding entity.

6. The RIO will submit the initial FCOI report and any subsequent reports to the Director of Research, Data, and Evaluation Services and Director Grants.

7. The Director Grants, or their designee, will submit FCOI reports to the awarding entity:

   a. When possible, prior to SCF's expenditure of any PHS funds if SCF has not eliminated the FCOI prior to expending PHS funds.

   b. For any FCOI identified subsequent to an initial FCOI report within sixty (60) days of identifying the FCOI.

   c. Annually with the annual progress report or multi-year progress report, if applicable.

   d. Following a retrospective review of a previously submitted report, if appropriate.

   e. Promptly if an investigator fails to comply with SCF's *Research Financial Conflict of Interest (FCOI) Procedure* or a FCOI management plan, or appears to have biased the design, conduct, or reporting of the PHS funded research.

8. Additional information may be provided to the awarding entity's grants management officer upon request.

E. Maintenance of Records

1. Training records and FCOI disclosure forms will be tracked and maintained by the Research department.

   b. One FCOI form per Research department employee will be completed

      i. All current projects will be listed on or attached to the form

      ii. Research department employees must report FCOI to any current projects.

c. FCOI documentation will be reviewed by the Research department annually

i. If a project starts mid-year, only staff assigned to the project will be asked if they have any FCOI's with the new project to report.

ii. FCOI's for those employees will be updated to list the new project and FCOI's

2. FCOI management plans and related documents will be maintained by the RIO.

3. All reports, including FCOI reports, and related correspondence between the funding entity and SCF will be maintained by the Planning and Grants department.

4. Records must be maintained for a period of at least three (3) years following the final expenditures report for the applicable PHS research/grant or per the requirement of the grant.

F. Subrecipient Requirements

1. When SCF carries out PHS-funded research through a subrecipient, SCF will take reasonable steps to ensure that any subrecipient investigator complies with this procedure by:

a. Establishing if the subrecipient will comply with SCF's *Research Financial Conflict of Interest (FCOI) Procedure* or that of the subrecipient as part of the written agreement with the subrecipient.

i. If the subrecipient investigators choose to comply with the subrecipient's FCOI policy or procedure, the subrecipient will certify compliance with its policy and procedure in the written agreement.

b. Including the time period(s) for the subrecipient to report any FCOIs to SCF.

2. When SCF participates in PHS-funded research as a subrecipient of another institution, SCF will specify in the subrecipient agreement whether it will comply with this procedure or that of other institution.

G. Public Accessibility

1. SCF will post this procedure on its public website and will make available all regulatory required elements pertaining to identified FCOIs held by senior/key personnel prior to expenditure of PHS funds, whenever possible.

    a. This information will be updated at least annually or within sixty (60) days of a newly identified FCOI; and will remain available for three (3) years from the date the information was most recently updated.

H. Any member of the workforce who violates this procedure may be subject to corrective actions, up to and including termination.

V. REFERENCES

A. 21 Code of Federal Regulations (CFR) Part 54- Financial Disclosures by Clinical Investigators

B. 42 CFR Part 50 Subpart F - NIH Check list for Policy Development, related to the 2011 revised Conflict of Interest Regulations Promoting Objectivity in Research

C. 42 CFR Part 93 Subpart C – Responsibilities of Institutions, Compliance and Assurances

D. 45 CFR Part 94 - Responsible Prospective Contractors

E. Allegations of Research and/or Scientific Misconduct Procedure

F. Corrective Action Procedure

G. NIH Grants Policy 15.2.1

H. Research Policy

VI. ATTACHMENTS

A. SCF Research FCIO Disclosure Form

B. SCF Research FCOI Subrecipient - Consultant - Contractor Commitment Form

C. SCF Research FCOI Subrecipient - Consultant - Contractor Attestation Form