



Objectivity in Research: POLICY ON FINANCIAL DISCLOSURE and FINANCIAL CONFLICTS OF INTEREST IN RESEARCH

Purpose: To establish standards that provide a reasonable expectation that the design, conduct or reporting of research conducted at NDRI will be free from bias resulting from Investigator financial conflicts of interest, and to comply with federal regulations (21 CFR Part 54, 42 CFR Parts 50, Subpart F and 93, and 45 CFR Parts 94).

Policy Overview: All research under the auspices of SSIC (“SSIC” refers to Social Sciences Innovations Corporation) must be designed, conducted and reported objectively and free from bias resulting from Investigator financial conflicts of interest. This policy pertains to employees, sub-contractors, consultants, collaborators, voluntary staff, students, and others who are involved in the design, conduct, review or reporting of research conducted at SSIC and under the agency auspices. SSIC has established the following requirements in the areas of: Financial Conflict of Interest (FCOI) training; FCOI disclosure, review and monitoring; reporting to sponsors; enforcement mechanisms and remedies for noncompliance; sub-recipient terms and conditions; and public accessibility.

Policy: The Board of Directors, administration, and staff of Social Sciences Innovations Corporation (SSIC) all bear the responsibility of serving the research mission of SSIC. That mission is enhanced by the sustained, active interaction of members of SSIC with business, government, not-for-profit groups, professional societies, academic institutions, and other individuals and organizations. Moreover, SSIC recognizes that the members of SSIC participate actively in community, political, religious, and cultural activities and institutions, and other personal and economic endeavors.

These many interactions inherently create the potential for conflicts of interest in which SSIC employees’ external activities, income or other interests affect—or reasonably would appear to affect—the manner or extent to which those individuals pursue research or other Institutional Responsibilities within SSIC. Such real or apparent conflicts, when not appropriately disclosed and addressed, can undermine public and professional confidence in the integrity of SSIC research and sponsored programs. The existence of a real or apparent conflict of interest does not necessarily mean that the outside activity at issue must be avoided or discontinued.

Often, conflicts of interest can be dealt with effectively through disclosure or other steps to resolve or manage the conflict.

This document sets forth SSIC policy on the disclosure, management, and resolution of financial conflicts of interest regarding SSIC research and other Institutional Responsibilities. Recognizing the broad variety of both professional settings in which conflicts may occur and means of responding to them, this policy specifies only the basic principles that should guide the resolution of financial conflicts of interest. This Policy includes the requirements necessary to conform to federal law regarding financial conflicts of interest in federally funded research, including the conflicts of interest regulations issued by the U.S. Department of Health and Human Services Public Health Service (“PHS”).

This document addresses financial conflicts of interest related to Institutional Responsibilities, including research, whether externally sponsored or internally funded, and sponsored programs.

1. Applicability

This Policy applies to all persons at SSIC who are “Investigators” on SSIC research projects or sponsored programs, as defined in Section 2 below. Additionally, it applies to key staff, sub-contractors, consultants, collaborators, voluntary staff, students, and others who are involved in the design, conduct, review or reporting of research conducted at SSIC and under the agency auspices.

2. Definitions

a. A “Conflict of Interest” means a Significant Financial Interest that could directly affect Institutional Responsibilities, including the design, conduct, or reporting of Research.

b. “Dependent” is defined as any person who receives more than one-half of his or her annual support from an Investigator, whether or not related to that Investigator.

c. “Family Members” are defined as the Investigator’s spouse or domestic partner and Dependents.

d. “Significant Financial Interest” is defined as anything of monetary value, whether or not the value is readily ascertainable, including, but not limited to, salary, commissions, consulting fees, honoraria, equity interests, interests in real or personal property, dividends, royalties, rent, capital gains, and intellectual property rights, other than:

- compensation from SSIC;
- income from seminars, lectures, or other educational activities 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;

- income from service on advisory committees, or review panels for a public 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 mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions.

e. “SSIC” shall refer to Social Sciences Innovations Corporation.

f. “Investigator” means SSIC staff who have responsibility for the design, conduct, review or reporting of research conducted at SSIC and under the agency auspices. It also applies to any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research funded by the PHS or other federal agencies, or proposed for such funding which may include, for example, collaborators, consultants, or sub-contractors.

g. “Research” means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development and any activity for which research funding is available from a PHS Awarding Component.

h. “Significant Financial Interest” means one or more of the following Financial Interests of the Investigator (and those of the Investigator’s Family Members) that reasonably appear to be related to the Investigator’s Institutional Responsibilities:

- With regard to any publicly traded entity, it is 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, the value of which exceeds \$5,000 from one enterprise or entity;
- With regard to any non-publicly traded/private entity, it is the value of remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator holds any equity interest;
- Intellectual property rights and interests, upon receipt of more than \$5,000 income related to such rights and interests;
- Salary, remuneration, or similar payments which exceed, or are expected to exceed, \$5,000 within any one-year period, when aggregated for the member and his or her Family Members; or,
- Any reimbursed or sponsored travel, related to an Investigator’s SSIC Responsibilities; provided, however, that Investigators need not disclose 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 institution that is affiliated with an Institution of higher education.

i. "Sponsored Program" means projects or activities, other than Research, undertaken within SSIC pursuant to funding from an external source.

j. "SSIC "Institutional Responsibilities" are defined as the responsibilities of an Investigator to perform activities that are undertaken directly to fulfill one's research, training, technical assistance, membership on institutional committees, research administration, or other service responsibilities within SSIC.

k. "SSIC Official" is the Executive Director who provides oversight in the solicitation and review of disclosures of Significant Financial Interests from Investigators, as well as the resolution of any FCOI. The Financial Conflict of Interest Officer will review disclosures and convene a COI Committee to develop management plan(s) for any FCOI. The FCOI Officer administers the duties outlined in applicable federal regulations.

3. Responsibility of Investigators

a. Investigators who are covered by this Policy share an obligation to insure that the design, conduct or reporting of research conducted at SSIC will be free from bias resulting from Investigator financial conflicts of interest and to conduct their relationships with each other and with SSIC with candor and integrity.

b. Pursuant to that obligation, Investigators share an obligation to identify and, when possible, avoid financial conflicts of interest. When conflicts cannot be avoided, Investigators must disclose outside financial relationships that are related to the Investigator's SSIC Institutional Responsibilities (IR) and work with SSIC officials to manage or resolve those conflicts.

c. Accordingly, Investigators must disclose any Significant Financial Interest of themselves or their Family Members that are related to the Investigator's SSIC IR, and any Significant Financial Interest of themselves or their Family Members in external companies or other organizations whose financial interests could appear to affect, or be affected by, their SSIC IR.

d. Disclosures under this Policy shall be made as soon as possible after a Significant Financial Interest that meets the disclosure standard arises. Disclosure shall be made according to the processes established by the SSIC Official.

e. If any application for external funding is involved, Investigators shall ensure that they have disclosed all Significant Financial Interests related to their SSIC Institutional Responsibilities prior to submitting the application to the applicable SSIC grant management office, and as soon as possible thereafter if a new Significant Financial Interest meeting the disclosure standard arises. Disclosures shall also be updated as soon as possible when an existing Significant Financial Interest ends or materially alters. The SSIC Disclosure Form and Transmittal Form for disclosure related to a grant submission are found on the SSIC intranet and are accessible to all staff.

4. Federally Funded Research

This policy fulfills federal regulations requiring institutions receiving federal funding to have in place a written, enforced policy and process to identify and manage, reduce, or eliminate conflicts of interest of persons engaged in the design, conduct, or reporting of federally funded Research.

In addition, to satisfying applicable requirements of federal law, Investigators must complete training prior to engaging in any Research related to any PHS-funded grant or contract in accordance with 42 C.F.R. Part 50.601 et seq.

5. Disclosure Policies and Procedures

a. Disclosure shall be made to the SSIC FCOI Officer pursuant to the applicable procedures on conflicts of interest. These procedures shall be designed to facilitate the local resolution or management of any conflict, and minimize administrative burden.

b. All such procedures shall be consistent with the following:

i. It is the obligation of each Investigator to disclose all Significant Financial Interests related to their SSIC Institutional Responsibilities.

ii. Investigators shall disclose annually all Significant Financial Interests that meet the standards of Section 3(c) above, and they shall update these disclosures within the annual period and within thirty days of (a) acquiring a new Significant Financial Interest that reasonably would appear to affect or be affected by their SSIC Responsibilities, or (b) the end or material alteration of an existing Significant Financial Interest; or (c) prior to submission of a PHS-funded grant proposal. .

iii. Investigators shall not be subject to burdensome or random disclosure requirements; however, this shall not restrict the use of disclosure as a tool for avoiding, resolving, or managing an on-going Conflict of Interest or the compliance with annual monitoring by the SSIC Official or designee.

iv. Disclosure shall be made to the SSIC FCOI Officer designated by the applicable procedures on conflicts of interest. Disclosure policies should require no more information than is necessary.

v. Disclosure should not be part of the collection of unrelated data (*e.g.*, annual reports). Disclosure documents shall be destroyed as soon as appropriate and in accordance with applicable legal requirements.

c. The SSIC FCOI Officer will determine whether an Investigator's Significant Financial Interest is related to his or her Research or Sponsored Programs activities and, if so, whether the Significant Financial Interest is a Conflict of Interest. The FCOI Officer may engage an SSIC FCOI Committee for final determination.

d. A Significant Financial Interest is related to Research or Sponsored Programs activities when the SSIC, through its SSIC Official, reasonably determines that the Significant Financial Interest:

- i. Could be affected by the Research or Sponsored Program activity; or,
- ii. Is in an entity whose financial interest could be affected by the Research or Sponsored Program activity.

6. Conflict Resolution and Management

a. Conflicts of Interest shall be avoided, resolved, or managed, as needed, pursuant to applicable policies and procedures on conflicts of interest. These policies and procedures shall be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, minimize administrative burden, and protect the privacy of SSIC employees and their Family Members.

b. Any SSIC employee may request advice about a potential Financial Conflict of Interest from the SSIC FCOI Officer without being required to disclose his or her name or identifying details of the potential conflict. Any unit of SSIC may request advice about a potential Conflict of Interest from the SSIC FCOI Officer provided that no more identifying information than necessary should be disclosed unless required by law or SSIC policy.

c. In the event a FCOI is disclosed to NDRI, the NDRI FCOI Officer will determine if the Financial Conflict of Interest is reportable and will insure that procedures are followed to report the FCOI.

d. In the event the FCOI Official determines there exists an FCOI, whether reportable or not, (s)he will convene a FCOI Committee to review all required information and follow all procedures to insure that the FCOI is reduced, eliminated and/or managed through the development and implementation of a management plan. The FCOI Officer will be Chair of the FCOI Committee. All FCOI decisions and management plans shall be reported to the NDRI Executive Director, who is the NDRI Official responsible for insuring all FCOI policies and procedures are followed.

e. Under local policies and procedures, the NDRI Official shall be charged with monitoring and recommending changes, as necessary, to the NDRI Policy on Financial Conflicts of Interest and monitoring recommended measures for resolving or managing specific Conflict of Interest cases.

f. Options for managing FCOI may include and are not limited to:

- public disclosure
- consent form disclosure
- modification of the research plan
- change of personnel or personnel responsibilities
- disqualification of personnel from participation in all or part of the research activities
- independent monitor

7. Training

- a. NDRI shall provide Conflict of Interest training to all Investigators receiving funding from the Public Health Service in accordance with C.F.R. Part 50.601 et seq. The NDRI FCOI training is available on the NDRI intranet and accessible to all staff. In addition, NDRI has added the CITI online FCOI Tutorial as a required training module, to be completed when staff complete or update their CITI Human Subjects training.
- b. Each Investigator must complete Conflict of Interest training prior to applying for or engaging in research related to any Public Health Service funded grant or sponsored project.
- c. Each Investigator must complete Conflict of Interest training at least every four years.

8. Public Accessibility

This Policy and disclosure of Investigators' Conflicts of Interest shall be available to the public to the extent required by C.F.R. Part 50.601 et seq.

9. Enforcement

- a. Enforcement of this Policy on Financial Conflicts of Interest is the ultimate responsibility of the NDRI Official and the Board of Directors, who may delegate that responsibility to other NDRI officials pursuant to this Policy. Principal responsibility for implementation and enforcement of this Policy shall reside with the NDRI Official.
- b. Violations of this Policy and implementing procedures, including the failure to file timely disclosures; filing incomplete, erroneous, or inaccurate disclosures; or failure to comply with prescribed procedures for managing or resolving conflicts of interest, will be dealt with in accordance with applicable NDRI policies and procedures.
- c. Appeals from administrative decisions concerning Conflicts of Interest are subject to applicable NDRI policies and procedures concerning review of administrative decisions.