1. INTRODUCTION

These policies and procedures are in addition to SRI International’s Standards of Conduct, and apply to research funded by agencies and departments of the U.S. Department of Health and Human Services (DHHS) and in particular the Public Health Service (“PHS”), National Institute of Health (“NIH”), as well as the National Science Foundation (“NSF”).

2. POLICY

It is the policy of SRI International (“SRI”) to ensure that Investigators on DHHS funded contracts or grants report any known significant financial interests of the Investigator, the Investigator’s spouse or dependent children may already have, or will have in the future (i) that would reasonably appear to be related to the Investigator’s responsibilities at SRI or that might be affected by the research for which the funding is sought; and (ii) in entities whose financial interests would reasonably appear to be so affected.

3. DEFINITIONS

3.1 “Investigator” means an SRI researcher who is the project director, the Principal Investigator (“PI”) or the Co-PI, regardless of the amount of time the investigator proposes to charge or actually charges to the project, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by DHHS or NSF. An “other person” would include collaborators or consultants. The term Investigator does not include General and Administrative employees, administrative assistants, Contract Administrators or others who may directly or indirectly charge a portion of their time against the project or who perform other than research work on the funded project.

3.2 “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 encompasses basic and applied research and product development. As used in this policy, the term includes any such activity for which research funding is available from DHHS or NSF.

3.3 “Significant Financial Interest” means anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). The definition does not include:

(a) salary, royalties, or other remuneration from the applicant institution (SRI);
(b) income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for 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;

(c) income 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;

(d) an equity interest in non-publicly traded entities that when aggregated for the Investigator and the Investigator’s spouse and dependent children, meets both of the following tests: (i) does not exceed five thousand dollars ($5,000) in value as determined through reference to public prices or other reasonable measures of fair market value; and (ii) does not represent more than a five percent (5%) ownership interest in any single entity; or

(e) salary, royalties, or other payments that when aggregated for the Investigator and the Investigator’s spouse and dependent children over the next twelve (12) months, are not expected to exceed five thousand dollars ($5,000).

3.4 “Institution” means an entity, organization, corporation, consultant, etc., and includes all categories of applicants for or recipients of DHHS/NSF funding.

4. REGULATORY REQUIREMENTS

This Policy is intended to comply with the NSF’s “Investigator Financial Disclosure Policy”, Chapter IV. A. of the NSF Award Administrative Guidelines (AAG) and PHS regulations in 42 CFR Part 50 Subpart F and/or 45 CFR Part 94, as appropriate.¹

5. PRACTICES AND PROCEDURES

5.1. Each Investigator shall be informed of this Policy, the Investigator’s reporting responsibilities, and the applicable regulations. This shall be accomplished by way of the Proposal and Annual Investigator Certificate(s), attached hereto, and as hereafter amended from time to time. Annually, the Investigator will complete and sign the Annual Investigator Certificate. In addition, any SRI employee who has contributed significantly to a project’s design, conduct or reporting must fill out an annual certificate. The PI for each project will be responsible for providing the names of other SRI employees who qualify as “Investigators” working on their projects. The responsible Contract Administrators shall ensure that the Investigator Certification is completed and signed by the PI for each proposal and by all Investigators annually on March 1st each year and that the original of such certification is sent to the Institutional Official. Annual Certifications shall cover the calendar year just completed.

5.2. If an Investigator anticipates a change in his/her circumstances during the course of a project, with regard to the conflict of interest policy, the Investigator shall notify the

Institute Official to determine what steps need to be taken to manage, reduce or eliminate the prospective, or actual, financial conflict of interest.

5.3. In the event that the funded research is carried out through subgrantees, subcontractors, or collaborators, the Contract Administrator shall notify the responsible Subcontract Administrator to take steps to ensure, by way of a certification, that any Institution receiving a subaward has an active and enforced financial conflict of interest policy that is consistent with the provisions of NSF’s “Investigator Financial Disclosure Policy”, Chapter IV. A. of the NSF Award Administrative Guidelines and PHS regulations in 42 CFR Part 50 Subpart F and/or 45 CFR Part 94, as appropriate. Any Institution receiving a subaward from SRI that does not have a financial conflict of interest policy will be required to comply with SRI’s policy, thereby ensuring that SRI is able to comply with the regulations.

5.3 SRI’s Institutional Official solicits and reviews financial disclosure statements from each Investigator who is planning to participate in DHHS or NSF funded research. This Policy permits the substitution of the Institutional Official as may be required. The Institutional Official shall, at a minimum, ensure that

(a) by the time an application/proposal is submitted to the DHHS or NSF, each Investigator who is planning to participate in the proposed research has submitted to the Institutional Official a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children); and

(b) all financial disclosures must be updated during the period of the award; either on an annual basis (March 1st) or as new reportable Significant Financial Interests are obtained.

5.4 The responsible Contract Administrator will enter the Investigator Certification as a Deliverable in the Contract Brief for all DHHS and NSF funded projects to assure that the annual certification is submitted to the Institutional Official.

5.5 The Institutional Official shall use as guidelines, the applicable regulations to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

5.6 The Institutional Official shall maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for:

(a) in the case of grants, at least three (3) years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b); and

(b) in the case of contracts, three (3) years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
5.7. The Policy enforcement mechanisms and sanctions, where appropriate, shall be the same as those contained in SRI’s Standards of Conduct under the section entitled Disciplinary Action.

5.8 The Contracts Administrator shall, in each application/proposal for funding to which the regulations apply, certify that:

(a) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting interests with respect to all research projects for which funding is sought from DHHS or NSF;

(b) prior to the SRI’s expenditure of any funds under the award, the Institutional Official, or his designated representative, will report to the awarding component the existence of a conflicting financial interest (but not the nature of the interest or other details) found by the Institutional Official and assure that the interest has been managed, reduced, or eliminated in accordance with the regulations; and for any interest that the Institution identifies as conflicting. Subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification;

(c) SRI agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institutional Official and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

(d) SRI will otherwise comply with the regulations.

6. INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

6.1 The Institutional Official must:

(a) review all financial disclosures,

(b) determine whether conflict of interest exists, and if so, determine what actions should be taken by SRI to manage, reduce, or eliminate such conflict of interest. A conflict of interest exists when the Institutional Official reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the DHHS- or NSF-funded research, and

(c) report any investigator Significant Financial Interest to the DHHS- or NSF-funding entity [42 CFR 50.605 (b), 45 CFR 94.5 (b)].

6.2 Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(a) public disclosure of significant financial interests;

(b) monitoring of research by independent reviewers;

(c) modification of the research plan;
(d) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(e) divestiture of significant financial interests; or
(f) severance of relationships that create actual or potential conflicts of interests.

6.3 Financial Conflict of Interest Training. Each Investigator must complete training prior to engaging in research related to any DHHS- or NSF-funded grant or contract and at least every four years, and immediately under the designated circumstances:
(a) SRI’s financial conflict of interest policies change in a manner that affects Investigator requirements.
(b) An Investigator is new to SRI.
(c) SRI finds an Investigator noncompliant with SRI’s financial conflict of interest policy or SRI’s management plan for the Investigator’s financial conflict of interest.