

Sciome, LLC, Policy for Managing Conflicts of Significant Financial Interests

INTRODUCTION

This document articulates Sciome's policy on the management or elimination of conflicts of significant financial interest between outside constituencies of Sciome investigators and the NIH-funded activities carried out by Sciome.

Under 45 CFR Part 94, Sciome, LLC, maintains an up-to-date written, enforceable policy on financial conflicts of interest to ensure that the design, conduct, and reporting of sponsored research will not be biased as a result of any conflicting financial interests. Each investigator who plans to participate in NIH-funded research on behalf of Sciome is required to disclose his/her significant financial interests and those of his/her spouse and dependent children. Sciome's Chief Financial Officer (CFO) and Chief Scientific Officer (CSO) will solicit and review the disclosures to reasonably determine whether an investigator's significant financial interest constitutes a financial conflict of interest relative to the NIH-funded research. If a financial conflict of interest is identified, Sciome will report the existence of such conflicting interest to the sponsor and act to protect the resulting research from bias due to the conflict of interest. This policy statement is intended to satisfy current Federal rules for disclosure of financial conflicts of interest with regard to projects funded by the NIH.

SCOPE

This policy and the associated procedures are applicable immediately to all NIH-sponsored program activity at Sciome carried out by Sciome employees, consultants, scientists, trainees, technicians, or other agents or research collaborators. The policy and the associated procedures are derived from 45 CFR Part 94. These procedures will be followed whenever Sciome or its employees submit a request for funding from NIH or participate in NIH-funded research. Sciome will take reasonable steps to ensure that subcontractors comply with this policy or the subcontractor's financial conflict of interest policy by specifying in the written subcontract agreement whether this policy or the subcontractor's policy will apply and requiring subcontractors to certify compliance.

DEFINITIONS

- a) Investigator — Any person, regardless of title or position, who is proposed by Sciome to participate in or is responsible for the design, conduct, or reporting of NIH-funded research.
- b) Institutional responsibilities — An investigator's responsibilities on behalf of Sciome.
- c) Financial interest — Anything of monetary value, whether or not the value is readily ascertainable.
- d) Significant financial interest — Includes one or more of the following interests of the investigator, his/her spouse, or his/her dependent children that reasonably appears to be related to the investigator's institutional responsibilities:
 - The value of any remuneration received from a publicly traded entity in the past 12 months and the value of any equity interest in the entity as of the date of disclosure that, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services (e.g., consulting fees, honoraria, paid authorship). Equity interest includes stock, stock options, or other ownership interests.
 - The value of any remuneration received from a non-publicly traded entity in the past 12 months that, when aggregated, exceeds \$5,000, or if any equity interest is held. Equity interest includes stock, stock options, or other ownership interests.

- Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

- Income from seminars, lectures, or teaching or service on advisory or review panels for government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher learning.
 - 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.
- e) Financial conflict of interest (FCOI) — A significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research. A conflict of significant financial interest is also considered to exist whenever a Sciome employee, consultant, research collaborator, or other agent receives financial or other material benefit through inappropriate use of knowledge or information confidential to Sciome.

POLICY STATEMENT

a) Mandatory Disclosure of Significant Financial Interests

In accord with relevant Federal regulations, Sciome is required to manage, eliminate, or reduce any potential conflicts of significant financial interest that may be inherent in the personal financial interests of an investigator. Sciome, therefore, requires investigators to disclose to Sciome any significant financial interests and those of his/her spouse and dependent children that could directly and significantly affect the design, conduct, or reporting of NIH-funded research. Investigators are required to provide updated disclosure information during the period in which the research proposal is pending and annually during the period of an award or within 30 days of discovering or acquiring a new significant financial interest.

b) Identification of Financial Conflicts of Interest

Sciome's CFO and CSO will review the disclosures of significant financial interests and determine whether the significant financial interest is related to NIH-funded research. If it is determined that no conflict of significant financial interest exists, the resulting negative finding will be filed in Sciome's Legal and Human Resources files. For negative findings, no further review is required. If a new significant financial interest is disclosed during the course of an NIH-funded project, Sciome will within 60 days review the disclosure and determine whether a financial conflict of interest exists.

c) Managing Financial Conflicts of Interest

When a financial conflict of interest is identified, Sciome's CSO will develop and implement a management plan that specifies the actions to be taken to manage the financial conflict of interest. Actions may include requiring public disclosure of the identified financial interests, modifying the research plan, requiring reduction or elimination of the financial interest, instituting a change of personnel responsibilities, or disqualifying personnel from participation in all or a portion of the research. Sciome will monitor investigator compliance with the management plan until completion of the project.

d) Appeal of Positive Findings

Investigators may appeal a positive finding to the CSO for a review of the conflict of significant financial interest determination. The review of an appealed positive finding must be completed prior to the expenditure of any funds under an award. In reviewing positive findings, the CSO will be guided by the following principles: 1) assuring adherence to all relevant company policies, 2) fully considering the nature and extent of the financial interests in the relationship of the investigator or his/her spouse or dependent children with the external constituencies, 3) giving special consideration to the terms and

conditions of sponsored project agreements that mitigate or complicate the given situation, and
4) consulting fully with the investigator and obtaining additional information from the investigator as deemed appropriate for the management of the apparent conflict of significant financial interest.

e) Maintaining Records

Sciome will maintain all records related to investigator disclosures of financial interests and Sciome's review of and responses to such disclosures for three years from the date of final payment by NIH.

f) Training

Prior to engaging in NIH-funded research, each investigator will be required to complete training on the company's policy on financial conflicts of interest, the investigator's responsibilities for disclosure, and the regulations in 45 CFR Part 94. Refresher training will be required at least every four years.

g) Compliance

If an investigator who is required under this policy to file a significant financial interest disclosure fails to do so or fails to disclose a significant financial interest on the disclosure form, the investigator may be subject to company and legal procedures. Intentional disregard for this policy, including non-adherence to the agreed-upon management plan, shall constitute serious misconduct and may be the basis for further administrative or legal inquiry.

h) Reporting

Prior to expending NIH funds, Sciome will submit an FCOI report to the funding agency detailing any investigator's financial conflict of interest. For any financial conflict of interest identified during the course of a project, Sciome will submit an FCOI report within 60 days. For any FCOI reported by Sciome, Sciome will subsequently submit an annual FCOI report specifying whether the financial conflict is still being managed or no longer exists.