I. Purpose & Scope

Implemented to comply with the 2011 Public Health Services (PHS) regulations on Promoting Objectivity in Research, this policy is applicable to all PHS Research Activities with an award issue date of August 24, 2012, or later, and to proposals for research activities submitted to PHS on or after August 24, 2012. PHS Research Activities that are ongoing as of August 24, 2012, will become subject to this policy as additional funds are requested through submission of a progress report, competing renewal application, proposal for supplemental funding, or through approval of a no-cost time extension. This Policy applies to the Principal Investigator and all other Investigators (regardless of position or title) who are responsible for the design, conduct, or reporting of a PHS Research Activity.

The Policy is applicable to all research activities supported by PHS and by other sponsors and programs that specifically request review consistent with the PHS regulations on objectivity in research. Policy GM09 complements HR06 Policy on Conflicts of Commitments and Interest of the Santa Fe Institute (hereafter “the Institute”).

II. Statement

The PHS regulations on Objectivity in Research (revised in August 2011) are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of PHS Research Activities will be free from bias resulting from any Investigator’s Financial Conflicts of Interest (FCOI).

The Institute, through this policy, its enforcement, and the procedures provided in GM09.1, ensures it compliance, including:

- Investigator training on Financial Conflicts of Interest, the responsibilities to disclose, and the PHS regulations.
- Stipulation of when investigators must disclose significant financial interest.
- Thresholds for investigators for disclosure and by type of entity and intellectual property disclosure.
- Disclosure by collaborators, under a subaward from the Institute.
- Types of review and reporting required, including need to conduct of preliminary reviews, when addition FCOI reports must be submitted, and deadlines for determinations and notifications.
- Appropriate records access and retention.
SFI Policy – Objectivity in Research

III. Sanctions

Failure by an individual to file a complete and truthful financial disclosure for pending proposals, or when a new interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed project monitoring bodies, will be grounds for discipline pursuant to applicable employee or student disciplinary policies. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause. Similarly, agreements with subrecipient organizations may be terminated for cause if that organization fails to comply with its obligations under the PHS regulations. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations and Institute policy.

IV. Definitions

For the purposes of this policy, the following terms shall apply:

Financial Conflict(s) of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of a PHS Research Activity.

Investigator: The Principal Investigator or project director and any other person regardless of title or position who shares responsibility for the design, conduct, or reporting of the results of a sponsored project with the Principal Investigator. This includes, but is not limited to, Key Personnel named on a proposal budget.

Key Personnel: A PHS research Principal Investigator or project director and any other personnel considered essential to work performance and identified as Key Personnel in the contract or grant proposal.

PHS Research Activity(ies): Any award for which research funding is available from PHS including research contracts, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects or research resources awards, and conference grants. Only Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) awards programs are excluded.

Principal Investigator (PI): An Investigator (normally a Resident or External Faculty member or Omidyar Fellow) who has primary responsibility for the scientific and technical conduct, reporting, fiscal, and programmatic administration of a sponsored project.

Significant Financial Interest (SFI): Anything of monetary value that meets the PHS thresholds (see Section II.C above) for reporting received by the Investigator (including the Investigator’s spouse or registered domestic partner, and dependent children for the following categories except travel) that reasonably appears to be related to or is in the same field of expertise as the Investigator’s Institutional Responsibilities. (See procedures for examples of SFI.)

V. References


New Mexico Public Records Act (Chapter 14, Article 3)
SFI Policy – Objectivity in Research

VI. Related Policies and Procedures

HR06  Policy on Conflicts of Commitment and Interest  [to be redrafted]
GM08  Training in Responsible Conduct in Research Policy
GM09.1 Procedures for Implementing Objectivity in Research Policy for Public Health Service Regulations
AD09.1 Records Retention Procedures

Authorization

8/28/2012
Date

Vice President for Administration
Title