I. Purpose & Scope

This procedure outlines steps for compliance with Policy GM09 regarding objectivity in research for Public Health Service (PHS) regulations and complements HR06 Policy on Conflicts of Commitments and Interest at the Santa Fe Institute (hereafter “the Institute”).

II. Responsibilities of Investigators

Investigators will complete a training/education program on Financial Conflicts of Interest, the responsibilities to disclose, and the PHS regulations:

1. Before engaging in PHS Research Activities and at least every four years thereafter while receiving PHS research funding, and
2. Whenever an Investigator is not in compliance with this Policy or has failed to comply with a plan put in place to manage or mitigate a Financial Conflict of Interest.

Investigators will disclose significant financial interest at the following times:

1. Initial disclosures must be made by all Investigators planning to participate on a proposed PHS Research Activity before the application for funding is submitted.
2. The Institute’s Investigators who are engaged in PHS Research Activities have an ongoing responsibility to update their disclosures throughout the period of PHS support:
   - Within thirty (30) days of acquiring or discovering any new significant financial interest; and/or
   - At least annually
3. New Investigators must complete a disclosure of significant financial interest before joining an ongoing PHS Research Activity.

Investigators will disclose to the Institute all significant financial interest that meet the following PHS thresholds:

1. For a publicly traded entity: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, or any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior twelve months and the value of any equity interest (including stock, stock options or other ownership interests, as determined by public prices or other reasonable measure of fair market value) in the entity as of the date of disclosure, which when aggregated, exceeds $5,000.
SFI Procedure – Implementation of Objectivity in Research Policy

[Investigators are not required to disclose significant financial interest in mutual funds or other investment vehicles such as retirement funds as long as the Investigator does not directly control the investment decisions made for these investment vehicles]

2. For a non-publicly traded entity: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior twelve months that exceeds $5,000, or any equity interest, including, but not limited to, stock, stock options, or ownership interest in the entity.

[Investigators are not required to disclose (a) payments made by the Institute, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the Institute; or (b) income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state, or local governments, a U.S. institution of higher education, or a research institute, academic medical center, or hospital that is affiliated with an institution of higher education.]

3. Intellectual property rights and interests: Income from each organization that exceeds $5,000 during the twelve months preceding disclosure of such rights and interests. However, significant financial interests do not include royalties received from the Institute related to patents or copyrights.

4. Travel: The occurrence of any sponsored or reimbursed travel must be disclosed whether payment is made to the Investigator directly, or expenses are paid on behalf of the Investigator by a for-profit or non-profit organization:
   a. either prospectively, by listing all travel that the Investigator anticipates will be sponsored or reimbursed during the next 12 months, or
   b. within 30 days of the occurrence if the trip wasn’t reported prospectively.

[Investigators are not required to disclose travel that is reimbursed or sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education.]

III. Disclosures by Collaborators

Collaborators from other institutions who share responsibility for the design, conduct, or reporting of research results, and who will be conducting research under a subaward from the Institute are expected to comply with the policies and procedures of the organization at which they are employed. Subawards issued by the Institute will indicate that the subrecipient organization is responsible for reviewing disclosures of significant financial interest and, if FCOI are identified, for sending the Institute notification of their ability to manage, reduce, or eliminate the identified conflicts, in accordance with PHS reporting requirements.
Collaborators who share responsibility for the design, conduct, and reporting of research results, and who will participate in research under an independent consulting agreement issued by the Institute should be identified as Investigators by the Institute’s PI and must complete the Institute disclosure forms. If, upon review, the Institute determines that these significant financial interests could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, these collaborators will be expected to adhere to the mitigation plans put in place to eliminate, reduce, or manage the identified conflicts of interest.

IV. Reviews and Reporting

A. Disclosed significant financial interests will be reviewed prior to acceptance of new awards, and before submission of a progress report, competing renewal application, proposal for supplemental funding, or through approval of a no-cost time extension. This information will be used by the Institute to conduct a preliminary review in order to reasonably determine whether any of an Investigator’s SFIs:

- Could be affected by the PHS Research Activity; or
- Are in an entity whose financial interest could be affected by the research.

If after review it is determined that an SFI is related to the proposed PHS Research Activity, there will be a second review conducted by the Conflict of Interest Review Committee (CIRC) or a Designated Official to determine whether the significant financial interest(s) reasonably appears to directly and significantly affect the design, conduct, or reporting of the PHS Research Activity and thereby constitute a FCOI that may need to be eliminated, reduced, or managed.

In accordance with the PHS regulations, plans put into place to manage identified FCOI will be monitored for compliance until the completion of the PHS Research Activity. Each management plan will specify the way in which that will be accomplished.

B. Initial reports of FCOI must be made to PHS prior to the Institute’s expenditure of any funds provided under a PHS Research Activity. When identified conflicts of interest are eliminated before research funds are expended, the Institute is not required to submit a report to PHS.

Additional FCOI reports must be submitted to PHS under the following circumstances:

1. Throughout the lifetime of an award when progress reports are submitted, or at the time that an award is extended (either through extension notification or an NIH prior approval request). When during the course of an ongoing PHS Research Activity a FCOI ceases to exist, updated information about the status of that FCOI should be provided with the subsequent progress report.

2. Within sixty (60) days of determining that a FCOI exists based on disclosure of a newly acquired SFI by an Investigator during the course of an ongoing PHS Research Activity.

3. Within sixty (60) days of determining that a FCOI exists for an Investigator who joins an ongoing PHS Research Activity.
C. When during the course of an ongoing PHS Research Activity, the Institute identifies an SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, the Designated Official will review the SFI within sixty (60) days to determine whether it is related to PHS Research Activities and whether a FCOI exists. If a FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis.

Whenever a FCOI is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose a SFI that was later determined to be a FCOI, or the Institute’s failure to review or manage the FCOI, or because the Investigator failed to comply with a previously implemented management plan, the Institute must within one hundred twenty (120) days of the determination of non-compliance complete a retrospective review of the Investigator’s activities and the PHS Research Activities. The purpose of this retrospective review is to determine if the ongoing PHS Research Activity was biased in its design, conduct, or reporting.

• Based on the results of the retrospective review, the previously submitted FCOI report must be updated to specify the actions that the Institute will take to manage the identified FCOI.

• If bias was found during the retrospective review, the Institute will promptly notify PHS and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines the Institute’s plans to eliminate or mitigate the effect of the bias.

V. Records Access and Retention

A. PHS regulations require that the Institute respond within five (5) business days to any public request for information about SFIs held by Key Personnel when the Institute has determined that the disclosed SFIs are related to PHS Research Activities and constitute FCOIs. Under the New Mexico Public Records Act, information provided on disclosure forms also will be made available to the public upon request.

B. Records of financial disclosures, Designated Official’s determinations, CIRC recommendations, and Institute action regarding management of a conflict of interest will be retained for at least three (3) years beyond the date of submission of the award’s final expenditure report, or until the resolution of any actions by PHS involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

VI. Definitions

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

**Conflict of Interest Review Committee (CIRC):** An Institute committee charged with determining if Significant Financial Interests that are related to the proposed research constitute financial conflicts of interest. The CIRC is appointed by the President.

**Designated Official(s):** Campus official(s) designated to solicit and conduct review of disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is
participating in a PHS Research Activity. The Designated Official(s) will determine whether an Investigator’s Significant Financial Interest is related to the Investigator’s PHS Research Activity and if related, whether the Significant Financial Interest constitutes a Financial Conflict of Interest.

**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.

**Institutional Responsibilities:** Teaching/education, research, outreach and public service on behalf of the Institute which are in the course and scope of the Investigator’s Institute appointment/employment.

**Investigator:** Any individual 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 Project Director, Principal Investigator, 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 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:** 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. Examples of significant financial interest include:

- *Income or honoraria* received for activities such as
  - providing expert testimony or consulting services;
  - serving on a board of directors, scientific advisory board, committee, panel, or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies;
  - acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a non-profit or for-profit organization; or
  - salary received outside of the Institute.
SFI Procedure – Implementation of Objectivity in Research Policy

- *Stock or stock options* in a company that is developing, manufacturing, or selling products or providing services used in an Investigator’s clinical practice, teaching, research, administrative, or committee responsibilities.

- *Receipt of income* from any organization other than the Institute for use or sale of patented or copyrighted intellectual property, such as software, textbooks, or other scholarly works for which royalties or licensing fees are received, including income from prior employers and other independent research institutes.

- *The occurrence of travel* by the Investigator which is reimbursed or sponsored by a for-profit or nonprofit entity, *excluding* a federal, state, or local government, a U.S. institution of higher education or an affiliated medical center/hospital or research institute.

IX. Related Policies and Procedures

HR06  Policy on Conflicts of Commitment and Interest

GM08  Training in Responsible Conduct in Research Policy

GM09  Objectivity in Research Policy for Public Health Service Regulations

AD09.1 Records Retention Procedures