

FINANCIAL CONFLICT OF INTEREST IN RESEARCH POLICY

Effective Date: 08/08/2012

Policy Owner: Chief Operating Officer

Policy Contact: Grants & Contracts

Version (Required)	Summary
04/01/2026	Formatting and minor updates.
01/17/2024	Updated SFI exemption and retrospective review language. Added the Clinical Research section.
10/31/2023	Formatting revisions, small edits, and sections added to align to Sage Bionetworks template; Added responsibilities, resources, and subrecipient management sections
10/14/2020	Formatting revisions
06/04/2018	Roles/titles updated
08/08/2012	Initial version of the policy

BACKGROUND

The purpose of the Policy is to maintain the objectivity and integrity of research at Sage Bionetworks (“Sage”) and ensure transparency in relationships with outside entities and individuals as it relates to Sage’s mission. This policy provides requirements for the disclosure of Financial Interests that comply with the disclosure requirements of federal regulations of the U.S. Department of Health and Human Services (HHS) and National Sciences Foundation (NSF).

SCOPE

This policy applies to all investigators responsible for the design, conduct, or reporting of research funded by Public Health Service (PHS) agencies or other sponsors requiring compliance with federal conflict of interest regulations.

This policy governs the disclosure, review, management, and reporting of Significant Financial Interests (SFIs) that may create a Financial Conflict of Interest (FCOI) in research conducted at or on behalf of Sage Bionetworks. It establishes requirements for Investigators to disclose relevant financial interests, for Sage to evaluate whether those interests constitute a conflict of interest, and for the institution to manage, reduce, or eliminate such conflicts when they arise.

The requirements of this policy apply to all research activities subject to federal Financial Conflict of Interest regulations, including proposals for sponsored research and funded research projects administered by Sage.

DEFINITIONS & ACRONYMS

Family: means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

Financial Interest: means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable.

Financial Conflict of Interest (FCOI): means a Significant Financial Interest (or, where the Institutional Official requires disclosure of other Financial Interests, a Financial Interest) that Sage reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

Institutional Official: means the individual within Sage that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. Unless otherwise nominated, the Grants & Contracts lead will be the Institutional Official for the purposes of this policy.

Institutional responsibilities: means the Investigator's professional responsibilities associated with their appointment or position at Sage, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator: means any individual who is responsible for the design, conduct, or reporting of PHS sponsored Research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service (PHS): means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated.

The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research: means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Significant Financial Interest (SFI): means a Financial Interest that reasonably appears to be related to the Investigator's institutional responsibilities, and:

- a) **Payments from and/or Equity in Publicly Traded Entities:** if with a publicly traded entity, the aggregate value of any salary or other payments for services (e.g., consulting fees, speaking fees, advisory board compensation, fees for a leadership position (such as director, trustee, or officer), received during the 12-month period preceding the disclosure, and the

value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000.:

- b) **Payments from and/or Equity in Non-publicly traded Entities:** if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received (e.g., consulting fees, speaking fees, advisory board compensation, fees for a leadership position (such as director, trustee, or officer), during the 12-month period preceding the disclosure exceeds \$5,000; or if with a non-publicly-traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure.
- c) **Intellectual Property Rights:** income exceeding \$5,000 related to intellectual property rights (e.g., patents, trademarks, service marks, and copyrights), and interests not reimbursed through Sage.
- d) **Travel:** includes reimbursed or sponsored (paid on behalf of the Investigator) travel valued at more than \$5,000 in aggregate over a 12-month period from the same entity.

Exclusions include travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with U.S. institutions of higher education.

Significant Financial Interest does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by Sage to the Investigator if the Investigator is currently employed or otherwise appointed by Sage including intellectual property rights assigned Sage and agreements to share in royalties related to such rights
- Income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, an accredited, domestic institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.
- Income from services on advisory committees or review panels for a U.S. federal, state, or local government agency, an accredited, domestic institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.

Subrecipient: means an individual or entity that is paid for conducting federally sponsored Research. Sage must take reasonable steps to ensure that all Subrecipients who receive funds through Sage comply with FCOI regulations.

POLICY

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and Sage to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy.

If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

DISCLOSURE OF FINANCIAL INTEREST

All Investigators are required to disclose their outside financial interests as defined above to Sage on an annual and on an ad hoc basis, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

a) **Annual Disclosures**

All Investigators must disclose their SFI that are related to the investigator's institutional responsibilities to Sage, through the Institutional Official on an annual basis. All forms should be submitted to the Institutional Official by January 31, for the previous calendar.

b) **Ad hoc Disclosures**

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their SFI to Sage, through the Institutional Official, within 30 days of their initial appointment or employment.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an ad hoc updated disclosure of his or her SFI with the outside entity. Sage will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any Significant Financial Interest they acquire or discover **during the course of the year within thirty (30) days of discovering or acquiring the SFI.**

c) **Travel**

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and SFI. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

If the disclosure form reveals a SFI, it will be reviewed promptly by the Institutional Official for a determination of whether it constitutes a FCOI. If a FCOI exists, the Institutional Official will take action to manage the FCOI including the reduction or elimination of the conflict, as appropriate.

A FCOI will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the Institutional Official determines that there is a FCOI that can be managed, they must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

The Institutional Official will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

REPORTING TO PHS

The Institutional Official will report FCOIs or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified FCOIs such that the prime awardee may fulfill their reporting obligations to the PHS.

INVESTIGATOR NON-COMPLIANCE

Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official will report the finding to the President who may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented.

The President's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the investigator and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. Sage will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

Retrospective Review

In addition, if the Institutional Official determines that a FCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a SFI that is determined to be a FCOI, failure by an Investigator to materially comply with a management plan for a FCOI, or Sage non-compliance (such as failure to review or manage a FCOI), the Institutional Official will complete a retrospective review of the Investigator's activities and the PHS-sponsored

research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the FCOI, name of the entity with which the Investigator has the FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the FCOI going forward. This retrospective review will be completed within 120 days from the date the non-compliance is identified. If bias is found, Sage will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

TRAINING

Each Investigator must complete training on this Policy, the investigator's responsibilities regarding disclosure, and the PHS regulations prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the investigator is new to Sage, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

SUBRECIPIENT MANAGEMENT

Subrecipients may follow their own FCOI policy if it is compliant with the funding agency. If they do not have a policy in place, they may follow all requirements of Sage's policy. Written agreements with subrecipients will include provisions requiring the subrecipient to comply with applicable regulations related to SFI disclosures and management of FCOIs consistent with PHS requirements, time periods to meet SFI disclosures to Sage, and FCOI reporting requirements as well as making sure any FCOI information is publicly available pursuant to the Public Accessibility section of this policy.

RECORD RETENTION

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, Sage may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, Sage will commit to responding to any requestor within five business days of the request, information concerning any SFI that meets the following criteria:

- The SFI was disclosed and is still held by the senior and key personnel;
- A determination has been made that the SFI is related to the PHS- funded research; and
- A determination has been made that the SFI is a FCOI.

The information to be made available shall be consistent with the requirements of 42 CFR Part 50 Subpart F. This policy shall be available through Sage's public website.

CLINICAL RESEARCH

In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by Sage as required by this subpart, Sage shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

REGULATORY AUTHORITY

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

RESPONSIBILITIES

Investigators (Including Principal Investigators): Investigators are required to complete SFI disclosures as outlined in the Disclosure of Financial Interests section of this policy. Investigators must complete FCOI training in a timely manner.

Institutional Official: The Institutional Official is responsible for the distribution, receipt, processing, review, and retention of disclosure forms. If determined that a SFI constitutes a FCOI related to a specific PHS funded Research project, this person shall develop and implement a written management plan.

REGULATORY AUTHORITY

This policy implements the federal regulations governing Financial Conflict of Interest in research:

- 42 CFR Part 50 Subpart F – Responsibility of Applicants for Promoting Objectivity in Research
- 45 CFR Part 94 – Responsible Prospective Contractors

The current version of these regulations is available through the Electronic Code of Federal Regulations (eCFR): <https://www.ecfr.gov>

REFERENCES

- NIH Financial Conflict of Interest (FCOI) Policy and Guidance
<https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi>
- National Science Foundation Proposal and Award Policies and Procedures Guide (PAPPG)
<https://www.nsf.gov/policies/papp>