

FINANCIAL CONFLICT OF INTEREST POLICY FOR INVESTIGATORS

Policy Statement

NYSCF recognizes that the broader scientific community is enhanced when members of the NYSCF community conduct high quality Research with the highest ethical standards. This policy is an essential component of furthering NYSCF’s mission and its commitment to scientific excellence.

Policy Purpose

The purpose of this policy is to:

- Promote public trust and confidence in NYSCF’s Research activities as a non-profit research institution.
- Promote objectivity in Research by establishing standards to ensure that the design, conduct, and reporting of Research is free from bias resulting from any actual, potential, or perceived Financial Conflicts of Interest.
- Safeguard NYSCF’s reputation for integrity, fairness, and effectiveness in Research and ensure that Investigators conduct all activities in keeping with the highest ethical standards.
- Ensure that NYSCF follows all applicable local, state, and federal requirements, including those which apply specifically to Financial Conflict of Interest determination, management, and reporting.

Definitions

Financial Conflict of Interest means a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct, or reporting of Research.

Financial Conflict of Interest Committee or “FCOI Committee” means NYSCF’s committee or the individual that advises the Institutional Official with respect to Financial Conflict of Interest matters.

Financially Interested Company means an entity whose financial interests could reasonably appear to be affected by the conduct or outcome of a Research project. The term “entity” means any corporation, limited liability company, partnership, limited partnership, limited liability partnership, joint venture, business trust, or other business organization, and any not-for-profit organization, charity, or foundation.

Financial Interest Related to Human Subjects Research is a financial interest in the sponsor, product, or service being tested, or anything of monetary value from a Financially Interested Company, including but not limited to:

- a) Officer's/Director's fees.
- b) Consulting fees.
- c) Compensation for service on an advisory board.
- d) Honoraria for lectures/training.
- e) Gifts.
- f) Other emoluments or in-kind compensation such as travel and entertainment from a Financially Interested Company (including from a third party if the original source is a Financially Interested Company) for any services not directly related to the reasonable costs of conducting human subjects Research as specified in the Research agreement.
- g) Compensation related to human subjects Research whose amount might be affected by the outcome of the human subjects Research.
- h) Equity interest of any kind and in any amount in a non-publicly or publicly traded Financially Interested Company (e.g., stocks, stock options, convertible notes, other ownership interests), including those for which the value may be affected by the outcome of human subjects Research, and those which represent a 5% or more interest in one single entity.
- i) Intellectual property related to the proposed human subjects Research.
- j) License fees, technology transfers, and/or current and future royalties from patents and copyrights.
- k) Board or executive relationships related to human subjects Research (regardless of compensation).
- l) Reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to an outside position or for consulting, lecturing, service on a scientific advisory board, data safety monitoring board, steering committee for a clinical trial, executive committee for a clinical trial, or other committee for an outside entity, or for any other purpose. (This requirement does not apply to travel that is reimbursed or sponsored by 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.)

Financial Interest Related to Non-Human Subjects Research means anything of monetary value received or held by an Investigator or a Related Party from a Financially Interested Company, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and

intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest Related to Non-Human Subjects Research does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state, or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or 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.

Financial Interest Related to Non-Human Subjects Research also includes any reimbursed or sponsored travel undertaken by the Investigator and related to the Investigator's Institutional Responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. (This requirement does not apply to travel that is reimbursed or sponsored by 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.)

Institution or NYSCF means New York Stem Cell Foundation, Inc.

Institutional Official or IO means the individual within the Institution who is responsible for overseeing the solicitation and review of the Investigator's disclosures of Significant Financial Interests, including those of the Investigator's Related Party, related to the Investigator's Institutional Responsibilities. For the purposes of this policy, the Institutional Official is designated as NYSCF's Chief Financial & Operating Officer.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of NYSCF which include, but are not limited to, activities such as Research, clinical care, business transactions, committee memberships, and service on panels.

Investigator means the principal investigator, co-investigator, and any other person regardless of title or position, including but not limited to any NYSCF employee, collaborator, volunteer, visiting scientist, or consultant, responsible for the design, conduct, or reporting of Research activities or responsible for preparing a proposal for Research funding.

Related Party means any member of the Investigator’s immediate family, specifically, spouse, domestic partner, dependent children, siblings, or parents residing with the Investigator, or equivalents by marriage, or other individuals residing in the household.

Significant Financial Interest or SFIs means a Financial Interest Related to Human Subjects Research or Financial Interest Related to Non-Human Subjects Research (together, a “Financial Interest”) that reasonably appears to be related to the Investigator’s Institutional Responsibilities (including those of the Investigator's Related Party):

- a) if with a publicly traded entity, the aggregate value of any remuneration 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; or
- b) if with a non-publicly traded entity, the aggregate value of any remuneration for services received during the 12-month period preceding the disclosure exceeds \$5,000; or
- c) an equity interest of any value is held with a non-publicly-traded company, during the 12-month period preceding or as of the date of disclosure; or
- d) income related to intellectual property rights (e.g., patents, copyrights) and interests not reimbursed through the Institution,
- e) non-royalty payments or entitlements to payments in connection with the Research that are not directly related to the reasonable costs of the Research (e.g., bonus or milestone payments to the Investigator more than reasonable costs incurred);
- f) serves as an officer, director, or in any other executive position in a Financially Interested Company, whether remuneration is received for such service; or
- e) is reimbursed or sponsored travel related to their Institutional Responsibilities.

For PHS-funded Research, Investigators must disclose any reimbursed or sponsored travel undertaken by the Investigator and related to the Investigator’s Institutional Responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. (This requirement does not apply to travel that is reimbursed or sponsored by 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.)

For purposes of this definition, “remuneration” includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, etc.); “equity interest” includes any stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit

organization; 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; income from seminars, lectures, or teaching engagements sponsored by 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; or income from service on advisory committees 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.”

Public Health Service or 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 the systematic investigation, study, or experiment including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, relating broadly to public health, including behavioral and social-sciences research, and further encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug), regardless of whether such activities constitute human subjects research.

Application

Adherence to this policy will maintain the integrity of Research at NYSCF. Although it is not possible to specify every action that might create a Financial Conflict of Interest, this policy sets out the ones that most frequently may present problems. If an Investigator has any question about whether an action or proposed course of conduct would create a Financial Conflict of Interest, the Investigator should immediately contact the Human Resources Department (HR), the Institutional Official (IO), and the Director of Clinical Research and Regulatory Compliance to obtain advice.

This policy applies to all Investigators, including PHS-funded Investigators, regardless of their FTE status. Investigators must avoid situations that might lead to a conflict, or even the appearance of a conflict, between the Investigators interests and their responsibilities to NYSCF. Investigators must not use their positions for personal gain or advantage or give that appearance. Investigators and their Related Parties must not ask for or accept gifts or favors of any sort from donors, grantees, or suppliers of NYSCF. Investigators, who are offered, receive, or anticipate that they may be

offered or receive a gift or favor from any donor, prospective, past or current grant applicant, grantee, or supplier of NYSCF should immediately advise HR, the IO, and, if pertaining to HSR, the Director of Clinical Research and Regulatory Compliance in writing. NYSCF requires declaration of Significant Financial Interests by each Investigator for a Financial Conflicts of Interest determination. Adhering to this policy will ensure that Investigators maintain NYSCF's standards for Research integrity and that NYSCF remains compliant with regulatory Financial Conflict of Interest requirements. The IO is responsible for ensuring implementation of this policy. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to the Institution's policies.

Policy

This policy is predicated on the expectation that Investigators (i) should conduct their affairs to avoid or minimize Financial Conflicts of Interest, and (2) must respond appropriately when Financial Conflicts of Interest arise. To that end, this policy informs Investigators about situations that generate Financial Conflicts of Interest related to Research, provides mechanisms for Investigators and the Institution to manage those Financial 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.

1) *Disclosure of Financial Interests Related to Research*

All NYSCF staff are required to disclose all Significant Financial Interests via the Financial Conflicts of Interest Disclosure Form and submit completed forms to compliance@nyscf.org on an annual and on an ad hoc basis, as described below. The FCOI Committee is responsible for the distribution, receipt, and initial processing of all disclosure forms. The FCOI Committee will review all disclosures, to identify and confirm whether any disclosure presents a Significant Financial Interest for Investigators. If a Significant Financial Interest is identified and the FCOI Committee reasonably determines that a Financial Conflict of Interest exists, the FCOI Committee will decide as to whether the conflict can be managed and submit a recommendation to the IO. The IO will then undertake their own independent evaluation and will make a final determination as to whether a Significant Financial Interest is present and a Financial Conflict of Interest exists, and if so determined, whether the Investigator will be required to eliminate or manage the Financial Conflict of Interest, as appropriate. The IO may suspend all relevant activities until the Financial Conflict of Interest is resolved or take such other action deemed appropriate by the IO.

a) *Annual Disclosures*

All forms should be submitted to compliance@nyscf.org by July 15th for the previous year (e.g., July 1st - June 30th).

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure (e.g., initial appointment or employment). All Investigators must submit an ad hoc disclosure concerning any Significant Financial Interest that they acquire or discover during the year. All ad hoc disclosures must be submitted to compliance@nyscf.org within thirty (30) days of the change event.

c) PHS-sponsored Research Disclosures

Prior to submitting applications for PHS-sponsored Research projects, the Investigator must affirm the current accuracy of their annual disclosure with the Vice President, Scientific Outreach and to the Director of Clinical Research and Regulatory Compliance or submit an ad hoc disclosure, using the above referenced form, to compliance@nyscf.org. The Institution will not submit a PHS-sponsored Research proposal unless the Investigator affirms their annual disclosure or submits an ad hoc disclosure as outlined above.

As stated above, all ad hoc disclosures must be submitted to compliance@nyscf.org within thirty (30) days of a change event. PHS-sponsored Investigators are required to disclose change event SFIs within thirty (30) days of identifying the SFI.

c) Travel

Investigators must also disclose reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to their Institutional Responsibilities. 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. As outlined above, this disclosure requirement does not apply to travel that is reimbursed or sponsored by 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.

Travel disclosures must be submitted to compliance@nyscf.org on or within thirty (30) days of a change event.

2) Review and Decision of the Institutional Official

As outlined above, if the FCOI Committee identifies a Significant Financial Interest that is also a Financial Conflict of Interest, the IO will make a final determination on whether the SFI constitutes a Financial Conflict of Interest. If the IO determines that a Financial Conflict of Interest exists, the IO will take action to manage the Financial Conflict of Interest including the disclosure, reduction, or elimination of the conflict, as appropriate.

A Financial Conflict of Interest will exist when the Institutional Official determines that a SFI could directly and significantly affect the design, conduct, or reporting of Research. If the IO determines that there is a Financial Conflict of Interest that can be managed, they will develop and implement a written management plan (e.g., public disclosure of financial conflicts of interest, modification of the research plan, severance of relationships that create financial conflicts, etc.). The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related Research goes forward, including PHS-sponsored Research.

The IO will periodically review the ongoing activity, monitor the conduct of the activity (including use of postdoctoral appointees and other personnel), to ensure open and timely dissemination of the Research results, and to otherwise oversee compliance with the management plan. Monitoring will be conducted until the completion of the Research project.

3) Reporting to PHS (for PHS-funded research)

The Institutional Official will report Financial Conflicts of Interest and non-compliance with this policy to PHS in accordance with PHS regulations at 50.605 (b). 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 sixty (60) days of any subsequently identified Financial Conflict of Interest such that the prime awardee may fulfill their reporting obligations to the PHS. If the Institution carries out the PHS-funded Research through a subrecipient (e.g., subcontractors or consortium members), the Institution will take reasonable steps to ensure that any subrecipient Investigator complies with PHS regulations at 50.605 (c).

4) Reporting to IRB

The Clinical Research Program Manager or authorized team member will report Conflicts of Interest or non-compliance with required management plans to the overseeing IRB at the time of initial submission, via a study amendment, and/or as reportable new information, as appropriate. If the IRB requires additional disclosures and/or modifications to the management plan, such information will be provided to the

Institutional Official for review and implementation. For clarity, the IRB's determination will take precedent as to the IO's review and determination as to whether a Financial Conflict of Interest exists.

5) Investigator Non-Compliance

In the event of an Investigator's failure to comply with this policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or such other action deemed appropriate by the Institutional Official is implemented.

a) *Disciplinary Action*

The IO'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 IO, and/or IRB, will be described in a written explanation and provided to the Investigator and, where applicable, the IRB. The IO will notify the individual of the right to appeal the decision. The Institution will promptly notify the PHS Awarding Component of the action taken or to be taken. The IRB will review the noncompliance, and act if necessary, following the policies and procedures of the human research protection program (HRPP). For PHS-funded Research, if the funding for the Research is made available to a prime PHS awardee, such notification shall be made directly to PHS by such prime awardee.

b) *Retrospective Review of PHS-funded Research*

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the FCOI Committee appointed by 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, project director/principal investigator, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, 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 Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the Institution 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.

6) Training

All NYSCF staff must complete training on this policy, including on Investigator's responsibilities regarding disclosure, and PHS regulations prior to engaging in Research funded by PHS. Training must be completed prior to engaging in Research funded by PHS, and at least every four (4) years thereafter. In addition, NYSCF Staff must also complete training immediately if this policy is substantially amended in a manner that affects the requirements of Investigators, if the Investigator is new to the Institution, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their Research activities. Please note training is now completed through the Collaborative Institutional Training Initiative (CITI) Program. NYSCF Staff must renew their training certification before it expires by taking either a refresher course or retaking the full course. For questions about training contact compliance@nyscf.org.

7) Record Retention

For PHS-funded Research, the Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of at least three (3) years from the date that the final expenditure report is submitted to the PHS or to the prime PHS awardee. The IO will retain all disclosure forms, conflict management plans, and related documents for all non-PHS-funded human subjects Research for a period of at least three (3) years after termination of IRB oversight. If any litigation, claim, financial management review, or audit is started before the expiration of an applicable three (3) year period, the IO shall retain the records until all litigation, claims or audit findings involving the records have been resolved and final action taken.

8) Confidentiality

The Institution may be required, by applicable federal, state or local laws or regulations, or for other adequate lawful reasons, to make certain information related to PHS-funded Research and non-PHS-funded human subjects Research under this policy available to third parties, including but not limited to the PHS Awarding Component, HHS, IRB, and to authorized requestors. If the Institution is required to provide disclosure forms, conflict management plans, and/or other related information to an outside entity, the Investigator will be informed of such disclosure. In addition, NYSCF will make publicly available such information as may be required by federal, state, or local laws or regulations.

9) Public Accessibility

Prior to the expenditure of any funds under a PHS-funded Research project, the Institution will ensure public accessibility via written response, outlined via a publicly accessible website. The Institution will respond to any requestor within five (5) business days of the request of information concerning any Significant Financial Interest disclosed to the Institution that meets the following criteria:

- a) The SFI was disclosed and is still held by the senior and key personnel;
- b) The Institution determines that the SFI is related to the PHS-funded research; and
- c) The Institution determines that the SFI is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of PHS regulation. The Institution will determine, in its sole discretion, whether information for non-PHS funded Research is made available through the publicly available website or on written request.

10) 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.