1. Purpose and Scope of Policy

The New York Genome Center (“NYGC”) is committed to operating in an ethical manner and in compliance with applicable law and regulatory requirements. Even the appearance of a significant conflict of interest in research at NYGC can be damaging to the reputation of NYGC.

This policy provides a comprehensive approach for the identification, disclosure, evaluation and oversight of financial conflicts of interest related to Sponsored Research (as defined in Section 3) The policy:

- Requires Investigators applying for, or receiving, Sponsored Research funding to disclose any Significant Financial Interests (“SFI”) (as defined below);

- Designates institutional officials who will review (i) disclosures statements, (ii) identify any financial conflicts of interest (“FCOI”) that could directly and significantly affect the design, conduct or reporting of the sponsored project, and (iii) determine appropriate measures to manage or eliminate any FCOIs;

- Establishes mechanisms for ensuring compliance with the policy and any stipulated remedial measures, and imposes sanctions, as appropriate, for an Investigator’s failure to comply;
• Requires institutional reporting to the funding agency of any FCOI, if mandated, and the maintenance of related records for three (3) years from the date of submission of final grant expense reports; and

• Mandates conflict of interest training for Investigators before they engage in research under a sponsored project and at prescribed intervals thereafter.

Members of the scientific staff, as well as other employees, will continue to be subject to NYGC’s existing conflicts of interest policy. Indeed, this policy supplements, not replaces, NYGC’s general policy on conflicts of interest.

NYGC considers compliance with these rules fundamental to maintaining continued public trust in the integrity of research conducted at NYGC. Members of the scientific staff are encouraged to direct any questions concerning the rules to NYGC’s Director, Research Administration.

This policy is in effect on the date reflected above and may change at any time at the discretion of NYGC, with or without notice. It applies to all NYGC employees and faculty members involved in the design, conduct or reporting of sponsored projects.

2. Policy/Principles

NYGC is dedicated to advancing research that benefits the public good, consistent with its status as a nonprofit, tax-exempt organization. Investigators participating in a sponsored project conducted at or under the auspices of NYGC have a duty to support this mission by conducting research free of any appearance of impropriety or conflict of interest.

An FCOI exists in a sponsored project when NYGC’s designated officials reasonably determine that an Investigator’s SFI could directly and significantly affect the design, conduct or reporting of the sponsored project.

To identify potential FCOIs, Investigators participating in a sponsored project must disclose SFIs of the Investigator or his/her Immediate Family (as defined below) that reasonably appear related to the Investigator’s Institutional Responsibilities (as defined below) to NYGC before and during the life of the sponsored project.

When an Investigator has a SFI, the Conflict of Interest Committee (“COIC”) will review the SFI to determine if it constitutes a potential FCOI, and, if so, whether the FCOI can be managed, or if it must be eliminated.
3. Definitions

- “Award” means any funding instrument (e.g., grant, contract, cooperative agreement, subaward) that comes from an external funding source (Sponsor or Prime Grantee).

- “Disclosure” means an Investigator’s report of SFI (and those of the Investigator’s spouse and dependent children) that reasonably appear to be related to the Investigator’s institutional responsibilities.

- “Financial Conflict of Interest” or “FCOI” means a Significant Financial Interest (as defined below) that could directly and significantly affect the design, conduct or reporting of the funded research.

- “Immediate Family” means an Investigator’s spouse, dependent child, or domestic partner.

- “Institutional Founding Member” or “IFM” means an entity listed at [https://www.nygenome.org/about-us/member-institutions/](https://www.nygenome.org/about-us/member-institutions/) as an Institutional Founding Member.

- “Institutional Responsibilities” means an Investigator’s professional activities on behalf of NYGC (e.g., teaching, administration, research or clinical care). Specifically, these include:

  o Research (includes activities such as proposing, conducting, and analyzing research and disseminating results);

  o Research consultation (includes participation in study sections, peer review of manuscripts);

  o Instruction/academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students and trainees, and/or participation in graduate or post-graduate training);

  o Administrative activities (including service on institutional committees or internal advisory boards, etc.); or

  o Special service activities conducted on behalf of the organization (including community service or outreach as NYGC’s representative).
• “Investigator” means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by an Award, or proposed for such funding, which may include, for example, collaborators, consultants or graduate students. These individuals may or may not be paid directly from the Award.

• “Prime Grantee” means the institution that applies for and/or receives funding from a Sponsor.

• “Significant Financial Interest” or “SFI” means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s Immediate Family) that reasonably appears to be related to the Investigator’s Institutional Responsibilities:

  o With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated (for the Investigator and the Investigator’s spouse and dependent children), exceeds $5,000. 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); 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;

  o With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

  o Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Investigators also must disclose the occurrence of any 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 (e.g., administrative, teaching or research activities). At a minimum, the Disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. 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.

The term SFI does not include the following types of financial interests:

  o Salary, royalties, or other remuneration paid by NYGC to the Investigator if the Investigator is currently employed or otherwise appointed by NYGC, including intellectual property rights assigned to NYGC and agreements to share in royalties related to such rights;
- Salary, royalties, or other remuneration paid by an Institutional Founding Member to the Investigator if the Investigator is currently jointly appointed by the Institutional Founding Member and NYGC, including intellectual property rights assigned to the Institutional Founding Member and agreements to share in royalties related to such rights;
- 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.

- “Sponsor” means the funding entity to which an application for funding is submitted. A Sponsor may be a federal, state, or local agency (e.g., NIH, DOD), a private or philanthropic organization (e.g., American Cancer Society, Lustgarten Foundation), or an industry sponsor (e.g., pharmaceutical company).

- “Sponsored Research” means a systematic investigation, study or experiment designed to develop or 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. This includes any such activity for which research funding is available from a government, philanthropic or corporate source (e.g., pharmaceutical companies) through a grant, contract or cooperative agreement.

- “Subrecipient” means an entity that receives a subaward from NYGC to carry out part of a Sponsored research project. The subrecipient may be a domestic or foreign educational institution, for-profit or nonprofit organization, or government entity. An individual cannot serve as a subrecipient.

4. Procedure

A. Disclosure Statements

Investigators, who include any person responsible for the design, conduct or reporting of the funded research, must disclose any SFIs at the following times:

- Upon submission of a funding proposal: Each Investigator planning to participate in a proposed sponsored project must complete and submit to the Office of Research Administration a Disclosure at the time of the submission of the funding application.
• **Annually during the period of the Award:** Investigators must submit a Disclosure annually during the term of the sponsored project.

• **New Financial Interests:** Investigators must submit a Disclosure within thirty (30) days of discovering or acquiring any new SFI during the term of the sponsored project.

Completed Disclosures will be treated as confidential and disclosed only on a need-to-know basis as required to perform the review and evaluation of the SFI, and to meet NYGC’s disclosure and/or reporting requirements under applicable laws, regulations, grants and/or contracts. The Chair of the COIC is responsible for ensuring that Investigators submit Disclosures in accordance with this Section A.

**B. Review of Financial Interests**

The Chair of the COIC will review each Disclosure from an Investigator to determine if the disclosed financial interest meets the threshold required under the definition of “Significant Financial Interest.” If the threshold is met, the COIC will review the Disclosure to determine (i) if the financial interest is related (as described below) to the Investigator’s sponsored project; and, if so, (ii) if such interest could constitute a potential FCOI by directly and significantly affecting the design, conduct or reporting of the sponsored project.

In determining if an Investigator’s SFI could directly and significantly affect the design, conduct, or reporting of the funded research, and therefore creates a FCOI, the COIC must consider the (i) role of the Investigator and the opportunity (if any) to bias the results; (ii) nature of the research being proposed; and (iii) value of the SFI in relation to the size and value of the outside entity. In addition, the COIC may also consider the following:

- Whether the research is of a fundamental nature directed at understanding basic scientific processes;

- Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely;

- Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention);

- Where the research involves human subjects;

- Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the Investigator’s research could have a significant impact on the company's business or finances;

- The magnitude of the SFI (e.g., the amount of consulting, or the percentage or value of equity);
• Where the SFI is in the Sponsor of the research, and the Sponsor also is a licensee of the Investigator's technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future;

• The number and nature of relationships an Investigator has with an entity (multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts);

• Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI;

• Whether other scientific groups are independently pursuing similar questions;

• Whether sufficient external review and reporting of the research and research results exists to mitigate undue bias;

• Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI; or

• Whether the project involves a subaward to an entity in which the Investigator has a SFI.

After a discussion of the Disclosure, the COIC must determine, by a majority vote, whether a FCOI exists, and, if so, if it can be managed or, alternatively, eliminated.

C. Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest

If the COIC determines that the FCOI cannot be managed, the FCOI must be eliminated. If the COIC determines that the FCOI can be managed, it will develop a written management plan. Examples of conditions or restrictions that might be imposed to manage FCOI include, but are not limited to:

• Public disclosure of SFIs;

• For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;

• Monitoring of research by independent reviewers;

• Modification of the research plan;

• Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

• Divestiture of SFIs;

• Reduction or elimination of the financial interest (e.g., sale of an equity interest);
• Written disclosure of the conflict to all individuals working on the research project;
• Annual reports on the research progress to the COIC; or
• Severance of relationships that create actual or potential FCOIs.

The Investigator must acknowledge in writing that he or she understands the decision of the COIC and will comply with any conditions imposed for managing or eliminating the FCOI described in the management plan. Should an Investigator decline or fail to agree with these conditions, NYGC will take appropriate disciplinary action, including without limitation suspending the Investigator’s research and, with requisite approval of the sponsor, designating a substitute Investigator.

The COIC will inform the relevant principal investigator, project director and/or the Investigator’s direct supervisor of the FCOI and management plan. The COIC will monitor compliance with the management plan on an ongoing basis until the completion of the Sponsored Research, the Investigator’s compliance with the conditions mandated by the COIC in any established management plan.

The COIC will keep a record of Investigator Disclosures that are brought to the COIC for review and the COIC’s review of, and response to, such Disclosures and all actions under this policy. Such records will be maintained and kept for at least three (3) years from the date the final expenditures report is submitted and in accordance with the terms and conditions of the award and relevant regulations.

NYGC will notify the Sponsor or Prime Grantee (in the case of a subaward) in writing of the existence and the nature of any FCOI and provide information about how the conflict will be managed or eliminated. No funding from a Sponsor or Prime Grantee will be expended until the FCOI has been reported to the Sponsor, or Prime Grantee, and NYGC receives permission to incur expenditures.

D. Public Accessibility to Information Related to Financial Conflicts of Interest

To the extent required by law or otherwise by the terms and conditions of a research award, contract or grant agreement, and prior to the expenditure of any funds under an award, NYGC will ensure public accessibility to information concerning any SFI that meets the following three criteria:

• The SFI was disclosed and is still held by the Investigator;
• COIC has determined that the SFI is related to the research funded through an award; and
• COIC has determined that the SFI is a FCOI.

NYGC may make information regarding the SFI available via a publicly accessible web site or, alternatively, by providing a written response to any individual who requests the information within five (5) days of receipt of the individual’s request. At a minimum, the information provided by NYGC will consist of the following:
• The Investigator’s name;
• The Investigator’s title and role with respect to the research project;
• The name of the entity in which the SFI is held;
• The nature of the SFI; and
• The approximate dollar value of the SFI in the following ranges: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

If NYGC uses a publicly accessible web site to comply with the public disclosure requirements of applicable laws and regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional SFI of the senior/key personnel for the sponsored project that had not been previously disclosed, or upon the disclosure of a SFI of senior/key personnel new to the funded research project, if it is determined by the COIC that the SFI is related to the research and is a FCOI.

Before making a public disclosure of information under this provision, NYGC will ascertain from the Investigator that the information provided is current as of the date of the request for public disclosure, and will note in its written response to the requester that the information is subject to updates, on at least an annual basis and within sixty (60) days of the NYGC’s identification of a new FCOI, which should be requested subsequently by the requestor.

Information concerning an Investigator’s SFI, as limited by this policy, will remain available, for responses to written requests or for posting via NYGC’s publicly accessible web site for at least three (3) years from the date that the information was most recently updated.

E. Retrospective Review

Whenever NYGC identifies a SFI that was not disclosed in a timely manner by the Investigator, or for whatever reason was not timely reviewed by NYGC, NYGC will determine whether the SFI constitutes a FCOI within sixty (60) days thereafter, and implement an appropriate management plan.

If the FCOI was not identified or managed in a timely manner, as when (i) the Investigator failed to disclose a SFI that subsequently was found by NYGC to constitute a FCOI; (ii) NYGC failed to review or manage such FCOI; or (iii) the Investigator failed to comply with the FCOI management plan, NYGC shall complete a retrospective review within one hundred and twenty (120) days of NYGC’s determination of noncompliance, which must determine whether any Sponsored Research conducted during the period of noncompliance was biased in the design, conduct or reporting of such research.
NYGC will document the retrospective review, which must include all of the following key elements: project number and title, name of the principal investigator, name of the Investigator with the FCOI, the name of the entity in which the Investigator has an FCOI, reasons for the retrospective review, detailed methodology used for the retrospective review, review findings and conclusions.

As appropriate, NYGC will update any previously submitted FCOI report with information describing how the FCOI will be managed going forward.

If bias is found after a retrospective require, NYGC will promptly notify the sponsor of any funded research, if required to do so by applicable laws and regulations and follow up with a mitigation report. The mitigation report must include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the sponsored research project and NYGC’s plan of action or actions taken to eliminate or mitigate the effect of the bias.

F. Reporting of FCOIs on Subawards

Prior to the expenditure of any funds under a subaward, NYGC will disclose any relevant FCOI to the Prime Grantee, together with information about how the FCOI will be managed or eliminated. NYGC will not incur subaward expenditures until it has received notification to do so from the Prime Grantee.

While the subaward is ongoing (including any extensions with or without funds), NYGC will provide to the Prime Grantee an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.

If a new FCOI is identified during an ongoing research project (e.g., upon the participation of an Investigator who is new to the research project), NYGC will provide to the Prime Grantee, within forty-five (45) days, an FCOI report that describes the nature of the FCOI and how it will be managed or eliminated by NYGC.

G. Subrecipients

If required under the terms and conditions of a Sponsored Research project, NYGC will require the written subaward agreement with a Subrecipient to identify the applicable FCOI policy governing the Subrecipient’s work. The Subrecipient will be required to provide certification that its FCOI policy satisfies Sponsor requirements or, if unable to provide such certification, NYGC’s policy will be applicable to the Subrecipient Investigators. As a rule, NYGC will require Subrecipients to maintain and administer their own FCOI policies and only in exceptional circumstances will NYGC assume primary responsibility for directly soliciting, reviewing and managing Subrecipient Investigators’ Disclosures. In addition, the written subaward agreement will establish timelines and information requirements that will allow sufficient time for NYGC to evaluate, as applicable, Subrecipient Disclosures or Subrecipient FCOI reports in order for NYGC to meet any applicable Sponsor reporting requirements.

H. Training Requirements
Each Investigator must complete the CITI Program financial conflicts of interest training course (or any other training required by NYGC) prior to engaging in research related to an award and at least every four (4) years, and immediately (as defined below) when any of the following circumstances apply:

- NYGC revises this policy, or procedures related to this policy, in a manner that affects the requirements of Investigators (training is to be completed within the timeframe specified in communications announcing such changes);

- An Investigator is new to NYGC (training is to be completed prior to his/her participation in the sponsored research at NYGC); or

- NYGC finds that an Investigator is not in compliance with this policy or a management plan issued under this policy (training is to be completed within thirty (30) days in the manner specified by the COIC).

I. Failure to Comply with This Policy

Any failure by an individual to adhere to this policy may be cause for disciplinary action, including, in severe cases, termination, and termination of the Award by the Sponsor, or in the case of a subaward, the Prime Grantee.

5. Superseded & Related Policies

A. Superseded Policies

a. Employee Conflict of Interest Policy and Procedure (Rev. March 31, 2015)

B. Related Policies

a. [Policy and Procedure on Procurement under Federal Funding (SPR-005)]

b. [Gift Policy]

6. Record of Changes

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<th>Description of Change</th>
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<td>12/1/2020</td>
<td>Edit policy to apply to all extramural funding, add subrecipient FCOI requirement; minor grammatical edits.</td>
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