



Policy for Disclosure of Financial Conflicts of Interest in Sponsored Research

Effective Date: April 25, 2014

Policy

The policy establishes the requirements regarding disclosure of Conflicts of Interest related to sponsored research proposals and awards. The policy applies to all individuals involved in the design, conduct, and/or reporting of sponsored research funded by government, private, philanthropic, and industry sponsors.

Purpose

The purpose of this policy is to provide guidance to all individuals involved in the design, conduct, and/or reporting of sponsored research at New York Genome Center.

Definitions

Award: Any funding instrument (e.g., grant, contract, cooperative agreement, subaward), which comes from an external funding source (Sponsor or Prime Grantee.)

Institutional responsibilities: An Investigator's professional activities on behalf of New York Genome Center (e.g., teaching, administration, research or clinical care). Specifically, these include:

- Externally sponsored research or scholarly activities (includes activities such as proposing, conducting, and analyzing research and disseminating results);
- Research (includes participation in study sections, peer review of manuscripts, or effort on non-sponsored research);
- Instruction/Supported Academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students and trainees, and participation in resident training);
- Administrative activities including serving as Department Chair, Program Director, or service on institutional committees, participation in department activities or internal advisory boards, etc.; or
- Special Service activities on behalf of New York Genome Center including institutional community service.

Investigator: 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 or consultants. These individuals may or may not be paid directly from the award.

Prime Grantee: An institution external to New York Genome Center, which applies for funding from a Sponsor. The Prime Grantee generally issues a subaward to New York Genome Center for the conduct of specific work on the sponsored award.

Significant Financial Interest:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities on behalf of New York Genome Center:

- (i) With regard to any publicly traded entity, a *significant financial interest* 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, 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;
- (ii) With regard to any non-publicly traded entity, a *significant financial interest* 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
- (iii) With regard to intellectual property rights and interests (e.g., *patents, copyrights*), a *significant financial interest* exists upon receipt of income of greater than \$5,000 related to such rights and interests.
- (iv) Third party reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse/dependent children) of greater than \$5,000 that is related to the Investigator's institutional responsibilities (i.e., administrative, teaching, research, or clinical activities) must be disclosed to New York Genome Center. The details of this disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. This disclosure requirement excludes travel paid for by New York Genome Center and does not apply to travel that is reimbursed or sponsored by an U.S. federal, state, or local government agency, an U.S. 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.

(2) The term *significant financial interest* does not include the following types of financial interests:

- (i) Salary, royalties, or other remuneration paid by New York Genome Center to the Investigator if the Investigator is currently employed or otherwise appointed by New York Genome Center, including intellectual property rights assigned to the New York Genome Center and agreements to share in royalties related to such rights;

- (ii) 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;
- (iii) Income from seminars, lectures, or teaching engagements sponsored by an U.S. 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 an U.S. 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: 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, SoNY), a private or philanthropic organization (e.g., American Cancer Society, Lustgarten Foundation), or an industry sponsor (e.g., pharmaceutical company).

Principles

Disclosure

Prior to the submission of an application for funding, the Principal Investigator and all other Investigators at New York Genome Center must have disclosed to New York Genome Center's Conflict of Interest Committee (COIC)/designated official an up-to-date listing of their Significant Financial Interests [SFIs] (and those of their spouse and dependent children), as defined above. Any new Investigator, who, subsequent to the submission of an application for funding, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to the designated official promptly and prior to participation in the project.

Each Investigator must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to New York Genome Center, pursuant to this Policy, or in a subsequent disclosure of SFI, and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in research under an award must submit an updated disclosure of SFI (including reimbursed travel) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Review by New York Genome Center's COIC/Designated Official

The COIC/designated official will conduct reviews of disclosures. The COIC/designated official will review any SFI that has been identified in a disclosure; these interests will be compared to each research award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award.

Guidelines for Determining "Relatedness" and Financial Conflict of Interest

The COIC/designated official will determine whether an Investigator's SFI is related to the research under an award and, if so, whether the SFI is a financial conflict of interest. An Investigator's SFI is related to the research under the award when the COIC/designated official reasonably determines that the SFI: could be affected by the research conducted under the award; or is in an entity whose financial interest could be affected by the research. The COIC/designated official may involve the Investigator in the determination of whether a SFI is related to the research supported by the award.

A financial conflict of interest exists when the COIC/designated official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the funded research.

In determining if an Investigator's SFI is related to the research under an award, and if so, whether the relationship creates a FCOI, the COIC/designated official considers the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the COIC/designated official may also consider the following:

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. 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); or
4. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. 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 research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the

- Investigator from that technology, both currently or in the future; or
8. 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; or
 9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
 10. Whether other scientific groups are independently pursuing similar questions; or
 11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
 12. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI; or
 13. Whether the project involves a subaward to an entity in which the Investigator has a SFI.

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

If a conflict of interest exists, the COIC/designated official will determine by what means – such as the individual’s recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the COIC/designated official will be guided by the principles discussed in this Policy the COIC/designated official will also take into consideration whether the Investigator’s ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- d) Modification of the research plan;
- e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f) Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- g) Severance of relationships that create financial conflicts;
- h) For research projects involving human subjects research, use of a data and safety monitoring board;
- i) Double-blind conditions;
- j) Provisions to conduct the work simultaneously at multiple sites;
- k) Written disclosure of the conflict to all individuals working on the research project;

- I) Annual reports on the research progress to the COIC/designated official.

If the COIC/designated official determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, via a Management Plan, to the individual, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor. The COIC/designated official will keep a record of the disclosure and other relevant information for at least three years. If the COIC/designated official prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

No expenditures on an award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any Management Plans determined by the COIC/designated official necessary to manage the Conflict of Interest. The COIC/designated official will communicate, in writing, with the Sponsor, or Prime Grantee in the case of a subaward, to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated. No expenditures can be incurred until the FCOI has been reported to the Sponsor, or Prime Grantee in the case of a subaward. In the case of a subaward, the Prime Grantee will notify New York Genome Center when it may incur expenditures.

The COIC/designated official will keep a record of Investigator disclosures of financial interests and the COIC/designated official's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three years from the date the final expenditures report is submitted and in accordance with the terms and conditions of the award and relevant regulations.

Public Accessibility to Information Related to Financial Conflicts of Interest

Prior to the expenditure of any funds under an award, New York Genome Center will ensure public accessibility, via a publicly accessible Web site or by written response to any requestor within five business days of a request, of information concerning any SFI disclosed that meets the following three criteria:

- (i) The Significant Financial Interest was disclosed and is still held by the investigator;
- (ii) New York Genome Center has determined that the Significant Financial Interest is related to the research funded through an award; and
- (iii) New York Genome Center has determined that the Significant Financial Interest is a financial conflict of interest.

The information that New York Genome Center will make available via a publicly accessible Web site or in a written response to any requestor within five days of request will include, at a minimum, the following:

- (i) The Investigator's name;
- (ii) The Investigator's title and role with respect to the research project;

- (iii) The name of the entity in which the Significant Financial Interest is held;
- (iv) The nature of the Significant Financial Interest; and
- (v) The approximate dollar value of the Significant Financial Interest 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 New York Genome Center uses a publicly accessible Web site to comply with the public disclosure requirements of the PHS regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional Significant Financial Interest of the senior/key personnel for the funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the funded research project, if it is determined by the COIC/designated official that the Significant Financial Interest is related to the research and is a financial conflict of interest.

If New York Genome Center responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within 60 days of the New York Genome Center's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the Significant Financial Interests of an individual, as limited by this Policy, will remain available, for responses to written requests or for posting via New York Genome Center's publicly accessible Web site for at least three years from the date that the information was most recently updated.

Reporting of Financial Conflicts of Interest on Subawards

Prior to the expenditure of any funds under a subaward, New York Genome Center will provide to the Prime Grantee an FCOI report regarding any Investigator's Significant Financial Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. New York Genome Center cannot incur 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), New York Genome Center will provide to the Prime Grantee an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.

For any Significant Financial Interest that is identified as conflicting subsequent to an initial FCOI report during an ongoing research project (e.g., upon the participation of an Investigator who is new to the research project), New York Genome Center will provide to the Prime

Grantee, within forty five days, an FCOI report regarding the financial conflict of interest and ensure that New York Genome Center has implemented a management plan and the Investigator has agreed to the relevant management plan.

Training Requirements

Each Investigator must complete training on *New York Genome Center Sponsored Research Policy on Conflicts of Interest* prior to engaging in research related to an award and at least every four years, and immediately (as defined below) when any of the following circumstances apply:

- 1) New York Genome Center revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators (training is to be completed within the timeframe specified in communications announcing such changes);
- 2) An Investigator is new to New York Genome Center research (training is to be completed prior to his/her participation in the research); or
- 3) New York Genome Center 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 30 days in the manner specified by the COIC/designated official).

In fulfillment of the training requirement, New York Genome Center requires its investigators to complete the CITI Conflict of Interest module in accordance with the requirements and expectations of this Policy. All investigators must print a certification of completion at the end of training, provide a copy to the Director of Sponsored Research for audit purposes, and retain a copy for their own records.

Failure to Comply with New York Genome Center's Sponsored Research Policy on Conflicts of Interest

When an FCOI is not identified or managed in a timely manner, including, for example, because the underlying Significant Financial Interest is not disclosed timely by an Investigator or, because a FCOI was not timely reviewed or reported by a second tier subrecipient or by New York Genome Center; or because an investigator failed to comply with a management plan; then New York Genome Center will within 90 days:

- a) Complete a retrospective review of the Investigator's activities and the research project to determine any bias in the design, conduct or reporting of research;
- b) Document the retrospective review consistent with the regulation;
- c) Document New York Genome Center's determination as to whether any research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with this Policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research; and
- d) Notify the Sponsor, or Prime Grantee in the case of a subaward, in writing.

If bias is found, New York Genome Center shall notify the Sponsor, or Prime Grantee in the case of a subaward, promptly and submit a mitigation report to them that shall address the following:

- Impact of the bias on the research project; and
- New York Genome Center's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, New York Genome Center shall submit FCOI reports annually to the Sponsor, or Prime Grantee in the case of a subaward, in accordance with the regulation and terms and conditions of the award. Depending on the nature of the Financial Conflict of Interest, New York Genome Center may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of New York Genome Center's independent retrospective review.

Clinical Research

If the Sponsor, or Prime Grantee in the case of a subaward, determines that one of its funded clinical research projects 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 New York Genome Center, 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.

Failure to Comply with This Policy

No expenditures of funds on an award will be permitted unless the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any COIC/designated official-approved FCOI management plan.

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.

Related Documents

Procedure on Disclosures of Financial Conflicts of Interest on Sponsored Research
Financial Conflict of Interest (FCOI) Form

References

Owner

Director, Sponsored Research