

Yeshiva University
Financial Conflicts of Interest Policy for Sponsored Programs
(November 2018)

General

The purpose of this Financial Conflicts of Interest Policy for Sponsored Programs is to ensure objectivity in the design, conduct and reporting of research through the proper disclosure and mitigation of financial conflicts of interest (FCOI). Yeshiva University (University) recognizes the importance of identifying and evaluating FCOI that may affect University research decisions, transactions and operations so that they may be properly managed in order to address any real or apparent bias in research which may undermine the research.

This Policy is intended to comply with the requirements of the federal regulations set forth in 42 CFR Part 50 and 45 CFR Part 94 for grants and cooperative agreements funded through Public Health Service (PHS). This Policy shall be construed in accordance with such regulations and, with respect to PHS-supported programs, shall be deemed to include any requirements set forth in such regulations that are not expressly set forth below.

The University's Office of the Provost is responsible for the interpretation and administration of this Policy and ensuring compliance with it.

Applicability

This Policy applies to all sponsored research conducted at or under the auspices of the University (whether PHS-supported or non-PHS-supported) and applies to all individuals (whether faculty, staff or students and regardless of their title or position) responsible for the design, conduct, or reporting of any such sponsored research. Such an individual (Covered Individual) may be a Principal Investigator (PI), a Co-PI, or other key personnel.

If FCOI disclosure is also required by another oversight committee, including the Institutional Review Board (IRB) for research involving human subjects, such disclosure should also be provided to the University's Office of Sponsored Program (OSP) in order to streamline the review process.

If the sponsored research involves a subrecipient (i.e., subcontractor, subgrantee or subawardee) at another institution, an agreement must be executed with the subrecipient setting forth whether this Policy or the subrecipient's policy will apply to the subrecipient's employees and agents. For PHS-supported projects, if the subrecipient's policy is used, the subrecipient will have to certify that its policy is compliant with 42 CFR Part 50 and 45 CFR Part 94 and that it will be responsible for ensuring compliance by its employees and agents with the federal regulations. The subrecipient will also be required to notify the University of FCOIs within a prescribed deadline. If this Policy will be used, then the subrecipient will be required to ensure compliance with this Policy by its employees and agents.

If the University is a subrecipient under another institution's grant/award, then the OSP shall determine if this Policy, or the other institution's FCOI policy, will be followed. It is generally expected that this Policy will be followed in such instance.

Definitions

Equity Interests: Stock, stock options, and other existing ownership interests in a commercial entity.

Financial Conflict of Interest (FCOI): A Significant Financial Interest (SFI), including for PHS Investigators, Sponsored Travel, that could directly and significantly affect the design, conduct or reporting of research.

Institutional Responsibilities: A Covered Individual's professional responsibilities on behalf of the University, including, but not limited to, activities such as research, research consultation, teaching, professional practice, and institutional administration (e.g., committee memberships and service on panels).

PHS Investigator: A Covered Individual working on a PHS-supported research project.

Related Party: A Covered Individual's spouse, domestic partner, or dependent child.

Remuneration: Any type of compensation for services, including salary and payments, such as consulting fees, paid authorship or honoraria, cash or in-kind gifts, and, for PHS Investigators, Sponsored Travel.

Significant Financial Interest (SFI): A financial interest (i.e., anything of monetary value) that is held or received by (A) a Covered Individual, or (B) a Covered Individual and one or more Related Parties, or (C) one or more Related Parties, and consisting of one or more of the following interests that reasonably appears to be related to the Covered Individual's Institutional Responsibilities:

- (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 (12) months preceding the disclosure and the value of any Equity Interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
- (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 (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Covered Individual (or his/her Related Parties) holds any Equity Interest (e.g., stock, stock option, or other ownership interest) in the entity.
- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(iv) In addition, PHS Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Covered Individual and not reimbursed to the Covered Individual so that the exact monetary value may not be readily available) related to their Institutional Responsibilities that exceeds \$5,000 (in aggregate for a single entity) (Sponsored Travel); provided, however, that 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) (IHE), an academic teaching hospital, a medical center, or a research institute that is affiliated with an IHE.

Significant Financial Interest (SFI) does not include the following types of financial interests: (A) salary, royalties, or other Remuneration paid by the University to the Covered Individual if the Covered Individual is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights; (B) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Individual does not directly control the investment decisions made in these vehicles; (C) income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an IHE, an academic teaching hospital, a medical center, or a research institute that is affiliated with an IHE; or (D) income from service on advisory committees or review panels for a federal, state, or local government agency, an IHE, an academic teaching hospital, a medical center, or a research institute that is affiliated with an IHE.

Disclosure Requirements

All Covered Individuals must provide complete, accurate, and prompt disclosure of all SFI (including Sponsored Travel, for PHS-supported projects), as well as any other financial interest that the Covered Individual believes might constitute an SFI, for themselves and their Related Parties. Disclosure should be made online at: fcoi@yu.edu.

Before accessing sponsored funding, the University will determine whether a Covered Individual's SFI disclosure is related to the project, and if so, whether the SFI constitutes an FCOI. An FCOI exists when the University reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the project. If an FCOI is identified, the University will manage the FCOI as needed, including development and implementation of a management plan.

When SFI Disclosures Are Required

All Covered Individuals applying for sponsored funding or conducting sponsored work must disclose SFIs:

- Before Application for Funding: Each Covered Individual who is planning to participate in sponsored activity must disclose SFIs no later than the time of application or submission of a formal proposal, if applicable.

- When Executing a Contract with an Entity Where No Application or Proposal is Required: Each Covered Individual planning to participate in research must disclose SFIs prior to expending any funds.
- Upon Discovery or Acquisition of a New SFI: Each Covered Individual must submit a disclosure within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) all new SFIs, including an episode of Sponsored Travel, or when there is a change in facts applicable to a previously disclosed potential conflict.
- For Active Awards: Each Covered Individual who is participating in sponsored activity must submit an updated disclosure of SFIs at least annually during the award period. The updated disclosure should include any new information that was not initially disclosed to the University or in any subsequent disclosure of SFIs, and should include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed Equity Interest).

What SFI Disclosures Are Required

Covered Individuals must disclose:

- The person(s) having the interest;
- The Covered Individual's relationship to such person(s);
- The name of the entity with which the Covered Individual has the SFI: and
- The nature and approximate monetary value of the SFI.

For Sponsored Travel, Covered Individuals also should state the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

Additional information also may be requested by the Chair/Director or RCOI Committee (as hereafter defined).

When completing the disclosure, Covered Individuals must take reasonably diligent steps to determine the scope of their actual and potential interests as they may represent significant secondary interests with respect to their Institutional Responsibilities. To the extent that the disclosure form requires information about actual or potential interests of a Covered Individual's Related Party, there is no requirement to undertake any additional fact-gathering, but only report what is already known.

In general, if there is uncertainty as to whether information is responsive to a question, err on the side of reporting.

Disclosure Obligations in Publications or Presentations

The University also expects Covered Individuals to disclose all financial interests related to their presentation or publication of research results. Such financial interests would include: (i) financial interests in entities supporting or otherwise connected to the presentation, publication or research, (ii) the Covered Individual's provision of consulting services on the subject of the research, and (iii) any other financial interests that the Covered Individual reasonably believes could be material to members of an audience or readers assessing the opinions, advice, or work presented by the Covered Individual. This includes the disclosure of a financial interest in an entity which owns or has a contractual relationship to the technology being reported or discussed.

Training (for PHS Investigators ONLY)

PHS Investigators must complete financial conflict of interest training prior to engaging in PHS-supported research and at least once every four (4) years while they are still engaged in PHS-supported research. PHS Investigators also must complete this training immediately in any of the following circumstances:

- When this Policy is revised in any manner that affects the requirements applicable to PHS Investigators;
- When the PHS Investigator is new to the University, even if the PHS-supported research has already begun; or
- When the University determines that the PHS Investigator is not in compliance with this Policy or an imposed management plan.

Please contact the OSP for information about accessing this training program.

Review Process

The University's Provost shall appoint a Research Conflict of Interest Committee (RCOI Committee) comprised of at least one individual. The Provost shall appoint a Chair of the RCOI Committee, who also shall serve as Director of the University's Research Conflict of Interest Program and is the Institutional Official for all research conflict of interest matters (Chair/Director).

The RCOI Committee shall consult with the OSP and the University's Office of the General Counsel. A majority of the members of the RCOI Committee will constitute a quorum, and the RCOI Committee may act by majority vote of the members present at a meeting (in person or by telephone or other electronic means) with a quorum, or by written or electronic consent of a majority of all members.

Promptly after submission of an FCOI disclosure (and in any event generally within fifteen (15) days), the RCOI Committee will review the disclosure and any other relevant information (e.g., research proposal, IRB application, etc.) and determine:

- Whether the Covered Individual's SFI is related to his/her research; and if so,
- Whether the SFI constitutes an FCOI.

If an FCOI is identified, generally within thirty (30) days, the RCOI Committee will prepare and submit a report to the Chair/Director detailing a recommended management plan, including any proposed conditions or restrictions to manage the FCOI. The Chair/Director will make a final determination as to how to manage the FCOI and will accept, reject or modify the RCOI Committee's recommendation.

Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

- Public disclosure of the FCOI (e.g., when presenting or publishing the research; to staff members working on the project; to the IRB and other applicable oversight committees);
- For research involving human subjects, disclosure of the FCOI directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan or protocol;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of a financial interest (e.g., sale of an Equity Interest); and
- Severance of relationships that create the FCOI.

In his/her discretion, the Chair/Director may elect to conduct an expedited review - instead of engaging the full RCOI Committee - for amendments or continuing reviews of SFIs which have been previously reviewed, appear to be related to SFIs covered under an active management plan, or can be easily addressed by standard management plan measures. These actions and all SFIs will be reported to the RCOI Committee as soon as practicable.

The Chair/Director will provide copies of the determination to the conflicted Covered Individual (and PI, if different), the Dean of the Covered Individual's Department, and the OSP, as applicable. The Covered Individual may appeal the determination as described below.

The Covered Individual must comply with any management plan; funding will be delayed until he/she agrees to comply.

It is expected that the determination of whether a FCOI exists and implementation of a management plan to manage the FCOI will be completed within sixty (60) days of submission of an FCOI disclosure.

Appeal

The Covered Individual may submit a written appeal to the University's Provost (or his/her designee) within ten (10) days from receipt of the determination. The appeal should include the specific provisions being challenged, the reason for the appeal, and the justification for a different outcome. The Covered Individual also may provide an alternative management plan and any supplemental information that might be helpful in reviewing the appeal. The decision of the University's Provost (or his/her designee) shall be final and not subject to further appeal.

Compliance with the Management Plan

The OSP shall be responsible to audit and monitor compliance with the management plan.

If it is determined that a Covered Individual has failed to comply with a management plan, the Chair/Director, in consultation with the RCOI Committee, will develop a corrective action plan and may impose sanctions on the Covered Individual, up to and including termination of employment. Other sanctions may be suspension or denial of eligibility to engage in a project. Such sanctions may require giving notice to professional bodies or journals, or to the public.

In addition, if it is determined that a Covered Individual has failed to comply with a management plan, the University will undertake a retrospective review of the Covered Individual's activities on the project to determine whether there was any bias in the design, conduct, or reporting of the project during the period of noncompliance. See "What Happens When the FCOI Is Not Identified and Managed" below.

New SFIs During Ongoing Research

In the event that a new interest is disclosed to the University (e.g., a Covered Individual new to an ongoing project discloses an SFI or an existing Covered Individual discloses a new SFI during an ongoing project) or the University identifies a disclosed interest that was not previously reviewed in a timely manner in accordance with this Policy, the Chair/Director, in consultation with the RCOI Committee, will promptly (and in any event within sixty (60) days), determine whether a FCOI exists, and if it does, implement a management plan in accordance with this Policy that specifies the actions that have been, and will be, taken to manage the FCOI.

What Happens When the FCOI Is Not Identified and Managed

In the event that an FCOI is not identified or managed in a timely manner (including as a result of a Covered Individual's failure to timely disclose an SFI that is subsequently determined by the University to constitute an FCOI; as a result of a Covered Individual's failure to comply with a management plan; or as a result of the University's failure to review or manage an FCOI), the University will, within one hundred twenty (120) days of the determination of non-compliance, complete a retrospective review of the Covered Individual's activities on the project(s) to determine whether there was any bias in the design, conduct, or reporting of the project during the period of noncompliance.

Documentation of such review will include the following key elements: (i) Project number and title; (ii) PIs or project directors; (iii) Covered Individual and entity resulting in the FCOI; (iv) Reason the retrospective review was completed; (v) Detailed description of methodology used to conduct the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.); and (vi) Findings and conclusions of the review.

Additional Requirements for PHS-Supported or NSF-Supported Projects

For PHS-supported projects, the OSP will coordinate the University's filing of such FCOI and other reports as required under PHS regulations, including before expending any funds under a PHS-supported project, and when an FCOI is not identified and managed. In addition, as required on an annual basis the University will submit FCOI reports to the PHS awarding agency specifying the actions that will be taken to manage the FCOI going forward. If the retrospective review finds bias in the design, conduct, or reporting of PHS-supported activity, the University will notify the PHS awarding agency promptly and submit a mitigation report, as required, which will include:

- The key elements documented in the retrospective review described above;
- A description of the impact of the bias on the research project; and
- The University's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

For PHS-supported clinical research, if the U.S. Department of Health and Human Services determines that a PHS-supported clinical research project (i.e., a project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment) has been designed, conducted, or reported by a Covered Individual with an FCOI that was not managed or reported by the University as required by the regulations, the University will require the Covered Individual to disclose the FCOI in each public presentation of the results of the clinical research and to request an addendum regarding such disclosure to previously published presentations.

For projects sponsored by the National Science Foundation (NSF), the Chair/Director will notify the NSF Office of General Counsel if the University determines that it is unable to satisfactorily manage a FCOI.

In all instances, the Chair/Director also may determine, in his/her discretion that interim measures are necessary regarding the Covered Individual's participation in the affected PHS or NSF-supported research, and the Covered Individual must comply with such measures.

Records

Records relating to all SFI disclosures, including the review of and response to the disclosures (whether or not resulting in an FCOI finding), and any other action under this Policy (including a retrospective review), will be maintained by the Chair/Director (or his/her designee) on behalf of the University for the longer of (i) three (3) years following the termination or completion of the

related project and submission of the final expenditures report, and (ii) resolution of any action involving such records; provided, however, that for PHS- and NSF-supported research, all records also should be maintained as required by 45 CFR 74.53(b), 92.42(b), or National Science Foundation, Grant Policy Manual, Ch. 510, Conflict of Interests Policy, or other applicable law, rule or regulation.

Public Accessibility

This Policy and all related forms will be made publicly available on the University's website.

In addition, as required by federal regulations, the University shall ensure public accessibility by responding, within five (5) business days, to a written request for information covering any SFI disclosed to the University that meets the following criteria:

- The SFI was disclosed and is still held by the Covered Individual;
- The University has determined that the SFI is related to PHS-supported research;
and
- The University has determined that the SFI is an FCOI.

The response will set forth: (i) the Covered Individual's name; (ii) the Covered Individual's title and role with respect to the project; (iii) the name of the entity in which the SFI is held; (iv) the nature of the SFI; and (v) the approximate dollar value of the SFI, 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.

Information concerning the SFIs of senior/key personnel (i.e., PI, project director, and any other person identified as senior/key personnel by the University in the grant application, progress report, or any other report submitted by the University) will remain available for responses to written requests for at least three (3) years from the date that the information was most recently updated.

When the PHS-supported project is conducted by a subrecipient investigator, and under their written agreement with the University the subrecipient is required to comply with the subrecipient's FCOI policy, the subrecipient will have the responsibility of making such information publicly accessible.

Requests for information should be addressed to:

Yeshiva University
Office of the Provost, BH 1310
500 West 185th Street
New York, NY 10033