

Yeshiva University
Financial Conflict (v)-4l CiTj EMC [(P) (FOI) Tc 0.004 Tw -17.23 -1.1[(P)-3l C (i(m)-4

_____). Yeshiva University(University) recognizes
the importance of identifying and evaluating FCOI that may affect University research decisions,

If the University is a subrecipient under another institution's grant/award, then the ~~CSA~~ ^{CSA} determine if this Policy, or the other institution's FCOI policy, will be followed. This generally

(iv) In addition, PHS Investigators also must disclose the occurrence of any reimbursed or

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 years while they are still engaged in PHS supported research. PHS Investigators also must complete this training immediately of the following circumstances:

- x When this Policy is revised in any manner that affects the requirements applicable to PHS Investigators;
- x When the PHS Investigator is new to the University, even if the PHS supported research has already begun; or
- x 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 OSG 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 within fifteen (15) business days).

- 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

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 not 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 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:

- x The key elements documented in the retrospective review described above
- x A description of the impact of the bias on the research project; and
- x 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 that research and to request an addendum regarding such disclosure to previously published presentations.

For projects sponsored by the National Science Foundation (NSF), Chair/Director will notify the NSF Office of General Counsel if the University determines 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 undertaken (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

