

NIH - FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

Based on the US Regulations for investigators funded by the Public Health Services (PHS)

INTRODUCTION

This FCOI policy intends to meet [U.S. Dept of Health and Human Services and PHS Regulations](#). It applies to all PHS-sponsored Investigators of Tel Aviv University (TAU) of which the NIH is the main source of funding. TAU's Conflict of Interest Committee (COIC) is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the COIC is implemented pursuant to TAU's policy.

Investigators intending to submit proposals to the *Susan G. Komen for the Cure*, *Alliance for Lupus Research*, *CurePSP*, *Patient-Centered Outcomes Research Institute (PCORI)*, and *Juvenile Diabetes Research Foundation (JDRF)* are also required to follow this policy since these foundations adopted PHS requirements regarding Financial Conflict of Interest.

DEFINITIONS

Family - any member of the Investigator's immediate family, specifically, any dependent children and spouse.

Financial Interest - anything of monetary value received or held by an Investigator or an Investigator's Family, 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 does NOT include:

- a) Salary, royalties, or other remuneration from TAU (or, for sub-recipients, your home 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 Federal, state or local governmental agencies; 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.

For Investigators, *Financial Interest* also includes any reimbursed or **sponsored travel** undertaken by the Investigator and related to his/her 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. It excludes travel reimbursed or sponsored by Federal, state or local governmental agencies, institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest (SFI) - a *Financial Interest* that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received 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 salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through TAU (or, for sub-recipients, your home institution); or
- e) is reimbursed or sponsored travel related to their institutional responsibilities.

Financial Conflict of Interest - a *Significant Financial Interest* that TAU's COIC reasonably determines that could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

Institutional responsibilities - the Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator - any individual who is:

- Identified as a Project Director (**PD**) or a Principal Investigator (**PI**), of a PHS funded project;
- A member of the research team identified as Key Personnel on the application, Grant or Cooperative Agreement, contract, progress report, etc.;
- Responsible for the design, conduct or reporting of a research funded by the PHS, or proposed for such funding. This may include, for example, collaborators or consultants.

POLICY PROCEDURE

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to PHS-funded research either directly or via sub-award, provides mechanisms for Investigators and TAU to manage those 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. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the COIC official.

1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests as defined above to the Research Authority (**RA**) at the time of proposal submission and on an annual basis. The COIC is responsible for the distribution, receipt, processing, review and retention of disclosure [forms](#).

There is a two-stage process to implement the disclosure, review and reporting requirements. This process, with the PHS financial disclosure [forms](#), is designed to simplify the administrative burden associated with financial disclosure and review at the *initial proposal submission stage* for new and competing continuation/renewal proposals (**Form A**).

Detailed financial information (**Form B**) will not be requested unless and until a proposal is likely to be funded, i.e., when a proposal passes the initial review group successfully, or when a Just in Time (**JIT**) request is received. This will allow the COIC to concentrate its efforts on those proposals that have a chance of being funded.

2) REVIEW AND DECISION OF THE COIC

If the disclosure forms reveal a Significant Financial Interest, it will be reviewed at a timely manner by the COIC for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the committee will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate.

A Financial Conflict of Interest will exist when the COIC determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the COIC determines that there is a Financial Conflict of Interest that can be managed, it must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

The COIC will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

3) REPORTING TO PHS

TAU's official will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. 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 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.

4) INVESTIGATOR NON-COMPLIANCE DISCIPLINARY ACTION

In the event of an Investigator's failure to comply with this Policy, the COIC may suspend all relevant activities or take other action deemed appropriate by the COIC pursuant to TAU's policy until the matter is resolved.

The COIC's administrative action regarding an Investigator's failure to comply with this Policy will be described in a written explanation to the investigator, and will notify the individual of the right to appeal it. The COIC Chair will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime

PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

5) TRAINING

Each Investigator must complete the FCOI [training](#) if he or she is requested to submit a JIT, or some other indication from the funding agency that implies it is likely to be funded. The training must be done prior to engaging in research funded by PHS, and at least every four years thereafter.

Please send your FCOI certificate in a PDF format to Mr. Eyal Schachter (eyalscha@tauex.tau.ac.il).

6) RECORD RETENTION

TAU's COIC will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final financial report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

7) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, TAU may be required to make such information available to the PHS Awarding Component, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to TAU, if requested or required. If TAU is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

8) PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, the RA will publish on its website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be published at TAU's website within 60 days will include:

- a) The Investigator's name.
- b) The Investigator's title and role with respect to the research project.

- c) The name of the entity in which the SFI is held.
- d) The nature of the SFI
- e) The approximate USD value of the SFI (USD ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; \$20,000-\$100,000; amounts above \$100K by increments of \$50K), 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.

9) SUB-RECIPIENTS OF TAU

For PHS-funded research that is carried out through a sub-recipient, TAU will take reasonable steps to ensure that any sub-recipient investigator complies with 42 CFR 50 subpart F, by incorporating in the *Statement of Intent* and in the sub-agreement, terms that establish whether TAU's FCOI Policy or the sub-recipient's own FCOI Policy will apply to its investigators.

Sub-recipient institutions who rely on their FCOI must report identified FCOI to TAU in sufficient time to allow TAU to report the FCOI to the NIH to meet its reporting obligations.

Sub-recipient institutions that must comply with TAU's policy must submit [Form C](#) to TAU in sufficient time to allow TAU to review, manage and report identified FCOI to the PHS agency.

CLINICAL TRIALS (IF APPLICABLE)

***Clinical Trial* - any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.**

Review of Significant Financial Interests Related to Clinical Trials

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

In the event of non-compliance with reporting and/or management of a financial conflict of interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected PHS-sponsored research.