

FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY¹

1. INTRODUCTION

- 1.1. This FCOI Policy intends to meet the 2011 Revised Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research ([42 CFR Part 50 Subpart F](#)) which promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

For further information please see [FAQs](#)

- 1.2. This FCOI Policy applies to all PHS-sponsored Investigators of the Weizmann Institute of Science (WIS) of which the NIH is the main source of funding. WIS's Vice President for Innovation and Technology Transfer (**Designated Official**) is responsible for ensuring implementation of this FCOI Policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Designated Official is implemented pursuant to WIS's Policy.
- 1.3. Investigators intending to submit proposals to any foundation that adopts PHS requirements regarding Financial Conflict of Interest are also required to follow this FCIO Policy.
- 1.4. This FCOI Policy does not exclude any other WIS applicable policy/ies.

2. DEFINITIONS

- 2.1. **Family** - any member of the Investigator's immediate family, specifically, any dependent children and spouse.
- 2.2. **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 WIS (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 any of the following USA entities: Advisory committees or review panels for Federal, state, or local

¹ Based on the US Regulations for investigators funded by the Public Health Services (PHS)

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** in the aggregate value exceeding \$5,000 per entity received during the 12 month period preceding the disclosure, undertaken by the Investigators and related to their 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 or from any of the following USA entities: Federal, state, or local governmental agencies, institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

2.3. ***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 per entity; 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 per entity; 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 in the aggregate value exceeding \$5,000 per entity, received during the 12 month period preceding the disclosure, related to intellectual property rights and interests not reimbursed through WIS (or, for sub-recipients, your home institution); or
- (e) is reimbursed or sponsored travel related to their institutional responsibilities in the aggregate value exceeding \$5,000 per entity, received during the 12 month period preceding the disclosure.

2.4. ***Financial Conflict of Interest*** - a *Significant Financial Interest* that WIS's Designated Official reasonably determines that could directly and significantly affect the design, conduct or reporting of Funded Research (as defined hereunder).

2.5. ***Funded Research*** – for the purpose of this FCOI Policy, Funded Research means research funded under Public Health Service (PHS) grants or cooperative agreements or by any foundation that adopts PHS requirements regarding Financial Conflict of Interest.

2.6. ***Institutional responsibilities*** - the Investigators' professional responsibilities associated with their Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

2.7. ***Investigator*** - any individual who is:

- (a) Identified as a Principal Investigator (PI), of a Funded Research;
- (b) A member of the research team identified as key personnel on the application, grant or cooperative agreement, contract, progress report, etc. of a Funded Research project;
- (c) Responsible for the design, conduct or reporting of a Funded Research, or proposed for such funding. This may include, for example, collaborators or consultants.

2.8. ***Relevant Funding Agency*** - Public Health Service (PHS) or any foundation that adopts PHS requirements regarding Financial Conflict of Interest.

3. **POLICY PROCEDURE**

This FCOI Policy is predicated on the expectation that Investigators should conduct their affairs to avoid or minimize conflicts of interest and must respond appropriately when conflicts of interest arise. To that end, this FCOI Policy informs Investigators about situations that generate conflicts of interest related to a Funded Research, either directly or via sub-award, provides mechanisms for Investigators and WIS 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 FCOI Policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Designated Official.

4. **DISCLOSURE OF FINANCIAL INTERESTS**

- 4.1. All Investigators are required to disclose their outside Significant Financial Interests as defined above to the Designated Official on an annual basis, through the Academic Affairs Office (AAO), for which purpose the Investigator will be required to fill out and submit an internal annual financial disclosure form. The Designated Official is responsible for the receipt, processing, review, and retention of disclosure forms.
- 4.2. All Investigators are required to disclose their outside Significant Financial Interests as defined above to the Grants and Projects Office (**RGP**) at the time of a grant application submission to a Relevant Funding Agency, for which purpose the Investigator will be required to fill out and submit an internal grant application financial disclosure form, prior to submitting the application.
- 4.3. During the period of the award, each Investigator who is participating in Funded Research, is required to submit an updated disclosure of Significant Financial Interests at least annually, and to submit to the Designated Official an updated disclosure of Significant Financial Interests within thirty days of discovering or acquiring a new Significant Financial Interest (e.g., through purchase, marriage, or inheritance).

5. **REVIEW AND DECISION OF THE DESIGNATED OFFICIAL**

- 5.1. If the disclosure form reveals a Significant Financial Interest, it will be reviewed at a timely manner by the Designated Official for a determination of whether it constitutes a Financial Conflict of Interest.

- 5.2. A Financial Conflict of Interest will exist when the Designated Official determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of a Funded Research.
- 5.3. If the Designated Official determines that there is a Financial Conflict of Interest that can be managed, the Designated Official will develop and implement a written management plan to manage the Financial Conflict of Interest including the reduction or elimination of the conflict, as appropriate. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related Funded Research goes forward.
- 5.4. The Designated Official 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.
- 5.5. Whenever, in the course of an ongoing Funded Research : (a) a Significant Financial Interest is disclosed, or (b) it has been identified that a Significant Financial Interest was not disclosed timely for whatever reason, the Designated Official shall, within thirty days: review the Significant Financial Interest; determine whether a Financial Conflict of Interest exists; and, if so, implement, a management plan that shall specify the actions that have been, and will be, taken to manage such Financial Conflict of Interest.
- 5.6. In addition, whenever a Financial Conflict of Interest is not identified or managed in a timely manner, WIS shall, within 120 days of determination of noncompliance, complete a retrospective review to determine whether any Funded Research or any portion thereof, conducted during the period of the noncompliance, was biased in the design, conduct, or reporting of such research. Retrospective review shall be documented. If bias is found, WIS will notify the Relevant Funding Agency promptly and submit a mitigation report.

6. REPORTING TO PHS

- 6.1. RGP will report financial conflicts of interest or non-compliance to the Relevant Funding Agency in the following circumstances:
 - 6.1.1. Within 60 days for an Investigator who is newly participating in the project.
 - 6.1.2. Within 60 days for new, or newly identified, FCOIs for existing Investigators.
 - 6.1.3. At least annually, to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
 - 6.1.4. Following a retrospective review, according to section 5.6 above, to update a previously submitted report, if appropriate.
- 6.2. If the funding for the research is made available from a prime awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 45 days of any subsequently identified Financial Conflict of Interest, such that the prime awardee may fulfill their reporting obligations to the Relevant Funding Agency.

7. INVESTIGATOR NON-COMPLIANCE DISCIPLINARY ACTION

- 7.1. In the event of an Investigator's failure to comply with this FCOI Policy, the Designated Official may suspend all relevant activities or take other action deemed appropriate by the Designated Official until the matter is resolved.
- 7.2. The Designated Official's administrative action regarding an Investigator's failure to comply with this FCOI Policy will be described in a written explanation to the Investigator. The Designated Official will promptly notify the Relevant Funding Agency of the action taken or to be taken. If the funding for the research is made available from a prime awardee, such notification shall be made promptly to the prime awardee for reporting to the Relevant Funding Agency.

8. TRAINING

Each Investigator must complete the NIH FCOI [training](#) or the relevant CITI 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 a Funded Research, and at least every four years thereafter.

Training is also required immediately when any of the following circumstances apply:

- (1) WIS revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- (2) An Investigator is new to WIS; or
- (3) WIS finds that an Investigator is not in compliance with this FCOI Policy or management plan.

9. RECORD RETENTION

WIS's Designated Official 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 Relevant Funding Agency, or to the prime awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three-year period. In case of any litigation, claim, financial management review, or audit, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

10. CONFIDENTIALITY

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

11. PUBLIC ACCESSIBILITY

- 11.1. Prior to the expenditure of funds, WIS 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:

- 11.1.1. The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
 - 11.1.2. A determination has been made that the Significant Financial Interest is related to the Funded Research; and
 - 11.1.3. A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.
- 11.2. The information to be published at WIS's website will be updated at least annually and within 60 days of the newly identified FCOI and will include:
- 11.2.1. The Investigator's name.
 - 11.2.2. The Investigator's title and role with respect to the research project.
 - 11.2.3. The name of the entity in which the Significant Financial Interest is held.
 - 11.2.4. The nature of the Significant Financial Interest.
 - 11.2.5. The approximate USD value of the Significant Financial Interest (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.
- 11.3. The information will remain available for three years from the date the information was most recently updated.

12. SUB-RECIPIENTS OF WIS

- 12.1. For Funded Research that is carried out through a sub-recipient, WIS 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 WIS's FCOI Policy or the sub-recipient's own FCOI Policy will apply to its investigators.
- 12.2. Sub-recipient institutions must report identified FCOI to WIS within 30 days of identified FCOIs to allow WIS to report the FCOI to the Relevant Funding Agency to meet its reporting obligations.

13. CLINICAL TRIALS (IF APPLICABLE)

***Clinical Trial* - any Funded Research study that involves interaction with human subjects.**

Review of Significant Financial Interests Related to Clinical Trials

- 13.1. Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.
- 13.2. In the event of non-compliance with reporting and/or management of a Financial Conflict of Interest involving a Funded (clinical) Research project, the Investigator must disclose the Financial Conflicts of Interest in each public presentation of the results of the affected Funded Research.