

THE INSTITUTE FOR MOLECULAR MEDICINE

THE INSTITUTE FOR MOLECULAR MEDICINE CONFLICT OF INTEREST (FCOI) POLICY

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The Institute for Molecular Medicine (IMM), as an institution that participates in Public Health Service (PHS) funded research, is required to have a robust Financial Conflict of Interest (FCOI) Policy that is enforced, regularly maintained, and meets the requirements of the 42 CFR Part 50, Subpart F (Promoting Objectivity in Research). IMM's policy is set forth by the Board of Directors and reviewed by this governing body regularly. The purpose of this FCOI Policy is to comply with applicable law and to ensure the objectivity of the research conducted by IMM and its employees.

The policy set forth herein enables IMM to certify in each application for funding that this Institution:

- Has in effect an up-to-date, written and enforced administrative process to identify and manage FCOI.
- Shall promote and enforce Investigator compliance with the regulation.
- Shall manage FCOI and provide initial and ongoing FCOI reports.
- Agrees to make FCOI and SFI information (including related Institutional reviews and determinations) available to HHS, promptly, upon request.
- Shall fully comply with the regulation's requirements.

Each Investigator at IMM has an obligation to act in the best interest of this non-profit research institution and to further its mission of contributing to the understanding of and the prevention and cure of catastrophic human chronic diseases, such as neurodegenerative disorders, autoimmune diseases, fatigue illnesses, rheumatic diseases, cancer, AIDS, and infectious and genetic diseases. This is being accomplished through innovative basic and translational research programs.

A. CONFLICT OF INTEREST

A conflict of interest exists when an Investigator has a Significant Financial Interest (SFI) that could directly and significantly affect her or his activities at IMM. Generally, this will be when the external interest provides an incentive to affect the individual's conduct of his or her research activities and when the individual has the opportunity to affect IMM's decision or other activity (for example, because he or she is the decision-maker or the principal investigator for a research project). Conflicts of interest can arise naturally from an individual's engagement with the world outside of IMM, and the mere existence of a conflict of interest does not necessarily imply wrongdoing on anyone's part. When conflicts of interest do arise, however, they must be recognized, disclosed and either properly managed or eliminated.

Investigators applying for and working on Public Health Services (PHS), National Institutes of Health (NIH), or National Science Foundation (NSF) funded research must disclose significant financial interests that are related to the Investigator's institutional responsibilities and must be in compliance with 42 CFR Part 50.

Investigators are all persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research proposed for funding by the PHS, the National Institutes of Health (NIH), or the National Science Foundation (NSF). These agencies, together with any other organizations providing funding through grant or contract to which the regulations contemplated herein apply, collectively, the **Funding Agencies**. This policy provides the framework to identify, evaluate and correct or remove real, apparent and potential conflicts of interest.

With respect to Subrecipients for NIH grant awards, IMM shall establish during the Subaward process, via a written agreement, whether a Subrecipient will follow the FCOI policy of IMM or the FCOI policy of the Subrecipient Organization (which complies with all PHS regulations). For Subrecipients using the FCOI policy of the Subrecipient Organization, IMM

shall require for Subrecipients to report identified FCOIs for its Investigators in a time frame that allows IMM to report identified FCOIs to the Funding Agencies as required by the regulation.

B. TRAINING REQUIREMENTS

Due to IMM being a small research institution, the IMM Board of Directors has the ability and resources to individually meet with each Investigator.

The Board of Directors will be responsible for meeting with each Investigator and training them on IMM's FCOI Policy and the Investigator's disclosure responsibilities as well as the Federal Regulations that the Policy is based on.

The Individual training shall be required to every four years. To accomplish the latter, the governing body shall keep a current log of all IMM Investigators, listing their original training and subsequent training dates. Every Investigator is required to complete the original training and the subsequent trainings no less than every four years.

For any Investigators new to the Institution, the FCOI training shall be part of their onboarding process. Any Investigator determined to not be in compliance with the policy or management plan will be required to immediately complete an FCOI training.

In the case IMM's FCOI Policy will change in a way that affects requirements of Investigators, the FCOI training, a new FCOI training would be immediately conducted with each Investigator.

C. SPECIFIC DEFINITIONS

The following definitions apply to this policy:

Funded Research means any research funded by a Funding Agency.

Investigator means any person who is responsible for the design, conduct or reporting of research funded by a Funding Agency.

Training Requirement means training related to Financial Conflict of Interest (FCOI) and required under law. All IMM Investigators are required to complete the Training Requirement. If any conflicts of interest are found or known, they must be disclosed. The training must be updated no less frequently than every four years or as designated based on grant award or role circumstances. Information and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site: (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>).

Significant Financial Interest (SFI) means a financial interest consisting of one or more of the following interests of the investigator (including those of the investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. 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 exceeds \$5,000. For the 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 in stock, stock options or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value;
2. With regard to any privately held entity, a significant financial interest exists if the value of any remunerations 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 interests (e.g. stock, stock options, or other ownership interest); or
3. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

With respect to the SFI, Investigators also must disclose (and such disclosure shall constitute an SFI Disclosure, defined below) the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities; 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), an academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education. This disclosure will include, at a

minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Upon receipt of this disclosure, the Policy Coordinator will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the Funding Agency research.

The term Significant Financial Interest does not include the following types of financial interests: salaries, royalties or other remuneration paid by IMM to the Investigator if the Investigator is currently employed or otherwise appointed by IMM, including intellectual property rights assigned to IMM and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirements accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures or teaching engagements sponsored by a 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, research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a 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.

A **Financial Conflict of Interest** or **FCOI** exists when IMM reasonably determines that an SFI could directly and significantly affect the design, conduct or reporting of Funded Research.

An **SFI Disclosure** is a report that each Investigator shall submit: (a) annually to the Policy Coordinator; (b) in the event of certain sponsored travel, as set forth in the definition of "Significant Financial Interest," above; (c) within thirty (30) days of an Investigator discovering or acquiring any significant financial interest; and (d) no later than at the time of application for PHS-funded research.

Management of an FCOI means taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of Funded Research will be free from bias.

An **Awarding Component** is the applicable sub-agency of a Funding Agency.

D. DISCLOSURES/REPORTING/DETERMINATION PROCESS

Each Investigator shall submit SFI Disclosures using the SFI Disclosure Form to the Board of Directors as follows:

1. No later than at the time of application for PHS-funded research.
2. An updated general SFI Disclosure annually.
3. Any new Investigator upon the start of employment at IMM.
4. Within 30 days if IMM revises its FCOI policy in a way that affect the requirements.
5. Whenever SFIs or internal responsibilities change materially from those described in the annual disclosure, the disclosure should be resubmitted as soon as possible, but no later than 30 days after the Investigator's knowledge or discovery of such events or acquiring any SFI.

Prior to the expenditure of funds from Funding Agencies, the Board of Directors will review each SFI Disclosure and determine if any SFIs relate to funded research, determine if an FCOI exists, and develop and implement management plans as needed to manage FCOIs.

In determining whether an Investigator's SFI is related to funded research, and if so related, whether the SFI is an FCOI, the Board of Directors shall consider all available evidence in light of the following concepts, in addition to any other concepts the Board of Directors may reasonably consider:

Protected Interests

- Research integrity
- Safety of human subjects
- IMM's reputation
- The Investigator's reputation

Relationship between the SFI and the Research

- Is the subject of the SFI or its products or services involved in the research, and how?

Nature of the SFI

- Equity, cash compensation, or in-kind compensation?
- Part of a diversified portfolio or a specific investment?
- Publicly traded or private company?
- Does compensation exceed fair market value?

Likelihood of influence

- Role of the Investigator in the research
- Potential gain to Investigator if research yields particular results
- Safeguards built into design

If no FCOI is found, the SFI Disclosure will be filed with the Board of Director's SFI Disclosure records.

If an FCOI is identified, it will be recognized, disclosed and either properly managed or eliminated. The identified FCOI will also be put on the FCOI report through the eRA Commons FCOI module (or, where IMM is a Subawardee, then IMM will report the FCOI as required under the applicable Subaward Agreement) prior to expending any Funding Agency funds. IMM will then report any new FCOIs to the Awarding Component within 60 days. The Board of Directors will monitor Investigator compliance with any management plans until the completion of the project.

IMM shall make available information concerning identified FCOIs held by senior/key personnel publicly accessible prior to the expenditure of funds. The information will include the minimum elements as provided in the regulation, be posted on a public website or made available within five calendar days of a written request, be updated at least annually, be updated within 60 days of a newly identified FCOI, and remain available for three years from the date the information was most recently updated.

E. RECORDS MANAGEMENT

IMM will maintain records of all SFI disclosures, and records of resulting IMM action, for at least three years from the date of submission of the final expenditures report for the applicable funding, or for such other periods of time as may be required under 45 CFR 75.361, if applicable.

F. FUNDED RESEARCH EXCLUSIONS

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are federal award mechanisms that allow start-up and small companies to compete for federal funding. The goal of these awards is to engage these entities in federally sponsored research and development and accelerate the transfer of scientific discovery and innovation to the public.

Funded Research is any project governed by Funding Agency regulations but excluding applications for Phase I support under SBIR and STTR programs.

G. COMPLIANCE AND PENALTIES FOR NON-PERFORMANCE

If an Investigator fails to comply with IMM's FCOI policy, within 120 days, IMM shall complete a retrospective review of the Investigator's activities to determine bias. If as a result of that determination, or at any other time, any bias is found, IMM shall submit a mitigation report to the applicable Funding Agency, in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias. IMM will work with the Investigator to set up an FCOI management plan to mitigate the situation. IMM is required to mandate the Investigator disclose the FCOI in each public presentation with research results if it was not reported up front. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future funding from Funding Agencies.

H. POINT OF CONTACT

If you have a conflict of interest or if you have a question to discuss, contact the IMM Board of Directors by email (grants.admin [at] immed.org).