

Policy of Financial Interests Related to U.S. Public Health Service (USPHS) Sponsored Projects for Promoting Objectivity in Research

Responsible Office: Board of Directors
Discussed and Issued: April 5th, 2012
Effective Date: August 24th, 2012

This IMM policy is based on the U.S. Department of Health and Human Services (DHHS) Objectivity in Research,” Code of Federal Regulations ([42 C.F.R. Part 50, Subpart F](#)) and will become effective on 24th of August 2012. It applies to all IMM investigators who are involved in research supported by U.S. governmental organizations. The Board of Directors of IMM review disclosures of financial conflict of interest and significant financial interests and their relationship to USPHS (including any organizational unit, agency or entity of the DHHS and any non-USPHS entity adopting the USPHS regulations on Responsibility of Applicants for Promoting Objectivity in Research for which USPHS Funding is Sought) funded research and determine whether any significant financial interests constitute a financial conflict of interest (FCOI).

1. Purpose and Scope

This policy implements the 2011 USPHS regulations on Responsibility of Applicants for Promoting Objectivity in Research for which USPHS Funding is Sought (USPHS regulations). These regulations are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct and reporting of Public Health Service funded research will be free from bias resulting from any Investigator’s financial conflicts of interest.

This policy is applicable to all research funded by the Public Health Service and other governmental organizations that adopt the Public Health Service regulations with an award

issue date of August 24, 2012, or later and to proposals for research activities submitted on or after August 24, 2012. This policy applies to all Principal Investigators and other researchers responsible for the design, conduct, or reporting of PHS funded research or research supported by other organizations adopting the USPHS regulations.

2. Financial Conflict of Interest (FCOI)

A financial conflict of interest (FCOI) could be connected to the research funded by USPHS in which the Investigator is engaged. This could directly and significantly affect the design, conduct and/or reporting of USPHS funded research. For the purpose of this policy, IMM research is defined as the systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. Thus, any activity for which research funding is available from the USPHS, such as research grants, cooperative agreements, career development awards, center grants, program projects or research resources awards, conference grants, etc. would be included under this policy. Excluded from this policy and consistent with the underlying PHS regulations are Phase I SBIR awards, Phase I STTR awards, and translational awards, such as U44 awards.

All scientists who have full or temporary appointment at IMM and are involved in the design, conduct, or reporting of research performed or to be performed with USPHS funding, including but not limited to the Principal Investigator, Co-Investigators, Post-doctoral Fellows, etc., are required to disclose FCOI. This reporting includes authorship on publications resulting from the research.

2. Significant Financial Interest (SFI): Significant financial interests are considered anything of monetary value, consisting of one or more of the following interests of the Investigator or the Investigator's spouse or registered domestic partner or dependent children that reasonably appear related to the Investigator's Institutional Responsibilities:

- a. For a publicly traded entity: Income or other payment for services, including salary, and any payment for services not otherwise identified as salary, including but not limited to consulting payments, honoraria, paid authorship, or any other payments received during the prior twelve months and the value of any equity interests (stock, stock options or other ownership interests, as determined by public prices or other reasonable measure of fair market value) in the entity as of the date of disclosure, which when aggregated, exceeds

\$5,000.

b. For a non-publicly traded entity: Income or other payment for services, such as salary and any payment for services not otherwise identified as salary, including but not limited to consulting payments, honoraria, paid authorship, any other payments received during the prior twelve months, which when aggregated, exceeds \$5,000 or any equity interest (regardless of valuation) including, but not limited to stock, stock options, or ownership interest in the entity.

c. Intellectual property rights and interests: Income from each organization that exceeds \$5,000 during the twelve months preceding disclosure from such rights and interests.

d. Travel: Reimbursement of any amount received during the prior twelve months made to, or on behalf of, the Investigator, regardless of amount, by a for-profit or non-profit entity.

3. Responsibilities

The Board of Directors at IMM is responsible for reviewing and implementing this policy, for the final decisions regarding the acceptability of disclosures, and for approval of any required management plan. The Board of Directors are also responsible for maintaining the Conflict of Interest policy on its website, providing advice and information on policies and procedures, reporting information about financial conflicts of interest and how such interests are being managed to USPHS, and responding to public requests for information regarding financial conflicts of interest.

Individual investigators are responsible for disclosing their financial interests as defined by this policy. Investigators who are collaborators at recipient institutions that receive indirectly USPHS funds through IMM are responsible for disclosing their financial interests in accordance the arrangement agreed upon between IMM and the recipient institution prior to submission of a proposal to the USPHS and/or in accordance with the terms and conditions of the award issued by IMM. Principal Investigators are responsible for ensuring that all investigators provide their disclosures in a timely manner and in accordance with this policy.

4. Policy

Investigators seeking USPHS research funding or receiving USPHS research support are required to disclose significant financial interest (SFI) related to their research at the following times:

a. Initial disclosures must be made by all Investigators no later than at the time of

application for USPHS funding.

b. Investigators who are engaged in USPHS funded research have an ongoing responsibility to update their disclosures through the period of the USPHS award within thirty (30) days of acquiring or discovering a new SFI and at least annually.

c. New Investigators must complete a disclosure of SFI before engaging in ongoing USPHS funded research.

Investigators do not need to disclose:

a. Financial interests in mutual funds or other investment vehicles from public and private companies or retirement funds where the Investigator or the Investigator's spouse, registered domestic partner or dependent children do not directly control the investment decisions made for these investment companies and organizations.

b. Income from lectures, teaching engagements, service on advisory committees, or review panels sponsored by federal, state or local governments, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

All Investigators must disclose sponsored or reimbursed travel either as a prospective estimate of all planned or anticipated travel for the 12 month period following the filing of the Investigator's disclosure form or within 30 days of the occurrence of the travel event, if the travel was not included in the prospective disclosure. Spouses, registered domestic partners and dependent children of Investigators are exempt from this disclosure requirement. In addition, Investigators are not required to disclose travel that is reimbursed or sponsored by federal, state or local governments, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

All Investigators must complete a training program or be familiar with disclosure of SFI and the USPHS regulations prior to engaging in the PHS funded research, and at least every two years thereafter. When an Investigator is not in compliance with this policy or has failed to comply with a plan to manage or mitigate a FCOI, the Board of Directors of IMM must be notified so that remedies can be implemented.

Investigators from other institutions, who share responsibility for the design, conduct or reporting of the research, and who will be conducting research under an indirect award from IMM that is funded by USPHS are expected to comply with the policies and procedures of the organization

at which they are employed. Indirect awards issued by IMM will indicate that the recipient organization is responsible for reviewing SFI disclosures, and if a FCOI is identified, for sending IMM notification of their ability to manage, reduce or eliminate the FCOI, in accordance with USPHS requirements. If a recipient organization does not have a policy that complies with the USPHS regulations, the recipient's authorized institutional official must agree in writing that IMM's policy will apply to the recipient's investigators until such time as the recipient organization implements a policy that complies with the USPHS regulations. A recipient organization's failure to comply with its policy or the USPHS regulations may result in the termination of the indirect award from IMM.

If an individual is performing under an independent consulting agreement issued by IMM and the nature of their work, duties and responsibilities satisfy the definition of Investigator, the IMM Principal Investigator must identify the consultant as an Investigator and the consultant must complete the IMM disclosure forms. If, upon review, IMM determines that a consultant's SFI is a FCOI, the consultant will be expected to comply with a plan to eliminate, reduce or manage the FCOI. Failure of a consultant to comply with a management plan may result in the termination of the consulting agreement.

5. Overview of Disclosure Review Process

With each USPHS proposal, progress report, supplemental or incremental funding or extension, all Investigators who disclosed a SFI at the time a funding application was submitted to USPHS will be asked, at the stage of the award process, to provide additional information about the SFI. This information will be used by IMM to conduct a preliminary review to reasonably determine whether any of the Investigator's SFI is related to the USPHS funded research. A SFI is related to the USPHS funded research if the SFI could be affected by the USPHS funded research; or is located in an entity whose financial interest could be affected by the research. If an Investigator does not disclose a SFI at the time the funding application was submitted, the Investigator must disclose the SFI at the time of the award. If after review, it is determined that a SFI is related to the USPHS funded research, there will be a second review to determine whether the SFI reasonably appears to directly and significantly affect the design, conduct or reporting of the USPHS funded research and thereby constitute a FCOI that may need to be managed, reduced or eliminated. Plans for managing an identified a FCOI will be monitored for compliance until the completion of the USPHS funded research. Each management plan will specify the following:

- Role and principal duties of the conflicted Investigator;

- Conditions of the FCOI management plan;
- How the management plan will safeguard objectivity in the research;
- Confirmation of the Investigator's agreement to the management plan; and
- How the management plan will be monitored to ensure compliance.

6. Reporting to USPHS

Initial reports of FCOIs must be made to USPHS prior to IMM's expenditure of any funds under an USPHS funded research project. Additional FCOI reports must be submitted to USPHS under the following circumstances:

(a) When progress reports are submitted throughout the life of the award, or at the time that an award is extended. When during the course of an ongoing USPHS funded research a FCOI ceases to exist, updated information about the status of that FCOI should be provided with the subsequent progress report.

(b) Within 60 days of determining that a FCOI exists based on disclosure of a newly acquired SFI by an Investigator during the course of an ongoing USPHS funded research project.

(c) Within 60 days of determining that a FCOI exists for an Investigator who joins an ongoing USPHS funded research project.

However, if FCOIs are eliminated before research funds are expended, IMM is not required to submit a report to USPHS.

7. Retrospective Review

When during the course of an ongoing USPHS research project, IMM identifies a SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, the Board of Directors will review the SFI within 60 days to determine whether it is related to the USPHS funded research and whether a FCOI exists. If a FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis. Whenever a FCOI is not identified or not managed in a timely manner, IMM must complete a retrospective review of the Investigator's activities and the USPHS funded research project within 120 days of the determination of non-compliance. The purpose of the retrospective review is to determine if the ongoing USPHS funded research project conducted during the time period of the

noncompliance was biased in the design, conduct, or reporting of such research. Based on the results of the retrospective review, any previously submitted FCOI report must be updated to specify the actions that IMM will take to manage the identified FCOI.

If bias is found during the retrospective review, IMM will promptly notify USPHS and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines IMM's plans to eliminate or mitigate the effect of the bias.

8. Records Access and Retention

IMM is required to respond to within 10 business days to any request for information about SFIs held by Key Personnel when IMM has determined that the disclosed SFIs are related to the USPHS funded research and constitute FCOIs. Records of financial disclosures will be retained for at least 3 years beyond the date of submission of the award's final expenditure report, or until the resolution of any actions by USPHS involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

9. Sanctions

Failure to complete the Disclosure or the Addendum or to comply with any conditions or restrictions imposed on the conduct of the project under this Policy will be grounds for discipline pursuant to applicable IMM employee disciplinary policies. In addition, IMM will be required to report violations of this policy to the USPHS and other applicable federal regulatory oversight agencies and/or offices. Sponsors may suspend or terminate an award and/or bar an Investigator from receipt of future USPHS awards in the event an Investigator fails to comply with the USPHS regulations. Finally, an Investigator's failure to disclose may also subject the Investigator to other actions involving civil or criminal codes.