

**INSTRUCTIONS AND RULES FOR FINANCIAL CONFLICTS OF INTEREST IN PHS FUNDED PROJECTS
AT INSTITUTO DE MEDICINA MOLECULAR JOÃO LOBO ANTUNES
("IMM'S FCOI-POLICY")**

In the U.S., the National Institutes of Health (NIH) provide research grants through the federal governmental authorities within Public Health Services (PHS). The PHS comprises various agencies, including, but not limited to:

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- Office of Global Affairs (OGA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Office of the Assistant Secretary for Preparedness and Response (OASPR)
- Office of the Assistant Secretary for Health (OASH)

In cases where researchers at IMM receive PHS funding, there are strict requirements enforced that involve the objectivity and independence of researchers' financial ties to businesses, that could influence the design, conduct or reporting of research.

iMM seeks to ensure the integrity of its research and to comply with the federal PHS requirements for institutions that seek research funding, therefore establishing the following instructions, rules and procedures in compliance to U.S. federal regulations. These require all investigators (including the investigator's spouse, domestic partner and/or dependent children) who perform, or will perform, research activities at IMM, and that are funded by PHS, to disclose compensation and paid incentives for their financial investments.

The following instructions, rules and procedures are done specifically for PHS funded projects.

A. DEFINITIONS

<u>Disclosure of significant financial interests</u>	An investigator's disclosure of significant financial interests to iMM.
<u>Financial conflict of interest (FCOI)</u>	A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
<u>FCOI report</u>	iMM's report of a financial conflict of interest to an organization unit of the PHS that provides funding for the research.
<u>Financial interest</u>	Includes anything of monetary value, whether or not the value being readily ascertainable.
<u>Institutional responsibilities</u>	An investigator's professional responsibilities on behalf of iMM, and as defined in this document, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Boards or Data and Safety Monitoring Boards.
<u>Investigator</u>	The principal investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS funded research, or proposed for such funding, which may include, for example, collaborators or consultants, whether or not they receive salaries or compensation under the grant.
<u>PI</u>	A project director or principal investigator of a PHS-funded research project; the PI is included in the definitions of senior/key personnel and investigator under this subpart.
<u>Subrecipient</u>	An organization or researcher that participates in research with the awardee Institution (e.g. subcontractors or consortium members).
<u>Management Plan</u>	An action plan to address a FCOI, which can include strategies for reducing or eliminating the financial conflict of interest, to ensure that the design, conduct, and reporting of research will be free from bias.
<u>PHS</u>	Is the acronym for Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
<u>Research</u>	Scientific experiments, theoretical work, or scientific studies through observation, to which the work or studies are done to acquire new knowledge and developed on a scientific basis. The term encompasses basic and applied research

(e.g. a published article, book or book chapter) and product development (e.g. a diagnostic test or drug). As used in this document, the term includes any such activity for which research funding is available from the PHS through a grant or cooperative agreement, including a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Significant financial interest (SFI)

A financial interest consisting of one or more of the following interests of the investigator (including investigator's spouse, domestic partner, and dependent children) that reasonably appears to be related to the investigator's Institutional Responsibilities:

1. With regard to any publicly traded entity [companies quoted on stock exchanges], a significant financial interest exists if the value of any remuneration [salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship, stocks, bonds, stock options, warrants, partnership interests, rights to patent or royalty payment, loans, lectureship fees, or fees for serving on boards of directors, scientific and other advisory boards)] received from the entity in the twelve months preceding the disclosure and the value of any equity interest (e.g. any stock, stockoption, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value) in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
2. With regard to any non-publicly traded entity [companies NOT quoted on stock exchanges], a significant financial interest exists if the value of any remuneration [salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship, stocks, bonds, stock options, warrants, partnership interests, rights to patent or royalty payment, loans, lectureship fees, or fees for serving on boards of directors, scientific and other advisory boards)] received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator's spouse, domestic partner or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest).
3. Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interests.
4. Reimbursed or sponsored travel (i.e. 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.

Exceptions to significant financial interests

- a) Salary, royalties, or other remuneration paid by the institute to the Investigator if the investigator is currently employed or otherwise appointed by the Institute.
- b) Intellectual property rights assigned to the Institute and agreements to share in royalties related to such rights.
- c) Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an United States Institution of higher education, any academic teaching hospital, any medical center, or any

research institute that is affiliated with a United States Institution of higher education.

d) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles.

e) Income from service on advisory committees or review panels for a Federal, state, or local government agency, an United States Institution of higher education as defined at 20 U.S.C. 1001(a), any academic teaching hospital, any medical center, or any research institute that is affiliated with a United States Institution of higher education.

f) Travel that is reimbursed or sponsored by a Federal, state, or local government agency, an United States Institution of higher education as defined at 20 U.S.C. 1001(a), any academic teaching hospital, any medical center, or a research institute that is affiliated with an United States Institution of higher education.

B. RESPONSABILITIES

Investigator Responsibilities

- Disclosing all significant financial interests that reasonably appear to be related to the investigator's institutional responsibilities.
- Providing updates to disclosed information as needed, namely within 30 days of discovering or acquiring a new significant financial interest.
- If acting as the PI of the award, providing a list of individuals who meet the definition of "investigator" within the required disclosure timeline.
- Completing all required training and education.
- Completing the annual disclosure form even if they have no financial interests to report.
- Ensuring that an updated FCOI in Research Disclosure is on file at the time of CAML's Ethics Committee or the Institutional Animal Ethics Committee (ORBEA-iMM) approval for any new research proposals.

Institutional Responsibilities

- Maintaining up-to-date, written, enforced instructions and rules on FCOI that complies with the relevant regulations ('42 CFR 50, Subpart F'), and make them publicly accessible at iMM's Web site.
- Informing each investigators of iMM's rules and instructions on FCOI, the investigator's responsibilities regarding disclosure of SFIs, and of these regulations.
- Requiring each investigator who is responsible for the design, conduct, or reporting of PHS funded research, or proposed for such funding, to complete compulsory training:
 - prior to engaging in research related to any PHS funded grant;
 - at least every four years and immediately when any of the following circumstances apply:
 - i) Institution revises its policy in a manner that affects the investigator;
 - ii) when an investigator is new to the Institution; or
 - iii) when the Institution finds an Investigator is not in compliance with the Institution's policy or a FCOI

management plan.

- If IMM carries out the PHS-funded research through a subrecipient (e.g. subcontractors or consortium members), the Institution (awardee Institution) will take reasonable steps to ensure that any IMM's subrecipient investigator complies with federal regulations stipulated in '42 CFR 50, Subpart F'.
- Designating IMM official(s) to solicit and review disclosures of SFIs from each investigator who is planning to participate in, or is participating in, the PHS-funded research.
- Requiring each investigator who is planning to participate in the PHS- funded research to:
 - Disclose to IMM's designated official(s) the investigator's significant financial interests (including investigator's spouse, domestic partner and dependent children) no later than the time of application for PHS-funded research.
 - Submit an updated disclosure of SFIs at least annually, in accordance with the specific time period prescribed by IMM, during the period of the award.
 - Submit an updated disclosure of SFIs within thirty days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new significant financial interest.
- Providing guidelines for IMM's designated official(s) to determine whether an investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is a financial conflict of interest.
- Implementing actions as deemed necessary to manage a FCOI, including any financial conflicts of a subrecipient investigator, through the implementation of a management plan.
- Providing initial and ongoing FCOI reports to the PHS as required.
- Maintaining records relating to all investigator disclosures of financial interests and IMM's review of, and response to, such disclosures (whether or not a disclosure resulted in IMM's determination of a FCOI) and all actions under IMM's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 C.F.R. 75.361 (see FAQ A.11) for different situations.

- Certifying, where applicable, that IMM's policy and procedures are up-to-date and (i) enforce through an administrative process to identify and manage FCOIs in all PHS funded projects; (ii) enforce compliance with the disclosure of SFIs; (iii) manage initial and ongoing FCOI reports; (iv) provide information promptly upon request to PHS in terms of disclosures of financial interests, IMM's review of, and response to, such disclosures in the determination of FCOI; and (v) fully comply with the requirements stipulated in '42 CFR 50, Subpart F'.

C. PROCEDURES:

1. Disclosure of Significant Financial Interests

It shall be the responsibility of the PI of a Research project to identify all Investigators who have a SFI requiring disclosure under this policy and to ensure that a FCOI Disclosure Form is prepared and submitted.

Before participating in PHS-funded projects:

Researchers who will conduct research at IMM as Investigators in a PHS-funded project, must send to Pre-Award a completed Conflict of Interest Disclosure Form [disclosing all significant financial interests (SFIs)] and a FCOI Training Certificate at the time of Grant Agreement Preparation (i.e. as soon as notified that the grant was awarded). Both documents must have been received by Pre-Award no later than the date of signing the Grant Agreement.

Ongoing PHS funded research:

Investigators must also disclose all SFIs within 30 days after he/she becomes aware of a new SFI or after a financial conflict of interest has been eliminated.

Annual reports:

PHS Investigators are responsible for completing the annual disclosure form even if they have no financial interests to report.

New investigators participating in an ongoing PHS funded project:

New investigators are also required to disclose SFIs to Pre-Award within 30 days of joining the research project.

To make a disclosure of SFIs, Investigators must use IMM's CONFLICT OF INTEREST DISCLOSURE (FCOI) FORM (see below section D).

2. **Reviewing Significant Financial Interests**

Pre-Award performs an initial review of all FCOI forms at the time of Grant Agreement Preparation. If there aren't any identified SFIs in the form (i.e. positive replies), Pre-Award informs the Project Management and saves the file in the respective shared folder in the server.

If there are any SFIs identified in the FCOI form, Pre-Award forwards the form to the Legal Office to determine which SFI may qualify as being a potential FCOI and, in such cases, refers to the FCOI Committee for review.

At IMM the FCOI committee for the identification, investigation, management and reporting of FCOI in PHS-funded research consists of the President of the Board of Directors, the 2 investigators representatives of the Investigators Council, IMM's Legal Counsel, the Head of Pre-Award and the area manager of Project management.. The Head of Laboratory affected by each case will also be co-opted to the committee.

The determination of a FCOI will be based on the following criteria:

1. Nature and extent of the financial interest in the relationship of the investigator/relative and the external organization.
2. Terms and conditions of sponsored project agreements that can reduce or increase the risks.
3. Impact on integrity of research data.
4. Risks to rights and safety of animal and/or human research subjects.
5. Potential risks of conflicts of interest.

If the FCOI Committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS funded research the situation will be address as a FCOI .

In all cases where a FCOI is identified, IMM will develop a management plan by the FCOI Committee, in collaboration with relevant researchers and institutions and report the case to the PHS funder. The terms of the FCOI management plan will be determined in

accordance with national law applicable to iMM

All management plans are required to be signed by the Investigator and the FCOI Committee. Compliance of the FCOI management plan shall be monitored by the Project Management Unit at the Finance and Operations Office and the Counsel of Investigators of iMM.

- In cases where iMM identifies an existing SFI that was not timely disclosed by an investigator during an ongoing PHS funded project: the FCOI Committee will review the disclosure within 60 days to determine if the SFI is related to PHS funded research and whether it constitutes a FCOI.
- In case the investigator fails to disclose a SFI that was determined to be a FCOI by iMM, or iMM fails to review and manage a FCOI, or the investigator fails to comply with a FCOI management plan: the FCOI Committee will determine noncompliance and complete a retrospective review of the investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. A retrospective review will be completed within 120 days of determining noncompliance.

3. Reporting Requirements to NIH

Prior to the disbursement of research funding:

Prior to the disbursement of research funding within the PHS-funded project, iMM will provide a FCOI report regarding all SFIs that prove to be a FCOI.

Other cases:

iMM must also provide a FCOI report within 60 days from the date:

- of a new SFI disclosure that is determined to be a FCOI,
- a new investigator with an identified FCOI begins participating in the project, or
- when iMM identifies a FCOI not previously disclosed.

In the FCOI report, iMM must specify:

- the grant/contract number, PI and name of investigator with FCOI;
- the nature of the FCOI (e.g. equity, consulting fees, travel reimbursement or honoraria);
- the value of the financial interest or a statement that the interest is one whose value cannot be determined through reference to public prices or other reasonable measures of fair market value;
- a description of how FCOI relates to PHS-funded research and the basis for determining that the financial interest conflicts with such research;
- a summary of the FCOI management plan.

4. Updates to the FCOI report

iMM will provide annual updates of the report for the duration of the research project. The annual report will include the status of the FCOI, changes to the FCOI management plan and justification if FCOI no longer exists.

Based on the results of the retrospective review, iMM will, if appropriate, update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. This updated report shall include the grant/project number, project title, PI, name of investigator with FCOI, name of entity for FCOI, reasons for the retrospective review, methodology utilized for the retrospective review, findings and conclusions of the review.

If bias is identified in the retrospective review, in accordance with US federal regulations, iMM must submit a mitigation report. The mitigation report will consist of key elements stipulated in the retrospective review above, and a description of the impact of the bias on the research project and iMM's action plan to eliminate or mitigate the effect of the biased actions taken. Depending on the severity of the financial conflict of interest identified, iMM may determine that additional interim measures are necessary with respect to the investigator's participation in the PHS- funded project between the date of determination of the FCOI or the investigator's noncompliance and the completion of iMM's retrospective review.

Reports will be submitted to the NIH funder by uploading an initial (original) and annual FCOI report using eRA commons as required by US federal regulations.

5. Subrecipient Requirements

If a research project involves subrecipients, the subrecipient institution must provide written assurance that they have a (local) policy or equivalent for managing financial conflicts of interest that complies with all applicable US federal regulations in accordance with PHS. If the subrecipient does not have its own policy, a written agreement must be drawn up between iMM and the subrecipient institution stating that iMM's rules and instructions will also apply to the subrecipient.

6. Training Requirements

All investigators receiving PHS funding must complete mandatory FCOI training during the following intervals:

- Prior to engaging in PHS-funded research and at least once every four years thereafter.
- When these rules and instructions are revised in any manner that affects the requirements of investigators.
- When an investigator is new to iMM and will take part in a PHS-funded project.
- When an investigator is noncompliant with iMM's rules and instructions or a FCOI management plan is in place.

iMM uses the Financial Conflict of Interest online tutorial provided by the National Institutes of Health for satisfying training requirements. Investigators must provide assurance they have completed the NIH tutorial by sending a copy of the Certificate of Completion to Pre-Award. The NIH tutorial is available at: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

7. Documentation and Accessibility Requirements

iMM will preserve all documentation that is part of the implementation of these rules and instructions and will manage any information provided, in accordance with applicable law, including Data Protection legislation. Save as permitted or required by law, information will not be shared outside the iMM without the individuals' permission.

This document will be published on iMM's public website and intranet.

D. ATTACHMENTS

IMM's CONFLICT OF INTEREST DISCLOSURE FORM

(per policy : [web site])

Name _____

Laboratory _____

Project Role: PI _____ Investigator _____ Consultant _____ Other _____

Project leader: _____ Project Period : _____

Project Title: _____

This Disclosure is:

my initial Disclosure
 my annual Disclosure

an addendum to my most recent Disclosure
 an addendum for travel purposes only to my most recent Disclosure

DEFINITIONS

- **Financial Interest:** Includes anything of monetary value, whether or not the value being readily ascertainable.
- **Significant financial interest (SFI):** A financial interest consisting of one or more of the following interests of the investigator (including investigator's spouse, domestic partner, and dependent children) that reasonably appears to be related to the investigator's Institutional Responsibilities:
 - With regard to any publicly traded entity [companies quoted on stock exchanges]:
 - the value of any remuneration [salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship, stocks, bonds, stock options, warrants, partnership interests, rights to patent or royalty payment, loans, lectureship fees, or fees for serving on boards of directors, scientific and other advisory boards)] received from the entity, in the twelve months preceding the disclosure when aggregated, exceeds \$5,000
and
 - the value of any equity interest (e.g. any stock, stockoption, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value) in the entity as of the date of disclosure when aggregated, exceeds \$5,000

- With regard to any non-publicly traded entity [companies NOT quoted on stock exchanges]:
 - the value of any remuneration [salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship, stocks, bonds, stock options, warrants, partnership interests, rights to patent or royalty payment, loans, lectureship fees, or fees for serving on boards of directors, scientific and other advisory boards)] received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000,
 - any equity interest (e.g. stock, stock option, or other ownership interest).
- Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interests.
- 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.

• **Non-Reportable Interests include:**

- Financial interests or activities that do not relate to your academic or professional work at IMM;
- Salary, royalties, or other remuneration paid by IMM or through IMM administered sponsored awards;
- 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 retirement accounts, as long as you do 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, United States Institution of higher education, any academic teaching hospital, any medical center, or any research institute that is affiliated with a United States Institution of higher education;
- Income from service on advisory committees or review panels for a Federal, state, or local government agency, a United States United States Institution of higher education, any academic teaching hospital, any medical center, or any research institute that is affiliated with a United States Institution of higher education;
- Travel expenses paid by IMM or by a sponsored research award to IMM;
- Travel that is reimbursed or sponsored by a Federal, state, or local government agency, a United States Institution of higher education, any academic teaching hospital, any medical center, or a research institute that is affiliated with an United States Institution of higher education.

1. Publicly Traded Entities [companies quoted on stock exchanges]:

(a) During the past 12 months, did you, your spouse, domestic partner, or your dependent children receive remuneration from any publicly traded entity that when combined amounted to greater than \$5,000(U.S. dollars)?

NO YES If YES, complete table below

Name of Entity	Type of Business	Type of Equity	Value in U.S. Dollars	Individual Receiving Remuneration: You/Spouse/Dependent Children

(b) Did you, your spouse, domestic partner, or your dependent children hold any equity interests in any publicly traded entity that when combined amounted to greater than \$5,000(U.S. dollars)?

NO YES If YES, complete table below

Name of Entity	Type of Business	Type of Equity	Value in U.S. Dollars	Individual Holding the Equity: You/Spouse/Dependent Children

2. Non-Publicly Traded Entities [companies NOT quoted on stock exchanges]:

(a) During the past 12 months, did you, your spouse, domestic partner, or your dependent children receive any remuneration from ANY non-publicly traded entity that when combined amounted to greater than \$5,000 U.S. dollars?

NO YES If YES, complete table below

Name of Entity	Type of Business	Amount in U.S. Dollars	Activity	Individual Receiving Remuneration: You/Spouse/Dependent Children

(b) During the past 12 months, did you, your spouse, domestic partner, or your dependent children hold ANY equity interests in any non-publicly traded entity ?

NO YES If YES, complete table below

Name of Entity	Type of Business	Type of Equity	Value in U.S. Dollars	Individual Holding the Equity: You/Spouse/Dependent Children

3. Non-profit entities: During the past 12 months, did you, your spouse, domestic partner or your dependent children receive any remuneration from a non-profit entity that when combined amounted to greater than \$5,000 U.S. dollars?

Do not include the following:

- Income from iMM or seminars, lectures and teaching engagements sponsored by U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; academic teaching hospitals or medical centers that are affiliated with U.S. Institutions of higher education;

- Income from service on advisory committees or review panels for U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; academic teaching hospitals and U.S. medical centers that are affiliated with U.S. Institutions of higher education; and
- Royalties or other payments on intellectual property rights in your response to this question.

NO YES If YES, complete table below

Name of Entity	Amount in U.S. Dollars	Activity	Individual Receiving Remuneration: You/Spouse/Dependent Children

4. Travel:

During the past 12 months, did a third party pay for greater than \$5,000 U.S. dollars (either for one trip or a combination of trips from a single entity) of travel for you, your spouse, domestic partner or your dependent children related to your responsibilities at IMM? Travel costs include meals, transportation, lodging, and registration fees.

NO YES If YES, complete table below

Destination	Duration of Trip	Estimated Value in U.S. Dollars	Purpose	Sponsor/Organizer Who Paid for the Travel

5. Intellectual property rights:

Have you or you, your spouse, domestic partner or your dependent children received any income greater than \$5,000 U.S. dollars, related to intellectual property rights and interests? (Do not include any intellectual property that has been assigned to IMM.)

NO YES If YES, complete table below

Short Description of Invention/IP	Is it Licensed/Patented/Patent Pending?	If receiving royalties/other payments greater than \$5,000, indicate the name of the entity providing the royalty/payment.

CERTIFICATION:

I certify that I have read and understand the **iMM's FCOI Policy** and have completed this Disclosure to the best of my knowledge and belief. Further, as someone who is identified as an investigator on a PHS proposal/award, subaward, or non-federal sponsor adopting the Public Health Services (PHS) regulations, I agree to comply with PHS regulatory requirements adopted as the **iMM's FCOI Policy** as well as acknowledge the following:

- No later than at the time of proposal/application I will ensure that a current financial interest disclosure is on file;
- I will fulfill my disclosure responsibilities at least annually or within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI during the period of the award whichever comes first, including the occurrence of any reimbursed or sponsored travel which is paid on my behalf, related to my responsibilities at **iMM**;
- If I fail to report a new SFI within 30 days, I will willingly participate in the required retrospective review of my research in order to determine bias;
- If I am a PI, I will appropriately identify individuals (i.e., "investigators") if any, in my proposal who are responsible for the conduct, design, or reporting of the research. I will take into consideration the role of the investigator, rather than their title and the degree of independence with which the investigator will work;

- If I am a PI, I will complete my progress report in a timely fashion to assist the PHS Grantee in its reporting requirements related to any identified and previously reported FCOIs;
- **iMM** may impose sanctions on me if I fail to comply with the PHS regulations and **iMM's** policy.

Investigator's Signature

Date

CONCLUSIONS

_____ No financial conflict of interest appears to exist.

_____ PROPOSALS: A financial conflict of interest may exist. An approved management plan shall be put in place.

_____ UPDATES: A financial conflict of interest may exist. An approved management plan shall be put in place.

Signature: _____

Position: _____

Date: _____