MAX PLANCK
FLORIDA INSTITUTE FOR
NEUROSCIENCE

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Financial Conflict of Interest Policy

Policy Number SR 12-01

Effective date: August 24, 2012
Updated: November 12, 2020, October 28, 2024

Designated Institute Official (DIO): Joseph Schumacher, PhD

PURPOSE
The purpose of this Policy is to ensure compliance of the Max Planck Florida Institute for Neuroscience (***Institute***) with Federal Regulations (42 CFR Part 50, Subpart F for PHS grants and cooperative agreements) which outlines the responsibilities of applicants for promoting objectivity in Public Health Service (PHS) funded research. The Policy aims to establish standards so that there is no reasonable expectation that the design, conduct, or reporting of research funded under NIH grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator. This regulation is commonly referred to as the Financial Conflict of Interest (FCOI) regulation.

APPLICABILITY
The policy applies to Investigators participating in PHS research, as defined by PHS regulations **including** sub-grantee/contractor/collaborating Investigators, but **excluding** applications for Phase I support under the SBIR and Small Business Technology Transfer (STTR) programs.

DEFINITIONS
1. ***HHS*** stands for the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
2. ***Institution (Institute***) is any domestic or foreign, public or private, entity or organization (excluding a Federal agency).
3. ***Investigator*** is the principal investigator and any other person, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the requirements of this subpart relating to financial interests, “Investigator” includes the Investigator's spouse and dependent children.
4. ***PHS*** means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.
5. ***PHS Awarding Component*** is the organizational unit of the PHS that funds the research.
6. ***Research*** is a systematic investigation designed to develop or contribute to overall knowledge relating broadly to public health, including behavioural and social sciences research. The term encompasses basic and applied research and product development. The term includes any such

activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

7. Significant Financial Interest (SFI) is anything of monetary value, including but not limited to one or more of the following interests of an Investigator (and those of the Investigator's Immediate Family Members) related to their Institutional responsibilities, when combined for the 12 months preceding the disclosure date, from a single Entity:

Nature of SFI	Disclosure Threshold
Remuneration, compensation, and/or other payments for services (e.g. consulting, speaking) when combined with any equity interest in a publicly traded entity.	Exceeds $5,000
Remuneration, compensation, and/or other payments for services (e.g., consulting, speaking) from a non-publicly traded entity.	Exceeds $5,000
Equity interests in a non-publicly traded company (e.g. start-up company). Equity includes stock, stock options, or other ownership interest.	$0 / Any Value
Intellectual property rights and interests	Exceeds $5,000
Sponsored or reimbursed travel*	Exceeds $5,000

**Disclosure of sponsored or reimbursed travel applies to PHS Investigators only and disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.*

SFI does NOT include:

a. Salary, royalties, or other remuneration from the ***Institute***.
b. Any ownership interests in the ***Institute***, if the ***Institute*** is an applicant under the SBIR Program.
c. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
d. Income from service on advisory committees or review panels for public or nonprofit entities.
e. Equity interests through 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.

8. ***Small Business Innovation Research (SBIR) Program*** is the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97–219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102–564.

9. ***Subrecipient*** is a legal entity that receives a Subaward from a pass-through entity to carry out a portion of a sponsored program. A Subrecipient has responsibility for programmatic decision making; has its performance measured in relation to whether objectives of a programmatic scope of work were met; and is responsible for adherence to applicable sponsored program requirements specified in the sponsored award, as opposed to providing routine goods or services for the benefit of the pass-through entity.
10. ***Subrecipient Investigator*** is an Investigator who is not an Institute employee or student and who participates in research overseen by the Institute through a subcontract, subaward, or other agreement.

POLICY STATEMENT

No employee of the ***Institute*** should have any interest, financial or otherwise, direct or indirect, or engage in any business or transaction or professional activity or incur any obligation of any nature that is in substantial conflict with the proper discharge of their duties in the best interests of the ***Institute.***
No investigator of the ***Institute*** should have any financial interest that will, or may be reasonably expected to, bias the design, conduct, or reporting of sponsored programs.
All investigators must have a current Disclosure Statement on file with the ***Institute***.

DISCLOSURE STATEMENT

The Disclosure Statement that is made a part of this conflict of interest policy as ***Attachment 1*** must be completed by investigators who are applying for funds from an external sponsor or those who have not filed a disclosure statement in conformance with ***Institute's*** conflict of interest policy.
Disclosure statements must be filed at the time of application and updated either annually or within 60 days of new reportable significant financial interests. This 60-day policy also applies to Investigators who are newly participating in the PI's project. Identified FCOI's held by senior/key personnel are required to be made publicly accessible prior to the expenditure of federal funding and will remain available for three years.

REAL, APPARENT, OR POTENTIAL CONFLICTS

All real, apparent, or potential conflicts of interest as defined under the **Policy Statement** must be disclosed for review and determination as to whether a violation of this policy exists.

COMPLAINTS AND INQUIRIES

Anyone may bring a complaint or make inquiries concerning possible violation of this conflict of interest policy. **All complaints or inquiries should be immediately reported to the DIO or designee.**
Upon receipt or notification of such complaint or inquiry, the DIO or designee shall immediately advise the CEO and the person against whom the complaint is made.

INVESTIGATOR TRAINING

Each investigator must complete FCOI training:

1. Prior to engaging in research related to PHS funded research
2. At least every four years
3. If the Institute revises FCOI policy that affects requirements of investigators

4. When an investigator is new to the Institute
5. When an investigator is found to be noncompliant with the Institute's FCOI policy

To complete training:

1. Go to https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html to reach the NIH FCOI tutorial
2. View tutorial and answer the review questions
3. At the end of the tutorial, click the "Certificate" button
4. When the certificate appears, type your name in the Participant's Name text box
5. Print to pdf, and send to osr@mpfi.org and copy MPFI's DIO, Joseph Schumacher, PhD at joseph.schumacher@mpfi.org.

PROCEDURES FOR INVESTIGATING FCOI

The DIO will review all financial disclosures. Affected individual(s) will be afforded confidential treatment to the maximum extent possible, and are entitled to a prompt and thorough investigation and an opportunity to comment on any allegations or findings resulting from the investigation. The DIO, or designee, shall advise the Director and CEO of the ***Institute*** of the substance of the disclosure. The CEO shall appoint an independent panel to determine whether a conflict of interest exists and, if so, determine what actions should be taken by the ***Institute*** to manage, reduce or eliminate such conflict of interest. This process may include the creation of a Mitigation Report containing specific recommendations. A conflict of interest exists when the designated panel reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research or the Investigator's institutional responsibilities. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

1. Public disclosure of significant financial interests
2. Monitoring of research by independent reviewers
3. Modification of the research plan
4. Disqualification from participation in all or a portion of the research funded by the PHS
5. Divestiture of significant financial interests
6. Severance of relationships that create actual or potential conflicts

In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, the ***Institute*** may require the management of other conflicting financial interests, as it deems appropriate.

Retroactive reviews, where the Institute's determination of non-compliance for significant financial interest not disclosed timely or previously reviewed or whenever a FCOI is not identified or managed in a timely manner, will be completed and documented within 120 days.

The FCOI Policy for PHS Projects also applies to Subrecipients. If an Investigator carries out PHS-funded research through a subrecipient, the ***Institute*** will take reasonable steps to ensure that any subrecipient Investigator complies with this policy. This will require a financial disclosure form to be filled out at the proposal stage, which includes certification that the subrecipient has a policy in place

that meets the PHS requirements. Alternatively, terms that verify the subrecipient has a financial conflicts of interest policy that meets the PHS requirements will be included as part of a written agreement with the subrecipient.

PHS NOTIFICATION

If the failure of an Investigator to comply with the conflict of interest policy of the ***Institute*** has prejudiced the design, conduct, or reporting of the PHS-funded research, the ***Institute*** will promptly notify the PHS Awarding Component of the action it has taken or intends to take. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the ***Institute*** for further action. These may include directing the ***Institute*** on how to maintain appropriate objectivity in the funded project.

The HHS may at any time inquire into the ***Institute*** procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the ***Institute*** has not managed, reduced, or eliminated the conflict of interest. The PHS Awarding Component may determine that suspension of funding under 45 CFR 94.6 is necessary until the matter is resolved.

RETENTION OF DOCUMENTATION

Detailed documentation of each review will be maintained for at least three (3) years, and will, upon request, be provided to the official (s) of the ***Institute***.

Documentation to substantiate an investigation's findings will be retained for at least three (3) years after completion of a final report.

APPEAL

An investigator or employee who disagrees with the determination of the review panel may appeal to the CEO of the ***Institute***, or the CEO's designee, for reconsideration of such determination. The determination of the CEO shall be final and binding.

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Disclosure of Significant Financial Interest Status

Federal regulations require that the *Max Planck Florida Institute for Neuroscience (Institute)* reduce or eliminate any actual or potential conflicts of interest that may be presented by the compensated outside activities and other financial interests of persons involved in sponsored research projects. In keeping with Federal Regulations (42 CFR Part 50, Subpart F), the *Max Planck Florida Institute for Neuroscience* requires that this form be submitted with every proposal for sponsored research or educational activities and be updated periodically.

Type of Disclosure**: (check one)* ☐Proposal Submission*** ☐***Annual Update*** ☐***Periodic Revision*** ☐***Transfer***

Investigator*: ***Department:***

Title of Proposal/Project:

Principal Investigator (if different)**:** _____

☐ I have no ***significant financial interest(s)**** that would reasonably appear to affect or be affected by this proposed or funded sponsored project.

OR

☐ I am disclosing the following ***significant financial interest(s)**** that would reasonably appear to affect or be affected by this proposed sponsored project, and I am attaching supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest:

- ☐ Salary or other payments for services such as consulting fees and honoraria.
- ☐ Equity interests, such as stocks and stock options.
- ☐ Intellectual property rights, such as patents, copyrights, and royalties.
- ☐ Travel paid on my behalf.
- ☐ Other significant financial interests that possibly would affect or be perceived to affect the results of the research, educational, or service activities funded or proposed for funding.
- ☐Further, I agree:
  - to update this disclosure annually during the period of the award and any time new reportable significant financial interests are obtained, and
  - to comply with any conditions or restrictions imposed by the *Max Planck Florida Institute for Neuroscience* to manage, reduce, or eliminate actual or potential conflicts of interest, or forfeit the award.

Investigator's Signature: _____ **Date:** _____
(original signatures only; a "per" signature is unacceptable)

***This form must accompany all proposals*.**

***Definitions**:

For the purpose of this disclosure, ***investigator*** is defined as the Principal Investigator/Project Director, Co- Investigator, and any other persons responsible for the design, conduct, or reporting of research, educational, or service activities funded (or proposed for funding) by an external sponsor.

For the purpose of this disclosure, ***significant financial interest(s)*** are defined as salary, other payment for services or intellectual property rights for an investigator, their spouse, and/or dependent children that, when aggregated over the next 12 months, are expected to exceed $5,000; and equity or ownership interests held by an investigator, their spouse, and/or dependent children that represent more than a 5 percent ownership interest or exceeds $5,000 in value.