

# MAX PLANCK INSTITUTE OF BIOCHEMISTRY

## Financial Conflict of Interest Policy

**Policy Number 1/2024**

**Effective date: 20/02/2024**

### PURPOSE

The purpose of this Policy is to ensure compliance of the Max Planck Institute of Biochemistry (***Institute***) with US 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. ***DIO (Designated Institute Official)*** The Designated Institute Official is responsible to enforce the FCOI policy in the respective Institute and will deal with complaints or inquiries. This function shall be performed by the Managing Director of the Institute.
2. ***HHS.*** The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
3. ***Institution (Institute).*** Any domestic or foreign, public or private, entity or organization (excluding a Federal agency).
4. ***Investigator.*** 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.
5. ***NIH*** means National Institutes of Health, one of the world's foremost medical research centers.

6. **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.
7. **PHS Awarding Component.** The organizational unit of the PHS that funds the research.
8. **Research.** 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.
9. **Significant Financial Interest.** Anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights); and travel paid on behalf of the investigator and not reimbursed to the investigator related to institutional responsibilities unless reimbursed or sponsored by excluded sources (by a federal, state or local government agency or an institution of higher education). The term 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. An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$5,000.
10. **Small Business Innovation Research (SBIR) Program.** *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.*

## 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**

Disclosure statements must be filed by Investigators 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 these complaints or inquiries should be immediately reported to the DIO. Upon receipt or notification of such complaint or inquiry, the DIO shall immediately advise the responsible Vice President and the Director of the department as well as 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;
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 <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> 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, and send to the DIO office

## **PROCEDURES FOR INVESTIGATING FCOI**

The DIO office 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 shall advise the Director of the department and the responsible Vice President of the substance of the disclosure. The Vice President 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.

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 74.62 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 responsible Vice President for reconsideration of such determination. The determination of the responsible Vice President shall be final and binding.