

# **FINANCIAL CONFLICT OF INTEREST POLICY**

## **Introduction**

The Public Health Service (PHS) has established regulations documenting standards and procedures to be followed by institutions that apply for research funding from the PHS to ensure that the design, conduct or reporting of funded research will not be biased by any conflicting interest of those investigators responsible for the research. (Title 42, CFR Part 50, subpart F). Under these regulations, which took effect October, 1, 1995, and revised in 2011, investigators are required to disclose to the Laboratory any Significant Financial Interests that would reasonably appear to be affected by the proposed research. The Laboratory is then required to review those disclosures and determine whether any of the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research, and if so, prior to the expenditure of awarded funds, take measures to protect such funded research from bias due to a conflict of interest.

The MDIBL Conflict of Interest policy applies to scientists receiving **PHS funding** through any grant award administered by MDIBL. Seasonal scientists with their own PHS-funded support should be aware that their research remains under the governance of the policies and procedures of their home institution.

## **Definitions**

**Financial Conflict of Interest**, actual or potential, occurs when there is a divergence between an individual's private interests and his or her professional obligations to the Laboratory such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, **financial or otherwise**.

**Investigator** means the principal investigator/project director or any other person at the Laboratory who is responsible for the design, conduct or reporting of research funded, or proposed for funding, by a granting agency. In this context, the term "Investigator" includes the investigator's or other key persons spouse and dependent children. Sub-grantee, contractors and collaborating investigators are included in this definition.

**Key Personnel means the personnel INTEGRAL to the project (such as PD's and PI's).**

**Sponsored Research** means a systematic investigation designed to develop or contribute to generalized knowledge relating broadly to science and/or public health. The term encompasses basic and applied research and product development.

**Significant Financial Interest** means anything of monetary value, including, but not limited to:

1. Salary, royalties from intellectual property rights or other payments for services (e.g. consulting fees, paid authorship, or honoraria) that, when aggregated for the investigator and the investigator's spouse and dependent children in the previous twelve months, are expected to exceed \$5,000 per year.
2. Equity interests (e.g. stocks, stock options, or other ownership interests) in business enterprises or entities that, when aggregated for the investigator and the investigator's spouse and dependent children, in the previous 12 months exceed \$5,000 in value or represent more than a 5% ownership interest for any one enterprise or entity.
3. Intellectual property rights and interests (for example patents and copyrights), upon receipt of income related to such rights and interests.
4. Reimbursed or Sponsored travel which is paid on behalf of the Investigator, (versus reimbursed travel made on behalf of the Institution where they are "employed").

NOTE: As a general rule of thumb the types of income listed above would be typical of income reported via a 1099 form rather than a W-2.

The term **Significant Financial Interest** does **not** include:

1. Salary, royalties, or other remuneration from the Laboratory; when employed by the laboratory.
2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
3. Income from service on advisory committees or review panels for public or nonprofit entities;
4. Any ownership interests in the institution, if the institution is an applicant in the Small Business Innovation Research (SBIR) program, including the Small Business Technology Transfer (STTR) program.
5. Income from Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights.
6. 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.

NOTE: As a general rule of the thumb, the types of income listed above would be those typically reported via a W-2 form.

## **MDIBL Procedure**

An essential step in addressing actual or apparent conflict of interest is for the individual involved to make full disclosure of the relevant information to the Administrative Director and Director, as described below.

1. All year-round MDIBL investigators engaged in PHS-sponsored research are required on the date of grant renewal to submit in writing a disclosure of their significant financial interests. (Current annual disclosure forms are attached as Exhibit A to this policy.) If there is no Significant Financial Interest to disclose, the Investigator shall so indicate on the Disclosure Form. If there is a Significant Financial Interest to disclose, the Investigator shall provide a full disclosure about the nature and amount of the interest, as well as any documentation, in a sealed envelope, marked "Confidential."
2. In addition, all "Key Personnel" **as we define them** must complete a disclosure form whenever the grant renews. Key Personnel are defined as any PD/PI or other person integral to the project.
3. Whenever the significant financial interests change materially, the disclosures are to be updated in writing within 30 days (including but not limited to marriage, inheritance, and purchases).
4. Whenever possible, individuals should attempt to disclose expected changes or newly anticipated conflicts before they occur.
5. Whenever an application for funding of a new research project is submitted, the individual will be required to certify that he or she has submitted a complete and accurate annual disclosure, and that the new research project does not present the potential for any actual or apparent conflicts of interest not already identified in the annual disclosure. If a new reportable Significant Financial Interest arises at any time during the period after the submission of a proposal through the entire period of any resulting award, the filing of an additional Disclosure Form is also required.
6. Postdoctoral appointees, other employees, and students **are not** required to submit annual disclosure forms, but **are required** to disclose potential conflicts of interests relating to MDIBL research (including use of research facilities) whenever they arise.
7. Investigators are to submit the annual disclosure forms and any updates and other reporting to the Administrative Director. When the disclosing individual is the Administrative Director, the disclosures are to go to the Director. When the disclosing individual is the Director, the disclosures are to go to the Chairman of the Board of Trustees.

The confidentiality of the disclosures will be respected as far as possible. In particular, the information on the forms will not be shared except with those with a need to know.

## **Review of Disclosures**

The Administrative Director or official designee shall conduct an initial review of all financial disclosures to determine if any disclosed Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. If the initial determination is made that there may be a potential for conflict of interest covered by this policy, then the matter will be referred to a Conflict of Interest Review Committee (COI Committee) composed of The Director, the Administrative Director, Director of Finance, and Sponsored Programs Accountant.

The COI Committee, with the cooperation of the Investigator, shall determine what conditions or restrictions, if any, should be imposed by the Laboratory to manage actual or

potential conflicts of interest arising from disclosed Significant Financial Interests. The COI Committee may also consult with others who may have relevant information.

A **Mitigation Report** will need to be prepared by the Lab if bias is found. The Mitigation Report will outline what steps will be taken to minimize any negative impact created as a result of non-compliance. The findings will be shared with the Board of Trustees as appropriate.

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include, but are not limited to:

- Public disclosure of Significant Financial Interests;
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of Significant Financial Interests;
- Severance of relationships that create actual or potential conflicts of interest.

The resolution by the COI Committee and investigator shall be incorporated into a Memorandum of Understanding that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the business enterprise or entity. The Memorandum of Understanding shall be signed by the Investigator and countersigned by the COI Committee.

Prior to the Laboratory's expenditure of funds awarded for the project, the Laboratory will assure the PHS sponsor that any identified conflicting interests have been managed, reduced or eliminated.

Whenever an Investigator has violated this policy or the terms of the Memorandum of Understanding, the Director of the Laboratory shall impose appropriate disciplinary action. If the failure of the Investigator to comply with this policy has biased the design, conduct or reporting of the funded research, the Laboratory will report such subsequent disclosure to the PHS Awarding Component within 60 days. The Laboratory will make information available, upon request, to the appropriate Government body regarding all conflicting interests identified by the Laboratory and how those interests have been managed, reduced, or eliminated to protect the research from bias.

Records of all financial interest disclosures, memorandum of understandings, and written reports of actions taken to manage actual or potential conflicts of interest, shall be retained by MDIBL until 3 years after the latter of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.

## **SUB-RECIPIENTS:**

As part of MDIBL's written agreement with all sub-recipients, we will review the sub recipient's Financial Conflict of Interest Policies and Practices to assure that they are in

compliance with PHS requirements. This review will take place annually, when sub-awards are renewed. If the sub-recipient cannot provide such certification, MDIBL will not enter into the agreement until the certification is provided by the sub-recipient and compliance is assured.

## **INVESTIGATOR TRAINING:**

Each Investigator must complete training prior to engaging in research related to any PHS-funded grant, and every four years thereafter. In addition, training must occur immediately should any of the following circumstances occur:

- An Investigator is new to the Institution
- The Institution finds an Investigator is non-compliant with the FCOI policy and/or management plan.
- The Institution's policy is changed to the extent that the requirements for Investigators are impacted.

Training is completed via the web and can be accessed using the following link:

**[grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm](http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm)** Investigators should complete the tutorial and upon completion print the certificate (follow prompts) and submit a copy to the business office.

The Business Office will be responsible for collection, maintenance, and confidentiality of all disclosure forms.