



Policy and Procedures for Managing Conflict of Interest Requirements Imposed by Federal Sponsors

EFFECTIVE NOVEMBER 29, 2021

POLICY

Molecular Instruments (“MI”) is committed to promoting objectivity in research. We support this objective through compliance with Public Health Services (“PHS”) rules regarding the disclosure of Significant Financial Interests and the management of Financial Conflicts of Interest affecting covered research activities. MI has implemented this policy and the following corresponding procedures which establish standards intended to provide a reasonable expectation that the design, conduct and reporting of research funded by the PHS, including the National Institute of Health (“NIH”), will be free from bias resulting from Financial Conflicts of Interest as defined hereunder. This policy and these procedures apply to all individuals who meet the definition of Investigator as defined hereunder.

PROCEDURES

The following pages describe the procedures for compliance with MI’s Policy for Managing Conflict of Interest Requirements Imposed by Federal Sponsors. As with all procedures, these may change from time to time to ensure the most efficient processes and effective compliance.

DEFINITIONS

Investigator is the project director or principal investigator, co-investigators, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of the research funded by PHS, or proposed for such funding.

Institution is the organization receiving the funding, in this case MI, a for-profit corporation.

Institutional Responsibilities includes an Investigator’s professional responsibilities on behalf of MI, including activities such as research, presentations, and other duties.

Significant Financial Interest (SFI)

The term Significant Financial Interest is defined by PHS as follows:

A. Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to relate to the Investigator’s Institutional Responsibilities:

- 1) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and other payments for services not otherwise identified as salary (e.g., consulting fees, paid authorships, or honoraria); equity interests

includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

2) With regard to any non-publicly traded entity, a significant financial interest exists if the aggregated value of any remuneration received from the entity, in the twelve months preceding the disclosure, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g. stock, stock option or other ownership interest);¹

3) Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income by the Investigator related to such rights and interests.

B. Included in the definition of Significant Financial Interest is the occurrence of any reimbursed or sponsored travel (i.e. "sponsored travel" is travel which is paid on behalf of the Investigator and not reimbursed directly to the Investigator so that the exact monetary value may not be readily available), related to the Investigator's institutional responsibilities.

C. The term significant financial interest does not include the following:

1) For MI employees, salary, royalties, or other remuneration from MI, including intellectual property rights assigned to MI and agreements to share in royalties related to such rights;

2) 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;

3) Income from seminars, lectures, or teaching engagements sponsored by a Federal, state or local government agency, an Institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute;

4) Travel reimbursements by Federal, state or local government agency, an Institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute;

5) Income from service or advisory committees or review panels for Federal, state or local government agency, an Institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute.

Disclosure is the submission of MI's Significant Financial Interest form through a private upload link provided by the Institutional Official. The Disclosure should include the details of the nature of any Significant Financial Interest, as defined above, of his/her spouse and/or dependent children.

For PHS proposals or awards involving an external collaborator who meets the definition of Investigator and who has a Significant Financial Interest, Disclosure can take one of two forms:

1) If the collaboration is with an Investigator whose institution complies with PHS policies, an annual certification from the institution asserting that it complies with NSF and PHS policy will suffice.

2) If the collaboration is with an Investigator acting as an individual or through an organization that does not comply with PHS policies, the collaborator Investigator(s) must file a Disclosure. To do so, the external Investigator must contact the Institutional Official at administrator@molecularinstruments.com.

¹ MI is a for-profit corporation. MI employees do not need to disclose ownership interests in MI as an SFI.

Financial Conflict of Interest (FCOI) is a Significant Financial Interest held by an Investigator that could directly and significantly affect the design, conduct, or reporting of his/her PHS funded research. The determination as to whether a Significant Financial Interest constitutes a Financial Conflict of Interest is made by the Institutional Official in collaboration with the CEO.

FCOI Management is action taken to address a financial conflict of interest, which may include reducing or eliminating the financial conflict of interest, to ensure to the extent possible, that the design, conduct and reporting of the research will be free from bias.

Senior/Key Personnel include the project director or principal investigator and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to PHS by MI.

Institutional Official the Administrative Manager of MI has been designated as the Institutional Official.

REQUIRED DISCLOSURES

Investigators are required to identify and disclose, or identify and re-verify, if previously disclosed, Significant Financial Interests before an application is submitted to PHS, and thereafter within 30 days of discovering or acquiring a new Significant Financial Interest. Disclosures must also be updated at least annually in connection with MI's annual Conflict of Interest disclosure process.

At the time a proposal is being prepared, the individual serving as principal investigator should alert any other individuals who may meet the definition of Investigator of the need to comply with these procedures. All individuals who are considered to be Investigators (including the principal investigator) are to determine if they have any Significant Financial Interests and, if so, each must file an electronic Disclosure of the nature and magnitude of the financial interest. All such Disclosures must be submitted to the Institutional Official before MI can forward the proposal to NIH.

The principal investigator and Institutional Official will ensure that Disclosures have been submitted. Before any expenditure of funds can occur, the Institutional Official must review the Disclosures and address any conflicts of interest.

DISCLOSURE REVIEW AND MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

MI will review disclosures of Significant Financial Interests in accordance with these procedures to determine whether an actual or potential Financial Conflict of Interest exists. MI's Institutional Official will review and work with the Investigator(s) to develop a management plan for any such conflicts before awarded funds are expended. Compliance with these procedures is an ongoing requirement that MI must fulfill in order to be eligible to receive funding from PHS.

The Institutional Official is designated by MI as responsible for reviewing disclosures of Significant Financial Interests and determining whether a Financial Conflict of Interest exists for purposes of covered Federal funding. When a Financial Conflict of Interest is identified, these individuals also are responsible for determining what steps need to be taken to manage the conflict prior to the expenditure of covered funding.

The Institutional Official receiving a Disclosure will: review the disclosure to determine if the disclosed Significant Financial Interest constitutes a Financial Conflict of Interest for purposes of the award. If any actual or potential Financial Conflict of Interest is identified, the Institutional Official will work with the Investigator to determine the steps that should be taken to manage the conflict and will prepare a proposed written management plan. The proposed management plan will be forwarded to the CEO who will review the Disclosure in the context of the proposed activity along with the management plan proposed by the Investigator and Institutional Official. Before permitting any expenditure of funds from the Federal sponsor, the CEO, in collaboration with the Institutional Official, will approve the management plan describing the conditions and possible restrictions that MI believes are necessary to manage the actual or potential Financial Conflict of Interest. The following are examples of conditions or restrictions that may be included in a management plan:

- public disclosure of significant financial interests;
- monitoring of research by independent reviewers;
- modifications to the research plan;
- disqualification from participation in all or a portion of the activity funded by the Federal agency that would impact the significant financial interest;
- divestiture of significant financial interests;
- severance of relationships that create potential or actual conflicts; or
- require placing of shares or other forms of equity ownership documents in a blind trust.

Copies of the approved management plan will be made available to the Investigator and the plan must be implemented before the expenditure of funds. Management plans will be monitored for compliance by the Institutional Official until completion of the project.

For PHS funded activities, all SFI must be reviewed by the Institutional Official and all potential FCOI completely addressed prior to expenditure of funds. Should an SFI arise during the term of the award, the Investigator must file a Disclosure within 30 days and the SFI must be reviewed by the Institutional Official and all potential FCOI completely addressed within 60 days of the Disclosure. If an Investigator does not file his/her Disclosure in a timely manner, additional compliance action by the Institutional Official and the MI will be required pursuant to 42 CFR 50.605.

REPORTING

The Institutional Official or CEO will make any required reports to PHS. PHS will review the reported Financial Conflict of Interests to determine if additional information is needed. PHS may decide that further action is needed to ensure the objectivity of the research or that the Financial Conflict of Interest has not been appropriately managed, reduced or eliminated. PHS may also require suspension of funding until the matter is resolved.

Reports will be provided as required by the regulation:

1. prior to the expenditure of funds
2. within 60 days of identification for an Investigator who is newly participating in the project
3. within 60 days for new, or newly identified FCOIs for existing Investigators
4. At least annually (at the same time as MI is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.

5. within 120 days of determination or noncompliance for a retrospective review to update a previously submitted report, if appropriate
6. To notify PHS if bias is found with the design, conduct, or reporting of funded research and to submit a mitigation report in accordance with the regulation
7. To notify PHS of non-compliance

TRAINING

For PHS funded or proposing Investigators, MI will provide Investigators with training regarding the requirements of these procedures:

- 1) prior to an Investigator's engagement in research related to any PHS funded project;
- 2) at least every four years;
- 3) whenever revisions to MI's FOIC policy affect requirements of Investigators
- 4) whenever an Investigator is new to MI
- 5) whenever an Investigator is found to be out of compliance with these procedures, or an applicable management plan.

The principal investigator will be responsible for certifying that all investigators have undergone the required training prior to their engagement in the covered research.

RECORDKEEPING

The Institute will maintain required records of all Disclosures and of all actions taken to manage actual or potential conflicts of interest for at least three (3) years from the date the final expenditure or project report is submitted to PHS or until the resolution of any legal or government action involving these records, whichever is later.

SUBRECIPIENT REQUIREMENTS

MI will include provisions in all covered subawards requiring subrecipients to comply with PHS rules related to the disclosure of Significant Financial Interests and management of Financial Conflict of Interests consistent with Federal requirements for covered awards.

PUBLIC ACCESSIBILITY OF FINANCIAL CONFLICTS OF INTEREST

Upon written request, MI is required to provide, within 5 business days, a written disclosure of Financial Conflicts of Interest held by Senior and Key Personnel proposing for funding or funded by PHS, including:

- 1) the Investigator's name;
- 2) the Investigator's title and role with respect to the research project;
- 3) the name of the entity in which the Significant Financial Interest is held;
- 4) the nature of the Significant Financial Interest;
- 5) the approximate dollar amount of the Significant Financial Interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

PRINCIPAL INVESTIGATOR RESPONSIBILITIES

MI requires that the designated principal investigator for an activity that is proposed to be, or actually is, funded by a covered Federal sponsor is required to:

- 1) Become familiar with these procedures

- 2) Distribute copies of this document to any individual who either meets or can reasonably be expected to meet the definition of Investigator and who will participate on any covered activity that is proposed to be, or is, Federally funded by PHS.
- 3) Ensure that they, themselves, and all individuals who satisfy the definition of Investigator:
 - (a) have reviewed their responsibilities with respect to this document and the MI Policy on Conflicts of Interest,
 - (b) have determined whether they have any Significant Financial Interests as defined in this document,
 - (c) have submitted a Disclosure(s) to MI; and
 - (d) have completed all required Col training.

The principal investigator must also indicate whether he or she knows of any potential Financial Conflicts of Interest between any Investigator, including him/herself, arising from a Significant Financial Interest and the proposed work.

- 4) Notify the Institutional Official of any external collaborators on PHS proposals that would fulfill the role of Investigator so that institutional certifications can be obtained, where appropriate.

POSTING OF THE POLICY AND PROCEDURES

MI will post this policy and procedures on its website. All current and future personnel receiving or proposing to receive funds from the covered federal sponsors are required to become familiar with these procedures.

SANCTIONS

Failure to timely comply with Disclosure requirements for PHS funded awards may result in delays in accessing funds or suspension of expenditures on PHS funded activities.

Individuals who fail to adhere to these procedures may be subject to suspension of funds, to removal from participation on the covered award and disciplinary action up to and including termination of employment. Individuals who fail to comply with an FCOI management plan may be subject to disciplinary action up to and including termination of employment.

ASSISTANCE

The Institutional Official can offer assistance to any individual on the interpretation of these requirements and the applicability to a specific situation.