

Financial Conflicts of Interest Policy

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Policy Introduction

Millennial Materials & Devices Inc. (MMD) (dba Millennial Scientific) is committed to protecting the integrity and objectivity of its research activities. Towards this goal, MMD ensures that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest. MMD has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest.

The procedures described in this policy were created and designed primarily to comply with the specific regulatory requirements for U.S. Public Health Service (PHS)-sponsored research. They have been developed to identify, manage, mitigate, neutralize, or eliminate actual, apparent, and potential financial conflicts of interest. The policy was written to be in conformance with the Code of Federal Regulations (A) (CFR) 42, Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought, and (B) 45 CFR Part 94, Responsible Prospective Contractors.

These regulations do not cover Small Business Innovation Research (SBIR) Program Phase 1 applications or awards but do apply to applicants and recipients under the SBIR Program Phase II. SBIR is the extramural research program for small business that was established by the Awarding Components of PHS and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the STTR Program, which was established by Pub. L. 102-564.

This policy is also used to identify, evaluate, and manage potential financial conflicts of interest relating to MMD's other research activities. For non-PHS research, the specific steps, timing, determinations, documentation, and notifications may be tailored as appropriate.

Definitions

For purposes of this policy, the following definitions shall apply:

Designated Official is the individual designated by MMD to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests.

Equity interest includes any stock, stock option, or other ownership interest, and its value may be determined through reference to public prices or other reasonable measures of fair market value.

Financial conflict of interest means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research as determined by MMD through the Designated Official.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Immediate family refers to an Investigator's spouse and dependent children.

Investigator means the project director/principal investigator and any other person who is responsible for the design, conduct, or reporting of the research or proposed research.

PHS means the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

Millennial Materials & Devices Inc. (dba Millennial Scientific)

Office: Research and Manufacturing Facility: Long Island High Technology Incubator,
Suite 123, 25 Health Science Drive, Stony Brook, New York 11790-3350;
Phone: 631-655-4736; Email: millennialmaterials@gmail.com; Web: www.millennialmaterials.com

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50, Subpart F, and 45 CFR Part 94.

PHS-funded Research means research funded under PHS grants, cooperative agreements, or contracts.

Public Health Service Act, or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Remuneration includes, for example, salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Research means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. 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). For PHS-Funded Research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.

Significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator and his/her immediate family that reasonably appear to be related to the Investigator's MMD project responsibilities, including:

- a) A financial interest in any publicly traded entity. Any remuneration, when aggregated exceeds \$5,000, received from the entity in the 12 months preceding the disclosure and any equity interest (e.g., stock, stock option, or other ownership interest) in the entity as of the date of disclosure.
- b) A financial interest in any non-publicly traded entity. Any remuneration, when aggregated exceeds \$5,000, received from the entity in the 12 months preceding the disclosure, in which the value when aggregated exceeds \$5,000, or when the Investigator or his/her immediate family holds any equity interest (e.g., stock, stock option, or other ownership interest).
- c) Income received from intellectual property rights and interests (e.g., patents, copyrights).
- d) Any 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 the Investigator's MMD project responsibilities.

Significant financial interest does not include the following:

- a) Salary, royalties, or other remuneration paid by MMD (or a subrecipient as applicable) to the investigator if the investigator is currently employed or otherwise appointed by MMD, including that paid for intellectual property rights assigned or licensed to MMD and agreements to share in royalties related to such rights.
- b) Any ownership interest in MMD (or a subrecipient as applicable) held by the Investigator (e.g., Employee Stock Ownership Plan).
- c) 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.
- d) Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education.
- e) Income from service on advisory committees or review panels for a Federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education.
- f) Travel that is reimbursed or sponsored by a Federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education.

Procedures

Training Requirements

MMD's designated official will:

- 1) Inform each investigator of the:
 - a) MMD's policy.
 - b) Investigator's disclosure responsibilities.
 - c) Federal regulation (See NIH's [FAQ L.1](#), and "FCOI Training" tutorial on NIH's FCOI website).
- 2) Require each PHS-supported Investigator to complete FCOI training:
 - a) Prior to engaging in research related to any PHS/NIH-funded grant.
 - b) At least every four (4) years.
 - c) Immediately, if:
 - i) MMD revises its FCOI policy that affects requirements of Investigators.
 - ii) An Investigator is new to MMD.
 - iii) An Investigator is not in compliance with the policy or management plan.

Disclosure, Review and Monitoring Requirements

MMD's designated official will:

- 1) Require each investigator to disclose their significant financial interests (SFIs) (see [FAQs D.8](#), and [E.26](#)) (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities that meet or exceed the regulatory definition of SFI:
 - a) No later than at the time of application for PHS/NIH-funded research (see [FAQ D.35](#)).
 - b) At least annually during the period of the award.
 - c) Within thirty (30) days of discovering or acquiring a new SFI.
- 2) Solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities for a determination of FCOI.
- 3) Provide adequate guidelines consistent with the regulation to determine whether an Investigator's SFI is related to PHS/NIH-funded research and, if so related, whether the SFI is an FCOI. The Investigator may be involved in making the determination of whether the SFI is related to the PHS/NIH-funded research.
- 4) Include the examples of conditions or restrictions that might be imposed to manage conflicts of interest (e.g., full public disclosure, appointment of an independent monitor, modification of the research plan, etc. see regulation and NIH's [FAQ F.1](#). for more information on how to manage an FCOI).
- 5) Add additional conditions to manage an FCOI is at MMD's discretion.

Note: An SFI is related to PHS/NIH-funded research when MMD's designated official reasonably determines that the SFI:

 - Could be affected by the PHS/NIH-funded research.
or
 - Is in an entity whose financial interest could be affected by the research.

An FCOI exists when MMD's designated official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.
- 6) Require, prior to MMD's expenditure of funds, to:
 - a) Review all Investigator SFI disclosures.
 - b) Determine if any SFIs relate to PHS/NIH-funded research.
 - c) Determine if an FCOI exists (e.g., the SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research).
 - d) Develop and implement a management plan to manage the FCOI(s).
- 7) Require, when an Investigator who is new to participating in the research project or when an existing Investigator discloses a new SFI, within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI.
- 8) Require, whenever an SFI is identified, that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed during an ongoing PHS/NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), within sixty (60) days review disclosures of SFIs, determine

whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage such FCOI going forward.

- 9) Take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.

NIH Reporting Requirements

MMD's designated official will:

1. Send initial, annual (i.e., ongoing) and revised FCOI reports, including all required information defined in the regulation and/or NIH's FAQ H.5, to the NIH via the eRA Commons FCOI Module for MMD and its subrecipients, if applicable, as required by the regulation and as stated below:
 - a. Prior to the expenditure of funds.
 - b. Within sixty (60) days of identification for an Investigator who is newly participating in the project.
 - c. Within sixty (60) days for new, or newly identified, FCOIs for existing Investigators.
 - d. At least annually (at the same time as when MMD is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
 - e. After a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.
2. Notify NIH promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research and include the requirement to submit a Mitigation Report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation.
 - a. Ensure the policy and/or procedures includes all reporting elements (e.g., entity name, name of the investigator with the FCOI, nature of SFI(s), value of the SFI(s), etc.) as required by the regulation.
3. Notify NIH promptly if an Investigator fails to comply with the MMD's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.
 - a. Notify NIH promptly and take corrective action for noncompliance with MMD's policy or the management plan.

Maintenance of Records

MMD's designated official will:

1. Maintain all FCOI-related records relating to all Investigator disclosures of financial interests and MMD's review of, and response, to such disclosures (whether or not a disclosure resulted in MMD's determination of a financial conflict of interest) and all actions under MMD's policy or retrospective review, if applicable:
 - a. For at least three (3) years from the date the final expenditures report is submitted to the PHS (NIH).
 - b. Or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

Enforcement Mechanisms and Remedies and Noncompliance

MMD's designated official will:

1. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance (e.g., letters of reprimand, restriction on the use of funds, etc.).
2. Complete a retrospective review (see FAQs in Section I) within 120 days of MMD's determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:
 - a. Failure by the Investigator to disclose a significant financial interest that is determined by MMD to constitute a financial conflict of interest.
 - b. Failure by MMD to review or manage such a financial conflict of interest.
 - c. Failure by the Investigator to comply with the financial conflict of interest management plan.
3. Document the retrospective review which shall include at a minimum the following key elements:
 - a. Project Number.
 - b. Project Title.

- c. PD/PI or contact PD/PI if multiple PD/PI model is used.
 - d. Name of the Investigator with the FCOI.
 - e. Name of the entity with which the Investigator has an FCOI.
 - f. Reasons for the retrospective review.
 - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed).
 - h. Findings of the review.
 - i. Conclusions of the review.
4. Ensure that in any case in which the Department of Health and Human Services determines that a PHS/NIH-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by MMD as required by the regulation, MMD shall require the Investigator involved to:
- a. Disclose the FCOI in each public presentation of the results of the research.
 - b. To request an addendum to previously published presentations.

Subrecipient Requirements

MMD's designated official will:

- 1. Address subrecipient requirements (See [FAQ K.1](#)).
- 2. Where applicable, establish, via a written agreement, whether the subrecipient will follow the FCOI policy of the awardee (MMD) or the FCOI policy of the subrecipient.
 - a. If applicable, obtain a certification from the subrecipient that its FCOI policy complies with the regulation.
 - b. If applicable, include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its investigators in a time frame that allows the awardee (MMD) to report identified FCOIs to the NIH as required by the regulation.
 - c. Alternatively, if applicable, include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee (MMD) to identify, manage and report identified FCOIs to the NIH.

Public Accessibility Requirements

MMD's designated official will:

- 1. Make the MMD's FCOI policy publicly accessible:
 - a. Post the FCOI policy on the MMD's public Web site.
- 2. Make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation, not the NIH Grants Policy Statement), publicly accessible prior to the expenditure of funds. See FAQs in [Section G.1](#). The publicly accessible information will:
 - a. Include the minimum elements as provided in the regulation.
Be posted on a Public Website or made available within five (5) business days of a written request (Determine which option will apply).
 - b. Be updated, at least annually (Web site only but any response to a written request should include the updated information).
 - c. Be updated, within sixty (60) days of a newly identified FCOI (Web site only but any response to a written request should include the updated information).
 - d. Remain available for three (3) years from the date the information was most recently updated.

Significant Financial Interest (SFI) Disclosure Form Information

The financial disclosure form used for “Investigators” to disclose their SFIs to MMD’s designated official for a determination of FCOI shall include at a minimum the following information:

- 1) Investigator’s name.
- 2) Entity name in which the Investigator (and spouse and dependent children) has an SFI.
- 3) Disclosure requirement that is consistent with the MMD’s definition of SFI.
- 4) Disclosure of financial interests in the 12 months preceding the disclosure and value of equity interest as of the date of disclosure.
- 5) Provide for disclosure of intellectual property (IP) rights and interests (e.g., patents, copyrights), upon the receipt of income related to such rights and interests (Note: MMD may impose a \$5,000 threshold for IP rights and interests as described in the [Final Rule](#) on page 53265).
- 6) Provide for the disclosure of reimbursed or sponsored travel that includes at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- 7) Ensure the SFI definition includes the “U.S.C. Code 20 U.S.C. 1001(a)” which refers to “domestic” institutions (see FAQs [E.21](#) and [E.24](#) and NIH Guide Notice [NOT-OD-18-160](#)).
- 8) Clarify that disclosure is required for all financial interests received from a foreign institution of higher education or the government of another country (see FAQs [E.21](#) and [E.24](#) and NIH Guide Notice [NOT-OD-18-160](#)).
- 9) The value of the SFI.
- 10) Provide a distinction whether the SFI is from a publicly traded or non-publicly traded entity.
- 11) Provide a description of the nature of the SFI (e.g., salary, royalties, consulting fees, honoraria, paid authorship, reimbursed or sponsored travel).
- 12) Provide an indication whether the SFI is related to any Public Health Service application and/or funded project and an explanation for the relatedness. Some information to consider:
 - a. MMD’s designated official(s) makes the determination whether the SFI is an FCOI (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research).
 - b. Per the preamble in the [Final Rule](#) (page 53261), “significantly” means “...the financial interest would have a ‘material effect on the research’...”.