

## **A. Persons covered by this policy**

This policy applies to all personnel, including all Members and full-time, part-time, temporary, and contract employees, of Mathematical Medicine LLC (MathMed) who are planning to participate in, or are participating in, National Institute of Health (NIH) funded research by means of a grant or cooperative agreement.

## **B. Preamble**

1. The primary goal of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest and to prevent an employee's activities from adversely influencing MathMed's operations.
2. This policy is implemented in accordance with 42 CFR Part 50 Subpart F - "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought" and 45 CFR Part 94 "Responsible Prospective Contractors" as well as all other relevant policies of federal funding and oversight agencies.

## **C. Statement of general policy**

1. The design, conduct, and reporting of Research funded under NIH grants or cooperative agreements should be free from bias resulting from Investigator financial conflicts of interest.
2. To provide a reasonable expectation of achieving the goal of this policy, Investigators shall complete appropriate training as required under this policy; Investigators shall disclose perceived and real financial conflicts of interest annually and provide new or updated disclosures in a timely manner; MathMed shall provide for the elimination or management of Financial Conflicts of Interest; and MathMed shall make disclosures to both the NIH and to the public as required under this policy.
3. Nothing in this policy shall be construed to permit, even with disclosure, any activity that is prohibited by law.
4. Nothing in this policy shall be construed to limit or abridge the authority of MathMed Members to take such action as they deem appropriate regardless of any action or inaction by an Officer of MathMed.

## **D. Definitions**

1. *Disclosure* means an Investigator's disclosure of significant financial interests to the MathMed.
2. *Financial Conflict of Interest (FCOI)* means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
3. *FCOI Report* means MathMed's report of a Financial Conflict of Interest to a PHS Awarding Component.

4. *Financial Interest* means anything of monetary value, whether or not the value is readily ascertainable.
5. *HHS* means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
6. *Institutional Official (IO)* means a MathMed designated official assigned to solicit and review disclosure forms from each investigator who is planning to participate in, or who is participating in, HHS funded research and to determine whether any reported Significant Financial Interest (SFI) is a FCOI.
7. *Company Responsibilities* means an Investigator's professional responsibilities on behalf of MathMed, and as defined by MathMed in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, training, professional practice, and service on panels.
8. *Investigator* means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators, subcontractors, or consultants.
9. *Manage* means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
10. *Member* means any employee of MathMed who participates in PHS-funded research.
11. *PD/PI* means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.
12. *Research* means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development. As used in this subpart, the term includes any such activity for which research funding is available from a NIH through a grant or cooperative agreement.
13. *Senior/key personnel* means the PD/PI and any other person identified as senior/key personnel by MathMed in the grant application, progress report, or any other report submitted to the PHS by MathMed under this subpart.
14. *Significant Financial Interest* means the following:
  - a. 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 be related to the Investigator's responsibilities at MathMed:
    - i. 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 disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

- ii. With regard to any non-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, when aggregated, 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), or a management or governance position; or
  - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- b. Travel:
- i. Investigators also must disclose the occurrence of 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 their Company responsibilities;
  - ii. provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institute 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 Institute of higher education.
  - iii. Disclosure for travel shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. MathMed will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS funded research.
- c. Exclusions: The term Significant Financial Interest does not include the following types of financial interests:
- i. salary, royalties, or other remuneration paid by MathMed to the Investigator if the Investigator is currently employed or otherwise appointed by MathMed, including intellectual property rights assigned to MathMed and agreements to share in royalties related to such rights;
  - ii. 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;
  - iii. income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institute 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 Institute of higher education; or
  - iv. income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institute 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 Institute of higher education.

## **E. Policy Implementation**

1. Review Requirement: MathMed has designated its Executive Director (ED) as the Institutional Official. Prior to expenditure of any funds under a HHS funded research project, MathMed's ED will solicit and review Investigator's disclosures containing SFI's to determine whether the SFI relates to the HHS funded Research and whether a FCOI exists.
2. If a FCOI exists, MathMed's ED will develop and implement a management plan that specifies the actions that have been and will be taken to manage such FCOI.
3. Disclosure Requirement: MathMed will inform each employee of MathMed's policy on Promoting Objectivity in Research, namely, that the investigator's responsibilities regarding disclosure require that a written disclosure be made as provided in this policy, and will inform the MathMed Member to anticipate the receipt of a new Disclosure.
4. Disclosure Frequency:
  - a. Disclosure must be made no later than at the time of application for NIH-funded research.
  - b. Disclosure must be made annually to MathMed. If no Significant Financial Interest is present a Disclosure must still be submitted that states "none". The date such annual Disclosure is due shall be set by the ED and disseminated to MathMed members.
  - c. In addition to the annual Disclosure, a new or updated Disclosure must be completed in a timely manner whenever a new or potential Significant Financial Interest arises or when a significant change occurs concerning an existing Disclosure.
  - d. In any event, Disclosure must be made within thirty (30) days of discovery or acquiring a new Significant Financial Interest.
  - e. Newly hired Investigators should make a Disclosure as part of their new hire employment process.
5. Training Required: Investigators shall complete FCOI training provided by MathMed on or before their becoming subject to this policy and then every four (4) years thereafter. Training will include information on MathMed's policy, Investigator's disclosure responsibilities, and the Federal regulation. Immediate training will be required if MathMed revises this policy in a manner that affects the Investigator, when an Investigator is new to MathMed, or as a result of a finding of noncompliance with this policy or a management plan, or other related misconduct. Training provided via: [https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)
6. Posting Requirement: If the ED determines FCOI exists prior to MathMed's expenditure of HHS funds and within sixty (60) days of receipt or identification of any additional SFI held by Senior/Key personnel related to the HHS funded Research and determined by MathMed's IO to be a FCOI, MathMed shall post to its publicly accessible website, [www.mathmed.org](http://www.mathmed.org), the following information concerning such SFI:
  - a. investigator's name, title, and role with respect to the Research project;
  - b. the name of the entity in which the SFI is held;
  - c. the nature of the SFI; and
  - d. approximate dollar value of the SFI (dollar ranges are permissible: \$0 - \$4,999; \$5,000-\$9,999; \$10,000-\$19,000; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000, or

- e. 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.
7. Management of FCOIs: Examples of conditions or restrictions to include in management plans can be:
  - a. Public disclosure of FCOI (e.g., when presenting or publishing the research);
  - b. For research projects involving human subjects research, disclosure of FCOI directly to participants;
  - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the research against bias resulting from the FCOI
  - d. Modification of the research plan
  - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - f. Reduction or elimination of the financial interest (e.g., sale of equity interest); or
  - g. Severance of relationships that create financial conflicts.

## **F. Violations and Sanctions**

1. Sanctions: Violations of MathMed policies, including the failure to avoid a prohibited activity or disclose a Significant Financial Interest in a timely manner, may include disciplinary actions up to and including termination of employment.
2. Clinical Research: In any case in which the HHS determines that a NIH-funded 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 a FCOI that was not managed or reported by the MathMed as required by this policy, the Members shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

## **G. Company Reporting**

1. MathMed, through its Members shall provide annual and revised reports of FCOI to National Institutes of Health (NIH) per the applicable regulations:
  - a. Prior to the expenditure of funds;
  - b. within sixty days of identification for an Investigator who is newly participating in the project;
  - c. within sixty days for new or newly identified FCOIs for existing investigators
  - d. at least annually (at the same time as when MathMed 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;
  - e. following retrospective review to update a previously submitted report, if appropriate.
2. MathMed, through its Members, shall notify NIH of bias found in the design, conduct, or reporting of NIH funded Research including whether Investigator failure to comply with this FCOI policy or management plan appears to have caused such bias. In the event bias

is found, MathMed will submit a Mitigation report in accordance with the regulation. The mitigation report must include, at a minimum, a description of the impact of the bias on the research project and MathMed's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

3. FCOI records shall be maintained for at least three (3) years from the submission of the final expenditure reports for the pertinent NIH funding or longer as required by other policy or regulation.

## **H. Subrecipients**

MathMed, through its Members, shall require sub-recipient compliance with pertinent FCOI requirements as mandated by PHS regulation:

1. If applicable, obtain a certification from the subrecipient that its FCOI policy complies with the regulation.
2. 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 MathMed to report identified FCOIs to NIH as required by the regulation.
3. Alternatively, if applicable, include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable MathMed to identify, manage, and report identified FCOIs to NIH.

## **I. Public Accessibility Requirement**

1. MathMed shall post this FCOI policy on the MathMed public website, as required by the regulation.
2. FCOI Informational requests by the public concerning identified FCOIs held by senior/key personnel should be made to the ED. The ED shall respond to requests for FCOI information within five (5) business days with minimum reporting elements as provided for under applicable regulations.