



# Financial Conflict of Interest Policy

## Purpose

This purpose of this Financial Conflict of Interest (FCOI) Policy is to ensure integrity in MassMatrix's research endeavors and compliance with the National Institute of Health's (NIH) requirements...

*"NIH requires recipient [institutions](#) and investigators (except Phase I SBIR/STTR applicants and recipients) to comply with the requirements of [42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought"](#) (FCOI Regulation), as implemented in the 2011 [Final Rule](#) for grants and cooperative agreements."*

As articulated by NIH...

*"...this regulation promotes 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."*

## Definitions

**Financial Conflict of Interest (FCOI)** - A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

**Grant Officer** - The MassMatrix designated person (the CEO or someone designated by the CEO) is responsible for ensuring compliance with this policy.

**Investigator** - 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 NIH, or proposed for such funding, which may include, for example, collaborators or consultants.

**Regulation** - [42 CFR 50, Subpart F, "Promoting Objectivity in Research"](#)

**Significant Financial Interest (SFI)**

1. 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 to MassMatrix:

- a. 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;
  - b. 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
  - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. 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 MassMatrix responsibilities. See 3. below for sources excluded from this disclosure requirement.
  3. The following are not considered *significant financial interests*...
    - a. Salary royalties, or other remuneration paid by MassMatrix to the Investigator if the Investigator is currently employed or otherwise appointed by MassMatrix;
    - b. Intellectual Property Rights assigned to MassMatrix and agreements to share in royalties related to such rights;
    - c. Any ownership interest in MassMatrix;
    - d. 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;
    - e. 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; or

- f. Income from service on advisory committees or review panels for a federal, state or local government agency, 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.

## **Investigator Requirements**

Training - Each Investigator must complete NIH's [FCOI training course](#):

1. prior to engaging in research related to any NIH funded project (except for Phase I SBIR grants) ;
2. at least every four years, and
3. immediately when any of the following circumstances apply:
  - a. MassMatrix revises its policy in a manner that affects the Investigator;
  - b. when an Investigator is new to MassMatrix; or
  - c. when MassMatrix finds an Investigator is not in compliance with MassMatrix's policy or management plan.

...and email a certificate of completion to the Grant Officer.

SFI Disclosure - Each Investigator must disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigator's MassMatrix responsibilities:

1. no later than at the time of application for NIH funded research,
2. at least annually during the period of the award, and
3. within 30 days of discovering or acquiring a new SFI.

To disclose a SFI, email the following information to the Grant Officer:

1. Entity - What is the name of the entity in which you or a family member have a SFI?
2. Who - Who has the SFI...you or a family member?
3. Nature - Describe the activity / interest of the SFI (i.e. consulting, sponsored or reimbursed travel, work performed, equity interest, patent / royalty, etc.),
4. Affect on Research - Could the SFI reasonably affect the outcome of your research? Why or why not?



5. Timeframe - Has the SFI exceeded \$5,000 in the last 12 months or do you anticipate it will in the next 12 months?
6. Additional Comments

## **Grant Officer Requirements**

Guidelines - In order to determine if an Investigator's SFI is related to NIH funded research and, if so related, whether the SFI is a FCOI, the Grant Officer will read and become familiar with the Regulation and the 2011 [Final Rule](#) for grants and cooperative agreements. The first fifteen disclosures will be discussed and reviewed with MassMatrix's Board of Directors. Guidelines will be developed through this review process with the Board.

Informing & Soliciting Investigators - At the beginning of every new grant budget period and before any new grant application submission, the Grant Officer will:

1. inform each Investigator of the Regulation, MassMatrix's FOCI Policy (i.e. this document) and Investigator's responsibilities regarding disclosure of SFIs and
2. solicit SFI disclosures.

Review of SFI Disclosures - Prior to the expenditure of any grant funds and / or within 60 days of a SFI disclosure, the Grant Officer will:

1. review all Investigator disclosures,
2. determine if any SFIs relate to the NIH funded research,
3. determine if an FCOI exists, and
4. develop and implement management plans as needed to manage FCOIs, including monitoring management plans until completion of the project.

## NIH Reporting Requirements

1. The Grant Officer will send initial, annual (through project completion and due at time of annual progress reports) and revised FCOI reports to NIH as follows:
  - a. prior to the expenditure of funds,
  - b. within 60 days of identifying a new FCOI,
  - c. annually, to provide status of existing FCOIs and any changes to the management plan if applicable, and
  - d. following a retrospective review to update a previously submitted report, if appropriate.



2. The Grant Officer will immediately notify MassMatrix's Board of Directors if an Investigator fails to comply with MassMatrix's FCOI policy or bias is found with the design, conduct or reporting of NIH-funded research.

Maintenance of Records - The Grant Officer will maintain all FCOI-related records in a manner that meets or exceeds regulatory requirements for at least 3 years from the date of the final expenditures report and from other dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable.

Quarterly Review - The Grant Officer will provide a quarterly review to the Board of Directors on all Investigator issues of policy noncompliance, including the adequacy of enforcement mechanisms, employee sanctions and other administrative actions.

Retrospective Reviews - The Grant Officer will complete and document, consistent with the Regulation, retrospective reviews within 120 days of MassMatrix's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner.

Subrecipient Requirements - The Grant Officer will ensure that all subrecipient agreements provide written clarification regarding whether the subrecipient will follow MassMatrix's FCOI policy or subrecipient's FCOI policy. If using the subrecipient's policy, the written clarification will include certification that the subrecipient policy complies with the Regulation and a requirement for the subrecipient to report identified FCOIs for its Investigators to MassMatrix within 30 days of determining an Investigator FCOI exists. If using MassMatrix's policy, the written clarification will include a requirement to solicit and review subrecipient Investigator disclosures as per MassMatrix's policy and to report any FCOIs to MassMatrix within 7 days of determining an Investigator FCOI exists.

Public Accessibility Requirements - The Grant Officer will ensure that the current FCOI policy is publicly available on MassMatrix's website.

The Grant Officer will also ensure that the required information concerning identified FCOIs held by senior / key personnel (as defined by the Regulation) is made available within 5 calendar days of a written request and remains available for three years from the date the information was most recently updated.



## **Board of Director and CEO Requirements**

Grant Officer Duties - The CEO will perform the duties of the Grant Officer for the one case in which the Grant Officer is also an Investigator. The Board of Directors will perform the duties of the Grant Officer for the one case in which the CEO is an Investigator.

Guidelines - In order to determine if an Investigator's SFI is related to NIH funded research and, if so related, whether the SFI is a FCOI, the first fifteen disclosures will be discussed and reviewed with MassMatrix's Board of Directors and the Grant Officer. Guidelines will be developed through this review process with the Board.

Noncompliance or Bias Issue - After receiving notice from the Grant Officer that an Investigator failed to comply with MassMatrix's FCOI policy or bias was found with the design, conduct or reporting of NIH-funded research, MassMatrix's Board of Directors will promptly review the issue, determine and implement corrective action and notify and report to NIH in accordance with the Regulation.

Quarterly Review - The Grant Officer will provide a quarterly review to the Board of Directors on all Investigator issues of policy noncompliance, including the adequacy of enforcement mechanisms, employee sanctions and other administrative actions.

