



## FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

### INTRODUCTION

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Effective interactions between research institutions, government, the private sector, and industry are essential to bring about the rapid application of scientific discoveries to address the needs of the nation and to maintain the efficient translation of research findings. However, the resulting relationships may involve financial interests that give rise to a Financial Conflict of Interest (FCOI) and may have potential to impact the design, conduct, or reporting of an Investigator's research in return for a financial benefit to the Investigator.

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of Magnus Medical (Company) research and to comply with federal regulations.

Financial conflicts of interest in research involve situations in which an investigator has a significant financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research. Magnus Medical developed the following FCOI policy in compliance with HHS regulation 42 CFR Part 50 Subpart F to ensure that the design, conduct, and reporting of research associated with the PHS/NIH-supported projects is free from bias resulting from an investigator's conflicting financial interest.

### DEFINITIONS

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The following definitions are provided as a reference and are considered key definitions in understanding the federal regulations of FCOI. A complete list of official definitions can be found at [42 CFR 50.603](#).

**Investigators** include the Principal Investigator/Project Director and any other individuals, regardless of title or position who is responsible for the design, conduct, or reporting of PHS/NIH-funded research, or proposed for such funding, and which may include for example, collaborators or consultants.

**Institutional responsibilities** mean an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**Financial interest** means anything of monetary value, whether the value is readily ascertainable.

**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.

**Financial Conflicts of Interest** in research involve situations in which an investigator has a significant financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research.

## FCOI TRAINING

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In compliance with federal regulations, all Magnus Medical Investigators who are planning to participate in or are participating in Public Health Service (PHS) funded research are required to review the Magnus Medical FCOI policy and complete the [FCOI Training module](#):

- Prior to engaging in research related to any PHS/NIH-funded grant
- At least every four (4) years
- Immediately, if:
  - Institution revises its FCOI policy that affects requirements of Investigators
  - An Investigator is new to an Institution
  - An Investigator is not in compliance with the policy or management plan

Upon completion of the training, a certificate of completion must be sent to the Research and Grants Finance Manager. Investigators should also retain a copy for their records.

## SIGNIFICANT FINANCIAL INTEREST

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- A Significant Financial Interest (SFI) is defined as a financial interest consisting of one or more of the following interests of **the Investigator and Investigator's spouse and dependent children** that reasonably appears to be related to the Investigator's institutional responsibilities:
  - **With regard to any publicly traded entity**, a significant financial interest exists if the value of any financial compensation in the past 12 months cumulatively exceeds \$5,000. Included are salary, consulting fees, honoraria, and equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value.
  - **With regard to any non-publicly traded entity**, a significant financial interest exists if the value of any financial compensation in the past 12 months, cumulatively exceeds \$5,000, or when the Investigator and Investigator's spouse and dependent children hold any equity interest (e.g., stock, stock option, or other ownership interest).
  - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 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 institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation—see below. For

example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by the Company directly (i.e. the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Company relating to the trip, such as purpose of the trip, identify of the payer/sponsor, destination and duration. The Company is required to determine if additional information is required (e.g. monetary value) and whether the travel constitutes a FCI with PHS/NIH-funded research.

**NOTE:** The above disclosure requirement **does not apply** to travel that is reimbursed or sponsored by a Federal, state, or local government agency in the United States, or a United States public or non-profit institution of higher education (as defined at 20 U.S.C. 1001(a)) or its affiliated hospital, medical center or research institute.

- All foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

The term significant financial interest **does not include** the following types of financial interests:

- Salary, royalties, or other remuneration paid by Magnus Medical to the Investigator if the Investigator is currently employed by Magnus Medical, including intellectual property rights assigned to Magnus Medical and agreements to share in royalties related to such rights.
- 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.
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency in the United States, a United States public or non-profit institution of higher education (as defined at 20 U.S.C. 1001(a)) or its affiliated hospital, medical center, or research institute.
- Income from service on advisory committees or review panels for a Federal, state, or local government agency in the United States, or a United States institution of higher education.

#### IDENTIFICATION OF PERSONS REQUIRED TO DISCLOSE AN SFI

The Principal Investigator of a Research Project will identify all Investigators who have to complete a significant financial conflict disclosure. The Principal Investigator and Research and Grant Finance Manager will be responsible for ensuring that annual updates and disclosures of new or increased financial interests are completed.

#### SUBMISSION OF SIGNIFICANT FINANCIAL INTEREST DISCLOSURE FORM

Each Investigator identified by the PI will be required to complete [SFI Disclosure Form](#):

- Before participating in any PHS/NIH funded research activities,
- Annually during the period of award, and

- Within 30 days of discovering or acquiring a new SFI. The discovery or acquirement may be due to marriage, purchase, or inheritance.

#### REVIEW OF FINANCIAL INTEREST DISCLOSURE FORM:

**A review of the SFI Disclosure Form** will be conducted by the PI, CEO and Research & Grant Finance Manager with input from the Investigator to determine whether a potential for conflict of interest exists. The requirement that an Investigator discloses a Significant Financial Interest under the terms of this Policy does not in and of itself imply the existence of an actual or potential Financial Conflict of Interest.

**A Financial Conflict of Interest exists** when Investigator's Significant Financial Interest is:

- Related to PHS funded research. An SFI is related to PHS-funded research when the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research, and
- An SFI is considered a FCOI when the SFI could directly and significantly (i.e., have a material effect) affect the design, conduct, or reporting of the NIH-funded research.

**If it is determined that there is a potential conflict of interest**, then steps will be taken to determine what measures are needed to manage, reduce or eliminate specific SFI to prevent the potential to compromise or bias professional judgment or objectivity regarding the design, conduct or reporting of research.

A management plan may be required to outline the terms, conditions, and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to) to be taken:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research, to staff members working on the project, etc.)
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest.
- Modification of the research plan
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research.
- Reduction or elimination of the financial interest (e.g., sale of an equity interest), or
- Severance of relationships that create financial conflicts

#### REPORTING REQUIREMENTS

Research and Grants Financial Manager is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the sponsor:

- **Initial report**

Prior to the Company's expenditure of any funds under a PHS/NIH-funded research project, the Company will provide to the sponsor an FCOI report regarding any Investigator SFI found by the Company to be a financial conflict of interest in accordance with the regulation. In cases in which the Institution identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of NIH-awarded funds, the Institution shall not submit an FCOI report to the NIH.

- **During on-going PHS/NIH-funded research projects**

Whenever, during the research project, a new Investigator discloses a significant financial interest or an existing Investigator discloses a new significant financial interest, the company will submit an FCOI report within 60 days after its determination that a new FCOI exists.

Whenever an Institution identifies a significant financial interest that was not disclosed timely to the sponsor, Magnus Medical will:

- Submit a FCOI report within 60 days of the discovery,
- 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 financial conflict of interest going forward.
- Complete a retrospective review within 120 days of discovery of noncompliance to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. Updated FCOI will be submitted to the sponsor. Required retrospective review elements are outlined in [42 CFR 50.605\(a\)\(3\)\(iii\)](#) and should at minimum include:
  - Project Number
  - Project Title
  - PD/PI or contact PD/PI if multiple PD/PI model is used
  - Name of the Investigator with the FCOI
  - Name of the entity with which the Investigator has an FCOI
  - Reasons for the retrospective review
  - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed)
  - Findings of the review; and

- **Annual FCOI report**

For any FCOI previously reported to the sponsor, the Company shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

Further, Magnus Medical will notify the sponsor promptly:

- **If bias is found** the Institution will notify and submit a **mitigation report** to the sponsor. The mitigation report will include, at a minimum, the key elements documented in the retrospective review (discussed above) and a description of the impact of the bias on the research project and the Institution'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). Thereafter, the Institution will submit FCOI reports annually.

- **If an Investigator fails to comply** with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research the institution will take corrective further described in [42 CFR 50.606\(a\)](#).

## MANAGEMENT PLAN

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The management plan is to be implemented prior to the company's expenditure of PHS funds awarded for the research project. The management plan will specify the actions that are required to manage the Financial Conflict of Interest, and will include a description of the key elements outlined below:

- The role and principal duties of the conflicted Investigator in the research project
- Conditions of the management plan
- How the management plan is designed to safeguard objectivity in the research project
- Confirmation of the Investigator's agreement to the management plan
- How the management plan will be monitored to ensure Investigator compliance
- Other information as needed.

Investigators must formally agree to the proposed management strategies. All management plans are required to be signed by the Investigator, the PI and CEO. Compliance of the management plan will be monitored by the Principal Investigator. Additional Management plan requirements are outlined below

## VIOLATIONS OF FCOI POLICY

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Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, disciplinary proceedings may be taken against the violating individual.

The company will follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy as described above. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved.

Additionally, in any case in which the sponsor determines that a PHS-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 financial conflict of interest that was not managed or reported by the Institution as required by this subpart, the Institution will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations .

## MAINTENANCE OF RECORDS

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Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the Executive team for three (3) years from the date the final expenditure report is submitted to the sponsor or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

## SUBRECIPIENT REQUIREMENTS

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When carrying out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), Magnus establish a written agreement (e.g., subaward contract) which confirms that the investigators of the subrecipient institution will comply with this policy or provide certification that their organization is in compliance with the Federal policy, 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F).

If an SFI is identified by the sub-award recipient, they are required to notify the PI and CEO of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced, or eliminated in accordance with federal regulations.

## PUBLIC DISCLOSURE AND RECORDS MANAGEMENT

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Magnus will publish the institution's policy on its public website. Magnus will also maintain public accessibility to Significant Financial Interests of senior/key personnel (as defined by the regulation) that were identified as FCOIs and reported to the sponsor. As such, Magnus will respond to all written requests for information within five business days and then releases the following information about such Significant Financial Interest.

- The name of the Investigator.
- The title and role of the Investigator with respect to the research project.
- Name of the entity with which the Significant Financial Interest is held.
- The nature of the Significant Financial Interest.
- Approximate value of the Significant Financial Interest as determined by:
  - dollar range \$0-\$4,999, \$5,000-\$9,999, \$10,000-\$19,999
  - amounts between \$20,000-\$100,000 by increments of \$20,000
  - amounts above \$100,000 by increments of \$50,000
  - or a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value.

Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential conflicts of interest, will be retained for a minimum of three years from the date the final expenditure report is submitted to the sponsor as required by [42 CFR 50.605\(a\)\(5\)\(i\)-\(iv\)](#). Upon the NIH request, Magnus Medical will also make information relating to any investigator



SFI disclosure and the institutional review available, whether or not the disclosure resulted in the institution's determination of an FCOI.

## FCOI IN RESEARCH INVOLVING HUMAN SUBJECTS

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Additional consideration will be given to conflicts of interest when the research involves human participants. In addition to the process outlined above, any significant financial conflict identified will be disclosed to the Institutional Review Board (IRB) responsible for review and approval of the associated protocols. Research will not begin/resume until the IRB has confirmed that appropriate steps have been taken to ameliorate any potential harm or potential harm to participants due to the significant financial conflict.

## USEFUL RESOURCES

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[FCOI Regulation 42 CFR Part 50 Subpart F](#)

[Financial Conflict of Interest](#)

[FCOI Training](#)

[Frequently Asked Questions \(FAQs\)](#)

[NIH Guide Notices Related to Financial Conflict of Interest](#)

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[Important Highlights of FCOI Regulatory Requirements for Foreign Institutions](#)