



# Financial Conflict of Interest (FCOI) Policy

## AiM Medical Robotics, Inc.

### 1. Purpose & Scope

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 research at **AiM Medical Robotics, Inc.** ("the Company") and to ensure compliance with federal regulations. This policy is designed to comply with **42 CFR Part 50, Subpart F**, *"Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought"* (the "FCOI Regulation"). This policy applies to all research projects funded by the Public Health Service (PHS), including the National Institutes of Health (NIH), via grants, cooperative agreements, or sub-awards. It mandates that the design, conduct, and reporting of such research remains completely free from bias resulting from Investigator financial conflicts of interest.

This policy applies to all **Investigators** (as defined below) participating in, or submitting proposals for, PHS/NIH-funded research on behalf of the Company.

### 2. Key Definitions

- **Investigator:** The Project Director (PD), Principal Investigator (PI), Key Personnel, and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of research funded by the PHS/NIH, which may include employees, subrecipients, collaborators, or consultants.
- **Institutional Responsibilities:** An Investigator's professional responsibilities on behalf of the Company, including but not limited to research, research consultation, professional practice, and service on company or external technical panels.
- **Financial Interest:** Anything of monetary value, whether or not the value is readily ascertainable.
- **Financial Conflict of Interest (FCOI):** A Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS/NIH-funded research.
- **Key Personnel:** The PD/PI and any other person identified as senior/key personnel by the Company in the grant application, progress report, or any other report submitted to the PHS/NIH.
- **FCOI Officer:** The individual designated by the Company to oversee this policy, including the collection, review, management, and reporting of SFI Disclosure Forms.



## Significant Financial Interest (SFI)

An SFI consists 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 institutional responsibilities:

1. **Publicly Traded Entities:** Remuneration received from the entity in the 12 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**.
2. **Non-Publicly Traded Entities:** Remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, **exceeds \$5,000**, or when the Investigator (or spouse/dependent children) holds **any equity interest** (e.g., stock, options, or other ownership interest).
3. **Intellectual Property:** Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such interests.
4. **Sponsored/Reimbursed Travel:** Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed directly to the Investigator), related to their institutional responsibilities. Disclosure must include the purpose of the trip, the identity of the sponsor/payer, the destination, and the duration. *Note: This excludes travel reimbursed or sponsored by U.S. Federal, state, or local government agencies, U.S. Institutions of higher education, or affiliated research institutes/teaching hospitals.*

## What is EXCLUDED from an SFI?

- Salary, royalties, or other remuneration paid by the Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company (including ownership interest in the Company itself, if the Company is a commercial or for-profit organization).
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions.
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, or a U.S. Institution of higher education.

## 3. Disclosure Procedures & Timeline

It is the responsibility of the Principal Investigator (PI) of a research project to identify all Investigators who have a role requiring disclosure under this policy and to ensure they submit an SFI Disclosure Form according to the timelines outlined below:

- **Initial Disclosure:** All Investigators must complete and submit an SFI Disclosure Form to the FCOI Officer *before* the Company submits a grant application or proposal to the PHS/NIH.
- **Annual Disclosure:** All participating Investigators must submit an updated SFI Disclosure Form annually. This documentation must be filed at the time specified by the FCOI Officer, usually coinciding with the preparation of the annual project progress report.
- **Ad-Hoc / New Disclosures:** If an Investigator acquires or discovers a new SFI (e.g., through marriage, inheritance, stock purchase, or consulting agreement) during the course of an active PHS/NIH grant, they must submit a new SFI Disclosure Form within 30 days of acquisition.



## 4. Review, Management, & Monitoring

Upon receiving an SFI Disclosure Form, the FCOI Officer will review the disclosure to determine if the SFI relates to the PHS/NIH-funded research and whether it constitutes an FCOI (i.e., could it directly and significantly affect the design, conduct, or reporting of the research).

If an FCOI is identified, the FCOI Officer will develop and implement a **Management Plan** within **60 days** of disclosure. This plan will specify the conditions and actions required to manage, reduce, or eliminate the conflict to ensure the research remains free from bias. Management strategies may include:

- Public disclosure of the financial conflict (e.g., when presenting or publishing research results).
- For research projects involving human subjects, disclosure of the FCOI directly to the participants.
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias.
- Modification of the research plan.
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
- Reduction or divestiture of the financial interest.
- Severance of relationships that create financial conflicts.

The Investigator must formally sign and agree to the Management Plan. The FCOI Officer will actively monitor compliance with the plan until the completion of the research project.

## 5. Federal Reporting Requirements

The FCOI Officer is responsible for reporting all identified FCOIs to the PHS/NIH funding component via the eRA Commons FCOI Module according to the following mandatory compliance framework:

Report Type	Submission Window	Required Contents
<b>Initial FCOI Report</b>	<b>Prior to expenditure of funds</b> under a new award.	Grant number, PI, name of Investigator with FCOI, entity name, nature of financial interest, value of interest (or statement that value cannot be readily determined), and key elements of the Management Plan.
<b>New FCOI Report</b>	<b>Within 60 days</b> of identifying a new FCOI during an ongoing project.	Same information as the initial report, outlining how the interest will be managed moving forward.
<b>Annual FCOI Report</b>	<b>Concurrently with the</b>	Status of the FCOI,



Report Type	Submission Window	Required Contents
	<b>annual progress report (RPPR).</b>	explanation of whether the Management Plan is still being followed, and any modifications made to the plan. Submitted annually until project completion.

## 6. Non-Compliance, Sanctions, & Retrospective Review

Investigators are expected to comply fully and promptly with this policy. Violations—including intentional failure to file a required disclosure, misrepresentation of an SFI, or failure to adhere to a mandated Management Plan—will result in disciplinary actions up to and including termination of employment.

### Retrospective Review Process

In the event that an FCOI is not identified, reviewed, or managed in a timely manner (e.g., an Investigator fails to disclose an SFI, or the Company fails to review a disclosure), the Company will complete a documented **Retrospective Review within 120 days** of the determination of non-compliance.

The Retrospective Review will evaluate whether the design, conduct, or reporting of the PHS/NIH-funded research was biased during the period of non-compliance.

- **If no bias is found:** The Company will document the methodology, findings, and update/implement a Management Plan moving forward.
- **If bias is found:** The Company will notify the PHS/NIH funding component immediately and submit a **Mitigation Report** outlining the exact actions taken to mitigate the effects of the bias (including project adjustments, data reviews, etc.).

### Clinical Research Special Clause

In any case where the Department of Health and Human Services (HHS) determines that a PHS/NIH-funded clinical research project designed to evaluate the safety or effectiveness of a medical device, drug, or treatment was designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Company, the Company will require the Investigator to disclose the FCOI in every public presentation of the results and request an addendum to previously published presentations.

## 7. Subrecipient Requirements

When AiM Medical Robotics carries out PHS/NIH-funded research through subrecipients (e.g., subcontractors, consortium members, or collaborators), the Company will establish a formal written agreement specifying whether the subrecipient will conform to this FCOI policy or the subrecipient's own institutional FCOI policy.

- If the subrecipient relies on its own policy, it must provide a certification that its policy



complies with **42 CFR Part 50, Subpart F**.

- The agreement will mandate that the subrecipient report any identified FCOIs to the Company within a timeframe sufficient to allow the Company to review and submit required FCOI reports to the PHS/NIH.

## 8. Record Keeping

The FCOI Officer will securely maintain all records relating to Investigator financial disclosures, the Company's review of and response to those disclosures, and all actions taken under this policy (including Retrospective Reviews and Management Plans). These records must be retained for **at least three (3) years** from the date the final expenditure report is submitted to the PHS/NIH, or from other applicable dates specified in **45 CFR 75.361**.

## 9. Public Accessibility

To ensure transparency, this FCOI Policy will be posted publicly on the Company's website. Additionally, information concerning identified SFIs held by Key Personnel that constitute an FCOI will be made available to the public within **five (5) business days of receiving a written request**. The response will include the Investigator's name, title, the name of the entity in which the SFI is held, and the nature and approximate dollar value of the financial interest. This information will remain available for at least three years from its last update.

## 10. Required Training

Each Investigator must successfully complete Financial Conflict of Interest training prior to engaging in any research related to a PHS/NIH-funded grant. Training must be repeated **at least every four (4) years**.

Immediate retraining is required if:

1. The Company revises its FCOI policy in a manner that affects Investigator requirements.
2. An Investigator is newly hired or appointed to a role covered by this policy.
3. An Investigator is found to be non-compliant with this policy or an active Management Plan.

The NIH Financial Conflict of Interest online tutorial serves as an approved training vehicle. Upon completion, Investigators must submit their certificate of completion to the FCOI Officer.