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1.0 Purpose

Imricor Medical Systems, Inc. (Imricor) observes the highest standards of professional and ethical conduct in all of its scientific and research activities regardless of the type of research or the source of funding. A broad trust that all employees share this dedication to scientific integrity is an essential value of Imricor.

The purpose of this policy is to establish standards for all Imricor employees that provide a reasonable expectation that the design, conduct, and reporting of research performed will be free from bias resulting from Investigator financial conflicts of interest.

2.0 Scope

This policy applies to Imricor Medical Systems, Inc. when it submits a proposal, or receives, Public Health Service (PHS) research funding by means of a contract and to each Investigator who is planning to participate in, or is participating in such research.

This statement of policy does not apply to SBIR Program Phase I applications.

3.0 Applicable Documents

The Imricor Medical Systems, Inc. Financial Conflict of Interest policy complies with 45 CFR Part 94; Responsible Prospective Contractors.

4.0 Definitions

The following terms, along with additional terms defined in 42 CFR 94, apply to this document.

Term	Definition
Contractor	An entity that provides property or services under contract for the direct benefit or use of the Federal Government
Disclosure of significant financial interests	An Investigator's disclosure of significant financial interests to an Institution
Financial Conflict of Interest (FCOI)	A significant financial interest that could directly and significantly affect the design, conduct or reporting of PHS-funded research
FCOI report	An Institution's report of a financial conflict of interest to a PHS Awarding Component
Financial interest	Anything of monetary value, whether or not the value is readily ascertainable
HHS	The US Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated
Institution	Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that submits a proposal, or that receives, PHS research funding
Institutional responsibilities	An Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest
Investigator	The project director or principal Investigator and any other person responsible for the design, conduct or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
Key personnel	Includes the principal investigator, project director, and any other personnel

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	considered to be essential to work performance and identified as key personnel in the contract proposal or contract
Manage	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
PD/PI	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
PHS	The Public Health Service, an operating unit of the DHHS, and any components of the PHS to which the authority involved may be delegated, including the NIH
PHS Awarding Component	The organizational unit of the PHS that funds the research that is subject to this part
Research	A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral or social-sciences research. The term encompasses basic and applied research and product development.
Significant financial interest (SFI)	<ol style="list-style-type: none"> 1. A financial interest consisting of one or more of the following interests of the Investigator, his/her spouse, and dependent children that reasonably appears to be related to the Investigator's institutional responsibilities: <ol style="list-style-type: none"> a. With regard to any publicly traded entity, a SFI 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 options, 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-public traded entity, a SFI 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, his/her 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 reimbursement 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 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. 3. The term SFI does not include the following types of financial interest: <ul style="list-style-type: none"> • Salary, royalties, or other remuneration paid by Imricor to the Investigator if the Investigator is currently employed or otherwise appointed by Imricor, including intellectual property rights assigned to Imricor and agreements to share in royalties related to such rights;

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	<ul style="list-style-type: none"> Income from investment vehicles, such as mutual funds or retirement accounts, provided the Investigator does not directly control the investment decision made in these vehicles; Income from seminars, lectures, or teaching engagements sponsored by a Federal, state or local government agency, an Institution of higher education as defined in 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 Income from service on advisory committees or review panels for a Federal, state or local government agency, an Institution of higher education as defined in 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
Small Business Innovation Research (SBIR) Program	The extramural research program for small businesses that is established by the Awarding Components of the PHS and certain other Federal <i>agencies</i> .

5.0 Roles and Responsibilities

Role	Responsibility
Research	Ensure all required investigators complete disclosure forms in a timely manner

6.0 Policy

6.1 Disclosure Requirements

Each Investigator who is planning to participate in the PHS-funded research is required to disclose to Imricor their SFIs as well as any SFIs for his/her spouse and his/her dependent children's prior to engaging in research related to PHS-funded contract. Imricor's Financial Disclosure Form can be found in Appendix A of this policy. Investigator's should send their initial annual disclosure form to info@imricor.com.

Each Investigator is required to submit an updated Disclosure Form to Imricor at info@imricor.com either within 30 days of discovering or acquiring a new SFI, or at least on an annual basis. If an Investigator does not have any SFIs to report, the Investigator must still complete the Disclosure Form annually.

6.2 Review of Disclosure and Management of FCOI

6.2.1 Review Requirement

Prior to Imricor's expenditure of any funds under a PHS-funded research project, Imricor key personnel shall review all Investigator disclosures of SFIs to determine whether any SFIs relate to PHS-funded research and determine whether a FCOI exists. If a FCOI exists, Imricor will develop and implement a management plan that will specify the actions that have been, and shall be taken to manage such FCOI. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- Public disclosure of FCOI (e.g., when presenting or publishing research)
- For research projects involving human subjects research, disclosure of FCOI directly to participants

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- 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 disqualification 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.

6.2.2 Disclosure/Identification of SFI

Whenever, in the course of an ongoing PHS-funded research project, an investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI to Imricor, the Imricor personnel shall, within 60 (sixty) days, review the disclosure of the SFI and determine whether it is related to PHS-funded research and whether a FCOI exists. If a FCOI exists, Imricor will 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. Depending on the nature of the SFI, Imricor may determine that additional interim measures are necessary regarding the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of Imricor's review.

Prior to Imricor's expenditure of any funds under a PHS-funded research project, Imricor shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a requestor within five business days of a request, of information concerning any SFI disclosed to Imricor that meets the following criteria:

- a. SFI was disclosed and is still held by key personnel as defined in this part
- b. Imricor determines that the SFI is related to the PHS-funded research
- c. Imricor determines that the SFI is a FCOI

The following information regarding the FCOI must be posted to the website.

- Name of the investigator with the FCOI, title, and role with respect to the research project
- Name of the entity in which the FCOI is held
- Nature of the SFI
- Value of the SFI (dollar ranges are permissible: \$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 the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

This information shall be updated annually. Imricor shall update the Web site within 60 days of:

- The receipt or identification of information concerning any additional SFI of key personnel for the PHS-funded research project not previously disclosed
- Upon disclosure of SFI of key personnel new to the PHS-funded research project and meeting the disclosure criteria

The Web site shall note the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of Imricor's identification of a new FCOI. Any SFI posted shall remain publicly accessible on the Website for at least three (3) years from the date the information was most recently updated.

6.2.3 Retrospective Reviews

Whenever a FCOI is not identified or managed in a timely manner including failure by an Investigator to disclose a SFI, failure by Imricor to review or manage such a FCOI or failure by the Investigator to comply with a FCOI management plan, Imricor will, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PSH-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the

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noncompliance, was biased in the design, conduct or reporting of such research. Documentation of the retrospective review shall include all of the following key elements:

- Project number
- Project title
- PI or contact PI if a multiple PI model is used
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has a FCOI
- Reason(s) for the retrospective review
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusion of the review

Based on the retrospective review, Imricor will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Imricor is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and Imricor'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). Therefore, Imricor will submit FCOI reports annually, as specified elsewhere in this part. Depending on the nature of the FCOI, Imricor may determine that additional interim measures are necessary regarding the Investigator's participation in the PHS-funded research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of Imricor's retrospective review.

6.2.4 Monitoring

Whenever Imricor implements a management plan, Imricor will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

6.3 Reporting of Financial Conflict of Interest

6.3.1 Initial FCOI Report

Prior to Imricor's expenditure of any funds under a PHS-funded research project, Imricor will provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found to be conflicting. Imricor will implement a management plan in accordance with Section 6.2 of this policy. In cases in which Imricor identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, Imricor is not required to submit an FCOI report to the PHS Awarding Component.

6.3.2 Subsequent FCOI Reports

For any significant financial interest that Imricor identifies as FCOI after Imricor's initial FCOI report during an ongoing PHS-funded research project, Imricor will provide to the PHS Awarding Component, within 60 days, an FCOI report regarding the FCOI. Additionally, Imricor will ensure it has implemented a management plan in accordance with Section 6.2 and, if required, complete a retrospective review and mitigation report according to Section 6.2 of this policy.

6.3.3 Contents of FCOI Report

Any FCOI report required under Sections 6.3.1 and 6.3.2 shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of Imricor management plan. Elements of the FCOI report shall include the following:

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1. Project/Contract number
2. PI or Contact PI if a multiple PI model is used
3. Name of the Investigator with the financial conflict of interest
4. Name of the entity with which Imricor has a financial conflict of interest
5. Nature of financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. Value of the financial interest (dollar ranges are permissible: \$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 the interests is one whole value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.
7. A description of how the financial interest relates to the PHS-funded research and the basis for Imricor's determination that the financial interest conflicts with such research; and
8. A description of the key elements of Imricor's management plan, including;
 - 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; and

6.3.4 Annual FCOI Report

For any FCOI previously reported by Imricor regarding an ongoing PHS-funded research project, Imricor shall provide to the PHS Awarding Component an annual FCOI report that addressed the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. Imricor shall provide annual FCOI reports to the PHS Awarding Components for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

6.4 Enforcement

If the failure of an Investigator to comply with Imricor's FCOI policy or a FCOI management plan appears to have biased the design, conduct or reporting of the PHS-funded research, Imricor shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Imricor for further action, which may include directions to Imricor on how to maintain appropriate objectivity in the PHS-funded research project.

The PHS Awarding component may inquire at any time into any Investigator disclosure of financial interests and Imricor's review of, and response to, such disclosure, regardless of whether the disclosure resulted in an FCOI. The PHS-Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that Imricor has not managed the FCOI in accordance with this policy.

6.5 Record Retention

Imricor will maintain records relating to all Investigator disclosures of significant financial interest, including the review and response to such disclosures (whether or not a disclosure resulted in the determination of a FCOI), and all actions under this policy, for at least three (3) years from the date of final payment or, where applicable, for the time periods specified in 48 CFR part 4, subpart 4.7.

6.6 Training

Each Investigator must complete training regarding Imricor's policy on FCOI, disclosure of significant financial interests, and associated Federal regulations prior to engaging in research related to any PHS-

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funded contract. Additionally, Investigators must complete training at least every four years, and immediately complete training when any of the following circumstances occur:

- Imricor revises its FCOI policies or policy in any manner that affects the requirements of Investigators;
- An Investigator is new to Imricor; or
- Imricor determines an Investigator is not in compliance with the Institution's FCOI policy or management plan.

6.7 Subcontractors/consultants

If Imricor conducts PHS-funded research through a subrecipient (e.g., subcontractors, or consortium members), Imricor personnel will take the following steps to ensure that any subrecipient Investigator complies with this policy.

1. Imricor will incorporate a written agreement with the subrecipient terms that establish whether this policy or the FCOI policy of the subrecipient will apply to the subrecipient's Investigators.
 - a. If the subrecipient's FCOI policy applies the subrecipient will certify as part of the written agreement above that its policy complies with applicable Federal regulations. If the subrecipient cannot provide such certification, the agreement will state that the subrecipient's Investigators are subject to Imricor's FCOI policy for disclosing SFIs that are directly related to the subrecipient's work for the awardee institution.
 - b. If the subrecipient must comply with Imricor's FCOI policy the written agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to Imricor. The time period(s) shall be sufficient to enable Imricor to provide timely FCOI reports to the PHS prior to the expenditure of funds, within sixty (60) days of finding any additional FCOI and annually thereafter.
2. If the subrecipient's policy applies, the agreement reference above will specify the time period(s) for the subrecipient to report all identified FCOIs to Imricor. The time period(s) shall be sufficient to enable Imricor to provide timely FCOI reports to the PHS prior to the expenditure of funds, within sixty (60) days of finding any additional FCOI and annually thereafter.

Appendix A

**Disclosure Form
3 pages**

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For each of the following questions, disclose the described financial interest that reasonably appears to be related to the research.

Investigator Information

Name:

Email:

Telephone:

Department:

Research Project:

Type of Disclosure

- Initial Disclosure Form (Submitted prior to engaging in PHS funded Research)
- Newly Acquired SFI (Submitted within 30 days of discovering or acquiring a new SFI during performance of a PHS funded Research award)
- Annual Update

Disclosure

1. Publicly Traded Entity

Have you, your spouse/domestic partner, and/or dependent children received income or payment for services in the past 12 months or own equity interest in any public traded entity related to your institutional responsibilities exceeding \$5,000 when aggregated? This does not include interests in mutual funds in which you do not directly control investment decision.

No Yes

If yes, please provide details

2. Non-Publicly Traded Entity

Income

Have you, your spouse/domestic partner, and/or dependent children received income or other payment for services, in the past 12 months, exceeding \$5,000, when aggregated, from any non-publicly traded entity? *This does not include payments from The Regents, or income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education or an affiliated research institute, an academic teaching hospital, or a medical center.*

No Yes

If yes, please provide details

Equity Interests

Do you, your spouse or registered domestic partner, and/or dependent children currently own, or have acquired in the past 12 months, any equity interest in any non-publicly traded entity related to your institutional responsibilities? This can include any stock, stock option or other ownership interest.

No Yes

If yes, please provide details

3. Intellectual Property Rights and Interests

Have you, your spouse or registered domestic partner, and/or dependent children received payments, in the past 12 months, for any intellectual property rights and interests (e.g. patents, copyrights) exceeding \$5,000 related to your institutional responsibilities?

No Yes

If yes, please provide details

4. Travel Reimbursement/Sponsorship

Have you received travel reimbursement or been sponsored for travel (i.e. travel expenses paid on behalf of Investigator and not reimbursed to Investigator) in excess of \$5,000 per entity in the 12 months prior to disclosure, by any entity related to your institutional responsibilities? This does not include travel sponsored or reimbursed by a U.S. federal, state, or local government agency, a U.S. institution of higher education or an affiliated research institute, an academic teaching hospital, or a medical center.

No Yes

If yes, please provide details

5. Training

Have you completed Imricor’s Policy for Financial Conflict of Interest required training prior to engaging in any PHS funded research and within the last four years.

No Yes

If yes, please provide details

6. Certification

The signature below certifies that this is a complete disclosure of all my significant financial interests related to my institutional responsibilities and I have used all relevant and available resources in preparing this Financial Interest Disclosure, and to my knowledge it is true and complete.

Name	Signature	Date