



Financial Conflict of Interest Policy for Federal Grants and Contracts

Purpose: The intent of this policy is to promote objectivity in research, to identify and eliminate or manage any possible threat to the integrity of the research conducted by the Company. This policy also assures our research complies with regulations issued by the Public Health Service (PHS), and federal regulations on Promoting Objectivity in Research (42 CFR Part 50 subpart F) and on Responsibilities of Institutions regarding Investigator financial conflicts of interest (45 CFR § 94.4).

Scope: This policy and associated procedures apply to all PHS-sponsored Research at the Company carried out by the Company's employees, consultants, students, trainees, or other agents of the Company. These procedures will be followed whenever the Company or its employees submit a request for funding to or expend funds from the PHS.

Policy Summary: All Investigators who plan to participate in or direct a sponsored Research project must disclose to the Company any significant financial interest which they have in any commercial enterprises that will participate in or may be affected by the performance or completion of the sponsored Research. Each significant financial interest will be reviewed by the Company to determine whether it constitutes an actual financial conflict of interest under this policy and federal regulations. For actual conflicts, the Company will take action to eliminate, reduce, or manage the conflict, as appropriate. If the Company determines that an investigator is noncompliant with this policy or a financial conflict of interest management plan, it will take appropriate action and report the matter to NIH.

Definitions: For purposes of this policy the following definitions are provided:

Company means Eclipse Orthopaedics.

Designated Official (DO) is a Company employee designated by the Company President to be responsible for carrying out this policy. The DO will determine which persons are Investigators on PHS-funded projects and solicit and review FCOI Disclosure Forms from Investigators annually.

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

FCOI Report means the Company's report of a financial conflict of interest to a PHS Awarding Component (such as the NIH).

Investigator in this context means the project director (PD) or principal investigator (PI) 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, consultants or contractors.

Immediate Family means an Investigator's spouse and dependent children or other adults who qualify as dependents under the Internal Revenue Code definitions.

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.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of key personnel and Investigator under this part.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS, including the National Institutes of Health (NIH).

Person means any legal person, including an employee, agent, consultant, student, trainee, or subcontractor.

Research includes any basic research, applied research or product development activity for which the company will seek or has been awarded funding from a PHS Awarding Component through a grant or cooperative agreement. This includes other funding mechanisms such as a career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Significant Financial Interest (SFI) means 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 to an outside observer would reasonably appear to be related to the Investigator's Research responsibilities:

- 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 the 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 in stock, stock options or other ownership interest, as determined through reference to public prices and 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 remunerations 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 interests (e.g., stock, stock options, or other ownership interest);
- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or

- d. 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 a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), or an academic teaching hospital, medical center, or research institute that is affiliated with an Institution of higher education. Details of this disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Company DO will, in accordance with this policy, determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.

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

- a. salaries, royalties, or other remuneration paid by the Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company, including
- b. intellectual property rights assigned to the Company and agreements to share in royalties related to such rights;
- c. any ownership interest in the Company held by the Investigator;
- d. income from investment vehicles, such as mutual funds and retirements 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, research institute that is affiliated with an Institution of higher education;
- f. income from service on advisory committees or review panels for 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.

SFI Disclosure Form is attachment A, which provides the instructions and a format for Investigators to disclose and document SFI's.

Policy

Roles and Responsibilities:

Company Responsibilities

1. The Company's President is responsible for overall compliance with the regulation and this policy.
 - a. The President may designate themselves or another Company employee to be the Designated Official (DO) to carry out the functions of developing, following, and enforcing this policy.
 - b. When an investigator does not comply with a FCOI management Plan, the President will take appropriate action to resolve the non-compliance. Action can include reassignment of responsibility, replacing 3rd-party Investigators, or separation of employment.
2. The Designated Official's responsibilities are to:

- a. Complete FCOI training
- b. Determine which persons are Investigators on PHS-funded projects. Investigators must be responsible for the design, conduct, or reporting of research. This may include employees, collaborators, consultants or contractors.
- c. Solicit, collect and review SFI Disclosure Forms from Investigators annually, when applying from PHS funding, and when new investigators join projects.
 - i. Maintain the confidentiality of the SFI disclosures except as required by federal law or agency award terms. In no case will a disclosure statement be released to a federal agency without prior notification to the affected individual.
- d. Review each SFI disclosed and determine whether it is an actual FCOI.
 - i. If no conflict of SFI is found, the SFI disclosure will be filed with the FCOI records. For negative findings no further review is required.
- e. Work with the PD/PI and Investigator to prepare a management plan that will reduce, minimize, eliminate or disclose conflicts of interest. The management plan must be approved by the DO before any expenditures are incurred against the federal grant.
 - i. Ensure Investigators comply with FCOI management plans.
 - ii. Report noncompliance to the Company President.
 - iii. Report noncompliance to the PHS per the requirements of 42 CFR § 50.605(b).
- f. Write and file the FCOI Report(s) to the PHS, per the requirements of 42 CFR § 50.605(b).
- g. Conduct retrospective reviews of noncompliance as required by 50 CFR. § 50.605.
- h. Ensure investigators are trained in the Company FCOI Policy and Investigator Responsibilities.
- i. Post the Company's FCOI Policy publicly, on the Company's Web site.
- j. Retain all FCOI-related records per the PHS policy.
 - i. Per the PHS policy, this include all records relating to all investigator disclosures of SFI's and the institution's review and response to such disclosures (whether or not a disclosure resulted in the institution's determination of an FCOI) for at least three years from the date the final expenditures report is submitted to the NIH.
 - ii. Include a record of the company's DO's.
- k. Maintain this policy and keep it current with the PHS requirements.

Investigator Responsibilities

Each Investigator's responsibilities are to:

1. Review and understand this FCOI Policy and 42 C.F.R Part 50, Subpart F;
 - a. Complete PHS FCOI training course before working on PHS-funded research (and at least every four years thereafter)
 - i. The course is available at <https://grants.nih.gov/grants/policy/foi/foi-training.htm>.
 - ii. Complete the course certification, sign the certificate and forward it to the DO. Certification is required with the Investigator's first disclosure form, and at least every four years thereafter.
2. Complete a Significant Financial Interest Disclosure Form (Attachment A)
 - a. upon hire and annually thereafter,
 - b. before filing a new funding application that anticipates their work as an Investigator, and

- c. within 30 days of becoming aware of a change in significant financial interest.
- 3. Work with the DO to Manage identified FCOI's and comply with the management plan.
- 4. Comply with all management plans for FCOI's.

Forms: Financial Conflict of Interest Disclosure Form –Attachment A



Attachment A

Significant Financial Interest Disclosure Form

Before completing this form, read the Company’s Financial Conflict of Interest Policy, complete the required training and understand the Investigator’s Responsibilities. If you have any questions regarding that policy, contact the FCOI Designated Official prior to signing this document.

Refer to the Financial Conflict of Interest Policy for clarification of terms.

Use multiple forms if needed.

Disclosure Type:

New Hire

Change of Financial Interest

Annual

Project Specific: Project Title/Grant #: _____

Employee Name & Title: _____

1. Do you, or does any member of your Immediate Family, have any Significant Financial Interest that to an outside observer would reasonably appear to be related to your Research responsibilities?
(Review the Policy for the definition of Significant Financial Interest.)

<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, please describe below the type and value of the financial interest (if known).
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2. Do any other conditions exist between you, or any member of your immediate family, and any person or entity which could reasonably be perceived by an outside observer as a potential conflict of interest?

<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, please describe below the nature and extent of the relationship(s) and the nature of the potential conflict.
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I certify that:

I have read the Company's Policy on Financial Conflict of Interest, completed the required training and have submitted a current certificate of completion to the DO.

I have made all required financial disclosures.

(For PI/PD's only) I have made every effort to ensure that all Investigators (see policy for definition) responsible for the design, conduct or reporting of the research have submitted required disclosures.

Signature and date: _____

Typed or Printed name: _____