

## FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

for Investigators and Subrecipients on Public Health Service (PHS)  
Grants, Contracts, and Cooperative Agreements

### 1. PURPOSE

This Procedure applies to the conduct of Research Projects receiving funding directly or indirectly as a recipient (grant award) or sub-recipient (sub-award), from any agency of the US Public Health Service (PHS), including the National Institutes of Health (NIH). It is intended to comply with the 2011 Revised Financial Conflict of Interest Regulation, 42 CFR Part 50, Subpart F, for PHS grants and cooperative agreements as implemented on August 24<sup>th</sup>, 2012.

The regulation is intended to promote research objectivity by providing a reasonable expectation that design, conduct and reporting of NIH funded research will be free from bias resulting from investigator financial conflicts of interest.

A copy of the Federal Regulation is available at the following url:

<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>

Details of the final rule are available under “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors” at the following url:

[https://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](https://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)

#### Abbreviations:

- SFI means significant financial interests
- FCOI means financial conflict of interest
- FCOI report means Lena Biosciences' report of a FCOI to a PHS Awarding Component
- PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH)
- PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this Policy

#### Applicability:

This Policy applies to all Investigators and Subrecipients who participate in research funded by grants, contracts, and cooperative agreements with the Public Health Service (PHS), including the National Institutes of Health (NIH), and other research funded by a government contract that incorporates the Regulations in its terms (collectively, “Covered Research”). The term “Investigator” means an employee, consultant, collaborator, or agent of Lena Biosciences who, regardless of title or position, is responsible for the design, conduct, or reporting of research proposed for funding, or actually funded, under Covered Research. The term “Subrecipient” means a grant subrecipient, subcontractor, or other person or entity who has responsibility for the design, conduct, or reporting of research proposed for funding, or actually funded, under Lena Biosciences Covered Research. Unless special circumstances apply, vendors of supplies and equipment to Lena Biosciences and vendors who provide routine testing services to Lena Biosciences without any significant knowledge of the Covered Research

are not Subrecipients. The requirements apply to SBIR/STTR Phase II awards, SBIR/STTR Phase I Awards are exempt.

Administration:

The Chief Executive Officer of Lena Biosciences (“Company”) shall designate an employee of Company to administer the Policy. Such employee shall be referred to in this Policy as the “Administrator” and shall fulfill all obligations that are assigned to the Institutional Official under the Regulations.

## **2. FCOI PROCESS**

### **2.1 Disclosure**

Significant Financial Interest (SFI), as defined in Appendix A, shall be disclosed by any Investigator prior to the receipt of funding from PHS sources, or if a conflicting SFI arises during the project.

### **2.2 Responsibilities**

Administrator is responsible for ensuring that SFIs of all personnel are identified and disclosed. The items listed in Appendix B may be used as a guide to the required information. Disclosures are reviewed and approved by Administrator. If a significant FCOI is determined, a management plan is defined and implemented to mitigate the FCOI effect on the project.

### **2.3 Reporting requirements to NIH**

Routine FCOI Reports are provided to NIH:

- a. Prior to expenditure of funds on an approved project (for example, a Just-In-Time submission for project approval)
- b. Within 60 days of FCOI identification for a new participant or change in FCOI situation for existing investigators.
- c. Annually, with the required annual progress report.
- d. As needed for changes in previous reports.

Findings of

- a. Bias in conduct or reporting of funded research
- b. Failure of an investigator to comply with this Company procedure
- c. Failure to comply with a FCOI management plan

are to be reported promptly with a mitigation report detailing actions taken.

Reports will be submitted via the eRA Commons FCOI Module.

Demonstration and Instructions are provided at the following urls:

<https://grants.nih.gov/sites/default/files/slideset-Financial-Conflict-of-Interest-FCOI-What-You-Need-to-Know-Nov2021.pptx>

[http://grants.nih.gov/grants/policy/coi/fcoi\\_webinar\\_2012/FCOI%208-14-2012\\_WEBINAR.pptx](http://grants.nih.gov/grants/policy/coi/fcoi_webinar_2012/FCOI%208-14-2012_WEBINAR.pptx)

and further information is available at the following url:

<http://grants.nih.gov/grants/policy/coi/index.htm>

## 2.4 Records

Records of FCOI documentation shall be maintained by the Administrator and retained for at least 3 years after submission of the project final expenditure report or, where applicable, from other dates specified in 45 C.F.R. 75.361.

## 2.5 Enforcement

a. Retrospective reviews, as defined in Appendix C, for SFI's not disclosed, not reviewed or not managed, or non-compliant in a timely manner shall be conducted, documented and reported within 120 days.

b. If the US Department of Health and Human Services (DHHS) determines that any PHS funded study to evaluate the device has been conducted or reported by an investigator with an unreported or unmanaged FCOI then:

- The FCOI must be disclosed in any public presentation
- An addendum be requested to previous publications

## 2.6 Sub-recipients

Sub-recipients of funding shall, as applicable:

- Provide certification of a FCOI policy in compliance with the regulation
- Provide notice of identified FCOI's in a timely manner permitting the grantee to report to NIH

These requirements also apply to the Company, if the Company is a sub-recipient.

## 2.7 Training

a. All Investigators on a PHS funded project shall receive training to include:

- Awareness of the Federal Regulation
- Review of this procedure
- Disclosure responsibilities

Training may be completed by use of the NIH provided web based tutorial at the following url:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

On completion, the FCOI certificate will be saved and printed as a record of the training.

b. Training shall be completed:

- prior to participating in PHS funded research
- at least every 4 years
- at any time when
  - this procedure is revised
  - a new employee is engaged on a PHS funded project
  - an investigator is not in compliance with this procedure or a FCOI management plan

c. Training records are maintained by the Administrator

Further training materials are available at the following urls:

[http://grants.nih.gov/grants/policy/coi/fcoi\\_webinar\\_20111130.htm](http://grants.nih.gov/grants/policy/coi/fcoi_webinar_20111130.htm)

[http://grants.nih.gov/grants/policy/coi/FCOI\\_NIH\\_Regional\\_Seminar-June\\_22\\_2012.ppt](http://grants.nih.gov/grants/policy/coi/FCOI_NIH_Regional_Seminar-June_22_2012.ppt)

<http://grants.nih.gov/grants/policy/coi/index.htm>

[https://grants.nih.gov/grants/policy/coi/coi\\_faqs.htm](https://grants.nih.gov/grants/policy/coi/coi_faqs.htm)

## **2.8 Public Access**

This procedure will be placed on a publicly accessible website. Identified FCOI's will be made available within 5 calendar days of a legitimate request. See Appendix B for required information.

## **3.0 APPENDICES**

APPENDIX A: Definition of significant financial interest

APPENDIX B: FCOI public disclosure requirements

APPENDIX C: Retrospective review requirements and documentation

## APPENDIX A: Definition of significant financial interest (SFI)

**A Significant Financial Interest consists of** one or more of the following interests of the Investigator (and those of the Investigator's spouse/partner and dependent children) that reasonably appear to be related to the Investigator's responsibilities on the PHS funded project.

- (i) **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 for the investigator, investigator's spouse and dependent children, 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;
- (ii) **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
- (iii) **With regard to intellectual property rights and interests (e.g., patents, copyrights)**, a significant financial interest exists upon receipt of income of greater than \$5,000 related to such rights and interests.
- (iv) **Third party reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse/dependent children) of greater than \$5,000 and reasonably appears related to the Investigators project responsibilities must be disclosed.
- (v) **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). Excludes travel paid for by the Company or affiliated companies and does not apply to travel that is reimbursed or sponsored by an U.S. federal, state, or local government agency, or an U.S. Institution of higher education.

**A Significant Financial Interest does not include**

- (i) Salary, royalties, or other remuneration paid by the Company or affiliates to the Investigator while employed or otherwise appointed by the Company. This includes any assigned intellectual property rights and agreements to share in royalties related to such rights.
- (ii) Any ownership interest in the Company held by the investigator.
- (iii) Income from investment vehicles, such as mutual funds and retirement accounts, where the Investigator does not directly control the investment decisions.
- (iv) Income from seminars, lectures, or teaching engagements sponsored by an U.S. federal, state, or local government agency, an Institution of higher education or similar.

- (v) Income from service on advisory committees or review panels for an U.S. federal, state, or local government agency or an Institution of higher education.

## APPENDIX B: FCOI public disclosure requirements

**The Company will provide within 5 days a response to a written request for information on any SFI that meets the following conditions:**

- (i) The Significant Financial Interest was disclosed and is still held by the PD/PI or any other person identified as senior/ key personnel by the Company in the award (or subaward) application for PHS funding or listed in a progress report, AND
- (ii) The Company has determined that the Significant Financial Interest is related to conduct of the research funded.

Information made available will include, at a minimum, the following:

- (i) The Investigator's name;
- (ii) The Investigator's title and role with respect to the research project;
- (iii) The name of the entity in which the Significant Financial Interest is held;
- (iv) The nature of the Significant Financial Interest; and
- (v) The approximate dollar value of the Significant Financial Interest in the following ranges: \$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:
- (vi) 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 list may also be used for internal disclosures per Section 2.2)

### **APPENDIX C: Retrospective review requirements and documentation**

**Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:**

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Company to constitute a Financial Conflict of Interest;
- Failure by the Company to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

**the Company shall, within 120 days of the Company's determination of noncompliance, complete a "Retrospective Review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.**

**The Company shall document the Retrospective Review which must include at least the following key elements:**

- A. Project number;
- B. Project title;
- C. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- D. Name of the Investigator with the FCOI;
- E. Name of the entity with which the Investigator has a financial conflict of interest
- F. Reason(s) for the retrospective review;
- G. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- H. Findings of the review; and
- I. Conclusions of the review.