Financial Conflict of Interest (FCOI)

LumiThera, Inc. is dedicated to maintaining public trust in the integrity of our research-related activities. The identification and responsible management of financial conflicts of interest (FCOI) are crucial both for safeguarding research objectivity and for compliance with federal regulations and LumiThera policies.

LumiThera seeks to ensure the integrity of its research and to comply with the federal Public Health Service's (PHS) requirements for institutions that seek research funding. The PHS has implemented regulations (Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought) ("FCOI Regulations") to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest. The FCOI Regulations are applicable to institutions that apply for or receive PHS1 grants or cooperative agreements for research and to each investigator (as defined below) planning to participate in or participating in such research. This policy (the "FCOI Policy") is implemented to fulfill LumiThera's obligation under the FCOI Regulations to maintain an up-to-date, written, enforced policy and process on investigator conflicts of interest.

The Signing Official is the person responsible for the procedures under this FCOI Policy but may designate one or more individuals to assist in any or all of these responsibilities and/or may delegate any or all of these responsibilities to one or more individuals.

A. Researchers Covered and Financial Interests That Must Be Disclosed

All "investigators" planning to or participating in PHS-funded "research" are required to disclose to LumiThera, Inc. his/her known "significant financial interests" (and those of his/her spouse and dependent children) that reasonably appear to be related to the investigator's "institutional responsibilities."

The term "investigator" means the project director or principal investigator 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 or consultants.

The term "research" means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement.

The term "institutional responsibilities" means an investigator's professional responsibilities on behalf of LumiThera, including research, research consultation, clinical or other professional practice, participation in scholarly events, institutional committee memberships;

and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

The term "significant financial interest" means a financial interest – defined as anything of monetary value, whether or not readily ascertainable – consisting 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 - 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 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.

2) Privately Held Entities - 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 and dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

3) Intellectual Property - Intellectual property rights and interests (e.g., patents, copyrights), must be disclosed upon receipt of income (e.g., royalties) related to such rights and interests. The filing of any patent application also should be disclosed.

4) Travel Expenses - 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 in the twelve months preceding the disclosure if the value of such travel, when aggregated from all sources, exceeds $5,000; 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. Disclosures relating to travel expenses must specify, at a minimum, the purpose and duration of the trip, the identity of the sponsor/organizer, and the destination.

Not included are the following types of financial interests: salary, royalties, or other remuneration paid by LumiThera to the investigator if the investigator is currently employed or otherwise appointed by LumiThera, including intellectual property rights assigned to LumiThera 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; and income from seminars, lectures or teaching engagements sponsored by, and 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.

B. Mandatory Investigator Training Requirements

The Signing Official is responsible for ensuring that each investigator is informed about (i) this FCOI Policy, (ii) the investigator's responsibilities regarding disclosure of significant financial interests relating to the investigator's institutional responsibilities and (iii) the FCOI Regulations.

The Signing Official shall ensure that each investigator completes training regarding items (i)–(iii) including the FCOI training module (link below) prior to engaging in research related to any PHS-funded grant or cooperative agreement at least every four (4) years and immediately under the designated circumstances: (1) LumiThera FCOI policies change in a manner that affects investigator requirements, (2) an investigator is new to LumiThera, or (3) LumiThera finds an investigator noncompliant with LumiThera's FCOI policy.

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

The Signing Official also shall ensure that each investigator completes training immediately when any of the following applies: (1) this FCOI Policy or procedures are revised in any manner that affects the requirements of the investigators or (2) LumiThera finds that an investigator is not in compliance with this FCOI Policy or a management plan.

"Immediately" shall mean the training is provided or made accessible and the investigators participate in the training expeditiously following the event that triggers the training requirement.

C. Disclosure Requirements

Prior to submission to PHS of an application for a research grant, the principal investigator shall identify to the Signing Official (1) all investigators (as defined above) anticipated to be participating in the research, (2) those who are senior/key personnel (as defined below) and (3) those who are subrecipients and the institution(s) employing them.

The term "senior/key personnel" means the project director or principal investigator and any other person identified as senior/key personnel in the grant application, progress report or any other report submitted to the PHS.

Also prior to submission of the application, the Signing Official shall ensure that each investigator submits a listing of his/her known significant financial interests (as described above) and those of his/her spouse and dependent children that reasonably appear to be related to the investigator's institutional responsibilities, if any. In accordance with Section H, the Signing Official shall ensure that subrecipient investigators either comply with this FCOI Policy or that their institution(s) provides assurances to enable LumiThera to fulfill the requirements of this FCOI Policy. In either case, the Signing Official shall ensure that the

proper documentation as required under the FCOI Regulations is executed, also in accordance with Section H. Disclosure forms will be made available by LumiThera General Counsel.

All disclosures for each investigator must be updated annually during the period of the award or within 30 days of discovering or acquiring (e.g., through purchase, marriage, inheritance, or expansion of responsibilities) a new significant financial interest. The Signing Official shall ensure that annual update forms are sent to and promptly returned by each investigator. (One annual disclosure is sufficient to cover all ongoing PHS awards. Disclosures shall be provided by an investigator at any other time upon request.

D. Review of Disclosures and Monitoring and Reporting FCOI

The Signing Official shall be responsible for reviewing all forms disclosing a significant financial interest, making the requisite determinations, and taking any subsequent action.

Prior to the expenditure of funds or, with respect to an ongoing PHS-funded project, within 60 days of the disclosure or discovery of a significant financial interest, the Signing Official shall:

1) review all disclosure forms and determine whether (a) an investigator's significant financial interest is related to PHS-funded research and (b) if so related, whether the significant financial interest is a financial conflict of interest (FCOI); and

2) in the case of an FCOI, develop and implement a management plan specifying actions that have been and shall be taken to manage the FCOI; and

3) submit initial and ongoing FCOI reports to the PHS Awarding Component as required under the FCOI Regulations [§50.605(b)(3), (4)].

An investigator's significant financial interest is related to PHS-funded research when the Signing Official reasonably determines that the significant financial interest could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. In determining whether an investigator's significant financial interest is related to PHS-funded research the Signing Official will consider all relevant factors and information, including but not limited to whether there is an ongoing relationship between the investigator and the payer.

A financial conflict of interest (FCOI) exists when the Signing Official reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. In determining whether there is an FCOI, the Signing Official will consider all relevant factors and information, including but not limited to the nature of the research, the magnitude of the financial interest and degree to which it is related to the research, the extent to which the interest could be directly and substantially impacted by the research, and the degree of risk to the human subjects, if any, that is inherent in the research protocol.

Prior to making the decision whether an FCOI exists, the Signing Official may impose interim measures, may ask the investigator to submit additional information and may meet or communicate with the investigator. The investigator may be encouraged to suggest procedures, protocols, or other measures designed to manage the FCOI.

"Manage" means taking action to address an FCOI, 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.

Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

1) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

2) For research involving human subjects, disclosure of financial conflicts to research participants;

3) Monitoring of the research by independent reviewers;

4) Modification of the research plan;

5) Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;

6) Reduction or elimination of the financial interest; and/or

7) Severance of relationships that create such conflicts.

For all management plans, the Signing Official shall (1) monitor ongoing investigator compliance and (2) submit annual updates to the PHS Awarding Component at the time and in the manner specified by the PHS Awarding Component, both until the completion of the PHS-funded research project to which the FCOI relates.

With respect to FCOI related to research sponsored by NIH, annual FCOI reports will be submitted through the eRA Commons FCOI Module for the duration of the project period (including extensions with or without funds) at the same time annual progress reports are required to be submitted and at the time of extension (if any).

If the FCOI is identified and eliminated prior to the expenditure of any PHS-awarded funds, no FCOI report need be submitted.

E. Noncompliance and Remedies

If an investigator has failed to comply with a management plan or, for whatever reason, an FCOI is one that was not identified, reviewed or managed in a timely manner, the Signing Official shall (in addition to the steps required in Section D above), within 120 days of the determination of noncompliance, conduct a retrospective review of the investigator's activities and the research project to determine whether any PHS-funded research or portion

thereof conducted during the period of noncompliance was biased in design, conduct or reporting. The review shall be documented consistent with the FCOI Regulations [§60.605(a)(3)(ii)(B)]. If bias is found during the course of the review, the Signing Official will promptly notify the PHS Awarding Component (which may take its own action and/or require further action by LumiThera and/or the investigator, as it deems appropriate) and submit a mitigation report consistent with the FCOI Regulations [§60.605(a)(3)(iii)]. If appropriate, the Signing Official will update the previously submitted FCOI report. In any event, the Signing Official shall submit FCOI reports annually thereafter.

For clinical research projects supported by the PHS, if the Department of Health and Human Services 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 was designed, conducted, or reported by an investigator with an FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the investigator shall disclose the FCOI in each public presentation of the results of the research (such as articles, manuscripts and oral presentations) and LumiThera shall request an addendum to previously published presentations.

F. Maintenance of Records

The Signing Official shall maintain all disclosure forms and related records of determinations made and actions taken for a period of three years from the date of submission of the final expenditures report to the PHS (or, where applicable, from other dates specified in 45 CFR 74.53(b)).

G. Enforcement Mechanism and Sanctions

All researchers to whom this FCOI Policy applies are expected to fully and promptly comply. The Signing Official may impose sanctions for noncompliance which may include, but is not limited to, the following:

1) Failure to make timely, full or accurate disclosures;

2) Failure to provide information requested;

3) Failure to update a disclosure form as necessary; or

4) Failure to comply with a management plan.

For LumiThera employees, sanctions may include suspension or dismissal, denial of eligibility to engage in the research at issue or other appropriate penalties. Such sanctions may require giving notice of relevant information to funding agencies, professional bodies or journals, or the public. The Signing Official will determine what sanctions, if any, are to be applied.

H. Public Accessibility Requirements

This FCOI Policy will be posted on LumiThera's publicly accessible website, as required by the FCOI Regulations.

Prior to expending any funds under a PHS-funded grant or cooperative agreement, LumiThera shall ensure public accessibility to information concerning an FCOI held by a senior/key personnel member by providing a written response to any written request, such response to be postmarked or dated (if replying by electronic means) within five (5) business days of the receipt of the written request. Such information shall consist of that required to be provided under the FCOI Regulations [§50.605(a)(5)(ii), (iii)], shall be updated at least annually and within 60 days of the receipt or identification of information concerning an additional significant financial interest, and shall remain available for three years from the date the information was most recently updated.

I. Additional Information

LumiThera may be asked to provide records related to this FCOI Policy, including disclosure forms, to the Department of Health and Human Services or other federal agencies or entities. LumiThera will provide the requested information and make any other disclosures necessary to comply with this FCOI Policy or as required by law. Such records may be requested and provided whether or not the disclosure resulted in a determination that an FCOI existed.