

FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

EFFECTIVE: MARCH 31ST, 2021

PURPOSE

This policy implements financial conflicts of interest (FCOI) disclosure requirements applicable to research funded by the U.S. Public Health Service (PHS). The requirements are set forth in 42 CFR Part 50 and 45 CFR Part 94 and are hereinafter referred to as the "PHS FCOI Regulations." As a condition for receiving PHS funding, these regulations require Lucira Health, Inc ("Company") to maintain an appropriate written policy on FCOI disclosure. These requirements are applicable to all research projects for which Company submits a proposal to or receives research funding from PHS. Each Investigator (defined below) who is planning to participate in, or is participating in such research, must follow this process. In addition, subcontractors/consultants who perform services within the definition of an Investigator must maintain a policy that complies with the aforementioned PHS FCOI Regulations or comply with this Policy.

This policy has been developed to address and comply with the specific federal agency requirements as defined in the PHS FCOI Regulations, which were developed to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring the design, conduct and reporting of research funded under PHS contracts, grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

SUMMARY OF PROCESS

The Principal Investigator of a research project will identify all Investigators who are subject to this policy and require each Investigator to disclose Significant Financial Interests (SFI) (as defined below) on the Significant Financial Interest Disclosure Form (Exhibit 1). Investigators must submit the form to the Chief Executive Officer (CEO) for review (1) 10 days prior to the due date of a proposal to a PHS agency for research funding or human subject research approval in which the Investigator will participate; (2) if the Investigator is new to participating in a PHS funded research project, 10 days prior to beginning work on the project; (3) within 30 days of discovering or acquiring a new SFI during the course of the research, or (4) at least on an annual basis on the anniversary date of the previous disclosure. Regardless of whether a SFI exists, all Investigators and key personnel are required to submit a SFI Disclosure Form annually.

The Significant Financial Disclosure Form and supporting materials are forwarded to the Chief Executive Officer (CEO) for review to determine whether any SFIs rise to the level of FCOIs. The Director of People Operations & Finance will be responsible for evaluating and instituting a plan for managing any FCOIs, for producing institutional reports and other required reports to external sponsors and governmental agencies, and for the general administration and enforcement of this policy.

Advance approval by the CEO is required prior to engaging in government-sponsored research. An SFI and FCOI review must be completed before any expenses are incurred under an award.

TRAINING

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes FCOIs. This course is required for anyone involved with a PHS funded project, which includes all Investigators, consultants and employees of Lucira Health, Inc. engaged in PHS-funded research or its compliance.

The course is accessible at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. Upon completion of the training, a certificate of completion must be turned into the CEO. You should retain a copy for your records. This training is required prior to engaging in research relating to any PHS- funded grant or as deemed necessary by the Company due to changes in the FCOI policy, non-compliance of the Investigator/Key Personnel or if the Investigator is new to the Company. At a minimum, the FCOI training shall be taken every

three (3) years.

KEY DEFINITIONS

The following definitions are provided as a reference and are considered key definitions in understanding the PHS FCOI Regulations. A complete list of official definitions can be found at 42 CFR 50.603.

Investigator – means the project director (PD) or principal investigator (PI) 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, which may include, for example, collaborators or consultants. For purposes of this definition, an individual is “responsible” for the design, conduct or reporting of research if he or she has been assigned to oversee or perform a task that could have a significant effect on the design, conduct or reporting of the research.

Institutional responsibilities – means an Investigator's professional responsibilities on behalf of the Company, and as defined by the Company, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Financial interest – means anything of monetary value, whether or not the value is readily ascertainable.

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

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.

Senior/Key Personnel – means the PD/PI and any other person identified as senior/key personnel by the Company in the funding application, progress report, or any other report submitted to the PHS awarding component by the Institution under the regulation.

Significant Financial Interest (SFI) – means as defined below.

(1) 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 reasonably appears to be related to the Investigator's institutional responsibilities:

- (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, exceeds \$5,000
- (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) Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

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) and 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) 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, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by

excluded sources provided in regulation. For example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by the Company directly (i.e. the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Company relating to the trip, such as purpose of the trip, identify of the payer/sponsor, destination and duration. The Company is required to determine if additional information is required (e.g. monetary value) and whether the travel constitutes a significant financial interest.

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

(i) salary, royalties, or other remuneration paid by the Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company; (ii) intellectual property rights assigned to the Company and agreements to share in royalties related to such rights; (iii) any ownership interest in the Company held by the Investigator; (iv) 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; (v) 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, or a research institute that is affiliated with an Institution of higher education; or (vi) income from service on advisory committees or review panels for a federal, state or local government agency, 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.

PROCEDURES

A. Identification of Persons Required to Disclose a Significant Financial Interest - It shall be the responsibility of the Principal Investigator of a research project to identify all Investigators who have a SFI requiring disclosure under this policy and to ensure that Investigators prepare and submit a SFI Disclosure Form to the CEO: (1) 10 days prior to the due date of a proposal to a PHS agency for research funding or human subject research approval in which the Investigator will participate; (2) if the Investigator is new to participating in a PHS funded research project, 10 days prior to beginning work on the project; (3) within 30 days of discovering or acquiring a new SFI during the course of the research, or (4) at least on an annual basis on the anniversary date of the previous disclosure.

B. Submission and Review of Significant Financial Interest Disclosure Form - Every Investigator having a SFI requiring disclosure under this policy shall prepare a fully-completed SFI Disclosure Form that shall be submitted to the CEO. An initial review of the SFI Disclosure Form will be conducted by the CEO to determine whether any SFIs relate to the PHS funded research and, if so related, whether a FCOI exists. An Investigator's SFI is related to PHS-funded research when the CEO reasonably determines that the SFI could be affected by the PHS funded research or is in an entity whose financial interest could be affected by the research. If it is determined that there is a FCOI, then steps will be taken to determine what measures are needed to address the FCOI. The CEO may require one or more of the following actions (but not limited to) to be taken as part of a management plan in order to manage, reduce or eliminate any actual or potential conflict of interest:

- Public disclosure of FCOI;
- Review of research protocols by independent reviewers;
- Monitoring of research by independent reviewers capable of taking measures to protect the design, conduct and reporting of the research against bias resulting from the FCOI;;
- Modification of research plan;
- Disqualification from participation in all or a portion of the research funded by the PHS;
- Divestiture of significant financial interests;

- Severance of relationships that create actual or potential FCOIs

All management plans are required to be signed by the Investigator and the Chief Executive Officer. Compliance of the management plan shall be monitored by the Director of People Operations & Finance.

C. Annual Reporting and After-Acquired Significant Financial Interests – All Investigators shall provide annual SFI Disclosure reports or more frequently if required by the management plan. Any Investigator who acquires a new or increased SFI shall promptly submit a new SFI Disclosure Form within 30 days of discovering or acquiring the new SFI. It is the Principal Investigator’s responsibility to ensure that any newly acquired Investigator on a research project submits the required SFI report to the CEO 10 days prior to starting work on the project.

D. Violations of Conflict of Interest Policy – Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the CEO shall make decision regarding the impositions of sanctions or disciplinary proceedings against the violating individual.

In addition, the Company shall follow the PHS FCOI Regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved.

E. Record Keeping – Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential FCOIs, shall be retained by the Director of People Operations & Finance for three (3) years from the date the final expenditure report is submitted to the PHS awarding component, or as required by 45 CFR 74.53(b) and 92.42(b) for different situations.

F. Sub-recipient Requirements – Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the PHS FCOI Regulations and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. If a FCOI is identified by the sub-award recipient, they are required to notify the CEO of the existence of the conflicting interest within 30 days of the identification of the FCOI and submit with this report a mitigation plan for Company’s review and approval. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with the PHS FCOI Regulations.

G. Federal Reporting – The Director of People Operations & Finance is responsible for the reporting disposition of matters involving disclosures of FCOIs in accordance with applicable federal requirements. The following reports are required:

i. Initial report – prior to the Company’s expenditure of any funds under a PHS-funded research project, the Company must provide to the PHS awarding component an FCOI report regarding any Investigator SFI found by the Company to be a financial conflict of interest in accordance with the regulation. Any FCOI report required under this policy will include sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI and to assess the appropriateness of Company’s management plan. The FCOI report will include the following minimum information:

- Project number;
- 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;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- 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 readily be determined through reference to public prices or other reasonable measures of fair market value;

- A description of how the SFI relates to the PHS funded research and the basis for Company's determination that the financial interest conflicts with such research; and
- A description of the key elements of Company's management plan including the following minimum information:
 - Role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan;
 - Explanation of how the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan; and
 - Explanation of how the management plans will be monitored to ensure Investigator compliance.

In situations in which Company identifies a FCOI and eliminates it prior to the expenditure of PHS awarded funds, Company is not required to submit a FCOI report to the PHS awarding component.

ii. During on-going PHS-funded research projects – the Company shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, the Company shall submit a FCOI report to the PHS awarding component within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.

iii. Retrospective review report- Whenever a FCOI is not identified, disclosed or managed in a timely manner or an Investigator fails to comply with a FCOI management plan, Company has additional review and reporting obligations. If in these situations Company determines that a SFI constitutes a FCOI, Company's CEO will, within 120 days of Company's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS funded research project to determine whether any PHS funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. Company is required to document the retrospective review. Documentation 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
- Conclusions of the review.

As necessary, based on the results of the retrospective review, Company will update any FCOI report previously submitted to the government, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Company will notify the PHS awarding component promptly and submit a mitigation report to the PHS awarding component. Minimally, the mitigation report must include the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and Company'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 and plan to disclose FCOIs in public presentations or addenda to previous publications). Thereafter, Company will submit FCOI reports annually. Depending on the nature of the FCOI, Company may determine that additional interim measures are necessary with regard to 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 Company's retrospective review.

iv. Annual FCOI report – For any FCOI previously reported to the PHS awarding component, the Company shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

H. Public Accessibility- As required by the PHS FCOI regulations, this policy is publicly available on our website at

www.lucirahealth.com.

Prior to Company's expenditure of any funds under a PHS funded research project, Company must ensure the public accessibility, via written response to any requestor within five business days of receipt, of information concerning any SFI disclosed to Company that is (a) held by Senior/Key Personnel performing services for the project, (b) related to the PHS funded research, and (c) determined by Company to be a FCOI. The FCOI information that shall be provided in response to such requests is set forth below:

- 1) Investigator's name;
- 2) Investigator's title and role with respect to the research project;
- 3) Name of the entity in which the SFI is held;
- 4) Nature of the SFI; and
- 5) Approximate dollar 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 references to public prices or other reasonable measures of fair market value.

Written responses to requests shall include a note that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Company's identification of a new financial conflict of interest, which should be requested subsequently by the requestor. Information provided in response to such requests shall remain available for at least three years from the date that the information was most recently updated.

The CEO will consult with the Company counsel concerning responses to requests for such information.

ERIK ENGELSON, CEO

DATE

Approved by:

Erik T. Engelson

March 31st, 2021
