

Financial Conflicts of Interest Policy

1. Purpose

This Policy, “Financial Conflicts of Interest (“FCOI”) Policy,” documents the requirements found in Health and Human Services (“HHS”) regulation, 42 CFR Part 50, Subpart F, “Promoting Objectivity in Research.” This regulation was 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 funded research (which includes National Institutes of Health (“NIH”) grants or cooperative agreements) will be free from bias resulting from Investigator financial conflicts of interest.

The NIH requires recipient institutions and their investigators to fully comply with all FCOI requirements, except for Phase I SBIR/STTR applicants and recipients. Subcontractors and consultants who perform services within the definition of an Investigator must either maintain a policy that complies with the requirements of 42 CFR Part 50, Subpart F or comply with this Policy.

2. Key Definitions

The following key definitions are provided as a reference for the purpose of understanding this Policy. A complete list of official definitions which apply to this Policy can be found at 42 CFR 50.603.

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.

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

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding. For purposes of this Policy, the Institution is defined as Kovina Therapeutics, Inc. (“Kovina”).

Institutional responsibilities means the Investigator's professional responsibilities performed on behalf of Kovina, and as defined by Kovina in this Policy, which may include for example: 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.

Investigator means the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of NIH-funded research, or proposed for such funding, and which may include, for example, subcontractors, collaborators or consultants.

PD/PI means the project director or principal Investigator of a NIH-funded research project

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.

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). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory

authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award

Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel by Kovina in the grant application, progress report, or any other report submitted to the NIH.

Significant financial interest (“SFI”) means:

(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 SFI exists if the value of any remuneration received from the entity in the 12 (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) and equity interest (e.g. stock, stock option, or other ownership interest)

(ii) With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 (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, upon receipt of income related to such rights and interests.

(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, however, this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation.

(3) The term SFI does not include the following types of financial interests:

- Income from seminars, lectures, teaching, service on advisory or review panels for US government agencies, US institutions of higher education, US academic teaching hospitals, US medical centers, or US research institutes affiliated with an institution of higher learning;
- 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; or
- Salary/Income from, or equity interest, in Kovina, if the Investigator is employed by Kovina

3. Training Requirements

Each Investigator must complete FCOI Policy training prior to engaging in PHS-funded research. Online training is provided using the NIH Office of Extramural Research FCOI online tutorial, located at: [FCOI Training Online Tutorial](#). The certificate of completion must be submitted to Kovina as evidence of the training.

Refresher training on this Policy will be required every three years. Additional training requirements will be required under the following circumstances:

- Kovina revises its FCOI policy in a manner that affects the Investigator;

- When an Investigator is new to Kovina; or
- When the Kovina finds an Investigator is not in compliance with the Kovina's policy or management plan.

4. Disclosure, Review and Monitoring Requirements

Each Investigator participating in PHS funded Research is required to disclose to Kovina any SFIs, including any SFI of their spouse or dependent children, prior to submission of an application for PHS funded Research. In addition, each Investigator is required to submit an updated disclosure of SFIs (including any SFI of their spouse or dependent children): (1) at least annually; and (2) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

If an Investigator does not have any SFIs to report, the Investigator must still complete the required disclosure form both initially and annually. Kovina's designated official(s) will review all disclosure forms and evaluate whether they contain any FCOI within 60 (sixty) days. If no FCOI is found, the disclosure forms will be maintained in accordance with the record retention section.

A FCOI exists when Kovina reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research. If a FCOI is identified, Kovina's designated official will develop and implement a management plan that include the appropriate steps to manage, reduce, or eliminate the conflict. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- Public disclosure of FCOIs (e.g., when presenting or publishing the research);
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- 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
- Severance of relationships that create financial conflicts.

The Investigator shall agree, in writing, to abide by the terms of the management plan. Kovina's designated official shall monitor compliance with the management plan until completion of the project.

5. Reporting Requirements

Initial FCOI Report: Prior to expenditure of any funds under a NIH-funded research project, Kovina shall provide to the contact designated in the relevant contract or grant document an FCOI Report identifying any FCOI relating to the NIH-funded research.

Subsequent FCOI Reports: For any SFI that is identified as a FCOI after Kovina's initial report, Kovina will provide to the NIH an updated FCOI report, regarding the FCOI within sixty (60) days of identification of the FCOI.

Annual FCOI report: For any FCOI previously reported to the NIH, Kovina shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

The contents of a FCOI Report shall include the following (at the minimum):

- Grant or Contract number;
- PD/PI or contact PD/PI;

- Name of Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of FCOI (e.g., equity, consulting fees, travel reimbursement);
- The value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20k-\$100k by increments of \$20k; amounts above \$100k by increments of \$50k), or a statement that the interest is one whose value cannot be readily determined;
- A description how the financial interest relates to NIH-funded research and the basis for Kovina's determination that the financial interest conflicts with such research; and
- Key elements of the Institution's management plan.

6. Record Retention

All FCOI-related records generated under this Policy will be retained for at least three years beyond the date of the final expenditure report submitted to the NIH or, where applicable, from other dates specified in 45 CFR 75.361, where applicable.

7. Enforcement, Remedies and Noncompliance

If an Investigator is found not to have disclosed a SFI, either as part of their initial disclosure or subsequently, the matter shall be referred to the CEO, who shall consider the nature of the failure to disclose to determine an appropriate sanction or administrative actions.

In the situation where a FCOI was not identified or managed in a timely manner, including failure by the Investigator to disclose a SFI that is determined by Kovina to constitute an FCOI; failure by Kovina to review or manage such an FCOI; or failure by the Investigator to comply with an FCOI management plan:

- a) Within 120 days of the determination of noncompliance, the CEO and/or CEO's designees shall 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.
- b) The retrospective review shall be documented in a record including at a minimum the following elements:
 - Project number and title;
 - PD/PI or contact PD/PI;
 - Name of the Investigator with the FCOI;
 - Name of the entity with which the Investigator has an FCOI;
 - Reason(s) for the retrospective review;
 - Detailed methodology used for the retrospective review;
 - Findings of the review; and
 - Conclusions of the review.
- c) Based on the results of the retrospective review, if appropriate, the CEO shall update the previously submitted FCOI Report, specifying the actions that will be taken to manage the FCOI going forward
- d) If the failure of an Investigator to comply with this Policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS funded Research, Kovina shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken by Kovina.

8. Subcontractors and Consultants

Subcontractors and consultants who perform services within the definition of an Investigator must maintain a policy that complies with the above-mentioned regulatory requirements or comply with this Policy. Kovina shall incorporate as part of a written agreement with the subcontractor or consultant terms that establish whether Kovina's FCOI policy or that of the subcontractor's or consultant's policy will apply to subrecipient Investigators. In addition, the written agreement will establish the appropriate time periods to allow Kovina to meet disclosure and/or FCOI reporting requirements.

9. Public Accessibility

Kovina will make the following information publicly available:

- Kovina's FCOI policy
- Information concerning identified FCOIs held by senior/key personnel (as defined by federal regulations) participating in PHS/NIH-funded research, publicly available prior to the expenditure of funds. The publicly accessible information will:
 - Include the minimum elements as provided in the regulation.
 - Be posted on Kovina's website or made available within five (5) business days of a written request.
 - Be updated, at least annually and/or within sixty (60) days of a newly identified FCOI.
 - Remain available for three (3) years from the date the information was most recently updated.