Kovina Therapeutics Inc.
Financial Conflicts of Interest Policy

1. Purpose

This Policy promotes objectivity in Public Health Service (PHS)-funded research, including National Institutes of Health (NIH) grants and cooperative agreements, by identifying and managing Investigator financial conflicts of interest. It implements 42 CFR Part 50, Subpart F.

This Policy applies to Investigators planning to participate in or participating in PHS-funded research, except Phase I SBIR/STTR applications and awards. Requirements for subcontractors and consultants are addressed below.

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 Kovina Therapeutics Inc. ("Kovina").

Institutional responsibilities mean an Investigator's professional responsibilities on behalf of Kovina, including research, research consultation, development, regulatory, administrative, and management responsibilities.

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 (HHS), 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 basic and applied research and product development. This Policy covers research supported or proposed for support through PHS grants or cooperative agreements.

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: These include domestic and foreign interests.

(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, honoraria, paid authorship) and equity interest includes stock, stock options, or other ownership interests valued using public prices or other reasonable measures of fair market value.

(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, when related income from an entity exceeds $5,000 in the preceding twelve months.

(2) Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, including that of their spouse and dependent children, when its value from an entity exceeds $5,000 in the preceding twelve months. Initial disclosure must cover the preceding twelve months; reportable travel must be disclosed within thirty (30) days of occurrence, including when the threshold is first exceeded. Disclose the trip purpose, sponsor/organizer, destination, and duration. Kovina may request additional information, including value, as needed. Travel paid by U.S. federal, state, or local government agencies, U.S. institutions of higher education, U.S. academic teaching hospitals, U.S. medical centers, or U.S. research institutes affiliated with an institution of higher education is excluded. These exclusions do not apply to foreign sources.

(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 U.S. federal, state, or local 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, royalties, or other remuneration paid by Kovina to an Investigator currently employed or otherwise appointed by Kovina, including intellectual property assigned to Kovina and agreements to share related royalties; or any ownership interest in Kovina held by the Investigator.

3. Training Requirements

Each Investigator must complete the NIH FCOI Training Online Tutorial and review this Policy and their disclosure responsibilities before engaging in PHS-funded research. The completion certificate and acknowledgment of policy review must be submitted to Kovina.

Refresher training is required at least every four years and immediately when:

- Kovina revises this Policy or related procedures in a way that affects Investigator requirements;
- An Investigator is new to Kovina; or
- Kovina finds an Investigator is not complying with this Policy or a management plan.

4. Disclosure, Review and Monitoring Requirements

Each Investigator must disclose domestic and foreign SFIs related to their institutional responsibilities, including those of their spouse and dependent children: (1) no later than submission of a PHS funding application, or before joining an ongoing project; (2) at least every twelve months during the award, updating previously disclosed interests and adding omitted information; and (3) within thirty (30) days of discovering or acquiring a new SFI. Disclosures are required initially and annually even when there are no SFIs.

The CEO will designate an official to collect and review disclosures and administer this Policy. An impartial alternate will handle matters involving that official's own interests. Before PHS funds are spent, all disclosures must be reviewed and any necessary management plan implemented. During an ongoing project, new or previously unreviewed SFIs must be reviewed and any necessary interim management plan implemented within sixty (60) days of disclosure or identification.

The designated official will determine whether an SFI could be affected by the research or is in an entity whose financial interests could be affected by the research. An FCOI exists if the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. If an FCOI is identified, the official will implement a written management plan. Possible conditions include:

- Public disclosure of the FCOI in presentations or publications and, for human subjects research, disclosure to participants;
- 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: Before NIH funds are spent, Kovina will report identified FCOIs through the eRA Commons FCOI Module and implement management plans. No initial report is required if the FCOI is eliminated before funds are spent. An authorized official will submit all NIH FCOI reports, including required reports for subrecipient Investigators.

Subsequent FCOI Reports: During an ongoing project, Kovina will report newly identified FCOIs within sixty (60) days of identification and ensure a management plan is implemented.

Annual FCOI Report: For previously reported FCOIs, Kovina will report their status, any management plan changes, or why an FCOI no longer exists. Reports are due with the applicable annual or multi-year

progress report or at an extension, as required by NIH, throughout the project period, including funded and no-cost extensions.

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

- Grant 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 the financial interest (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 of 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, including the Investigator's role and duties, conditions imposed, safeguards for objectivity, confirmation of the Investigator's agreement, and how compliance will be monitored.

6. Record Retention

Kovina will retain all FCOI-related disclosures, reviews, determinations, and actions, whether or not an FCOI is found, for at least three years from submission of the final expenditure report to NIH, or for the applicable period under 2 CFR 200.334 and award terms. Kovina will promptly provide these records to NIH/HHS upon request.

7. Enforcement, Remedies and Noncompliance

Noncompliance with this Policy or a management plan will be referred to the CEO, or an impartial alternate if the CEO is involved, for appropriate sanctions or administrative action.

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 determining that an FCOI was not identified or managed timely, Kovina will complete a retrospective review to determine whether research conducted during the noncompliance was biased in its design, conduct, or reporting.
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) After the retrospective review, Kovina will update any previously submitted FCOI report as appropriate to reflect new information and the actions taken or planned to manage the FCOI.
d) Kovina will promptly notify NIH of corrective actions if noncompliance appears to have biased the research. If a retrospective review finds bias, Kovina will promptly notify NIH and submit a mitigation report containing all retrospective review elements listed above, the impact of the bias, and actions taken or planned to eliminate or mitigate its effects. If HHS determines that PHS-funded clinical research evaluating the safety or effectiveness of a drug, device, or treatment involved an unmanaged or unreported FCOI, Kovina will require the Investigator to disclose it in each public presentation of the results and request addenda to previously published presentations.

8. Subcontractors and Consultants

For subrecipient Investigators, a written agreement will identify which institution's FCOI policy applies. If the subrecipient's policy applies, it must certify regulatory compliance and report identified FCOIs to Kovina. Otherwise, its Investigators must follow this Policy and disclose SFIs directly related to their work for Kovina. The agreement will set disclosure and reporting deadlines that allow Kovina to meet its review, management, and NIH reporting obligations. Kovina will ensure applicable Investigator training and management plan monitoring. These requirements apply to subcontractors and consultants who meet the Investigator definition.

9. Public Accessibility

Kovina will make the following information publicly available:

- Kovina's current FCOI policy will be posted on its public website and submitted through the eRA Commons Institution Profile. Both copies will be updated when the Policy changes.
- Before funds are spent, required information about FCOIs still held by senior/key personnel and related to the PHS-funded research will be available as follows:
    - Include the Investigator's name, title and project role; the entity's name; the nature of the interest; and its approximate value using the ranges above, or a statement that its value cannot be readily determined.
    - Be provided within five (5) business days of a written request.
    - Responses will contain current information and state the response date, that information is subject to updates at least annually and within sixty (60) days of a new FCOI, and that updated information may be requested.
    - Remain available for three (3) years from the date the information was most recently updated.

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