EIP Pharma, Inc: Financial Conflict of Interest Policy

I. Purpose and Scope

This policy document outlines the commitment of EIP Pharma, Inc ("EIP") to objectivity in research, and internal processes designed to ensure that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOIs).

EIP's FCOI policy ("this Policy") provides a framework to comply with requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research" for which PHS Funding is Sought" (FCOI Regulation), of the Federal Register pertaining to PHS-funded research.

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This Policy describes types of FCOIs, restrictions on significant financial interests (SFIs) for EIP employees, identifies when disclosure should be provided, and explains EIP's administration and enforcement procedures. This Policy is applicable to Investigators, as defined below, who participate in EIP's PHS-funded research. Participation includes having an active role in the development of protocols, the conduct of clinical trials, as well as the reporting of study results.

II. Definitions

Disclosure of significant financial interests: An Investigator's disclosure of significant financial interests to an Institution.

Designated Official(s): Individual(s) responsible for the implementation of the FCOI Policy, designated by EIP.

Equity Interest: Any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

Financial Conflict of Interest (FCOI) A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report: An Institution's report of a financial conflict of interest to a PHS Awarding Component.

Immediate Family: Investigator/senior/key personnel's spouse or domestic partner and dependent children.

Investigator: The project director or principal Investigator or 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. Investigators include, but are not limited to, Senior/Key personnel.

Institution: Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding. EIP is considered “the Institution” for the purposes of this Policy.

Institutional responsibilities: An Investigator's professional responsibilities on behalf of EIP, and as defined by EIP in its FCOI 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.

Manage: Take 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.

PHS: 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: The organizational unit of the PHS that funds the research that is subject to the regulation.

The FCOI Regulation or Regulation: 42 CFR Part 50 Subpart F, Promoting Objectivity in Research, applying to grants and cooperative agreements.

Remuneration:
Salary and any payment for services, including consulting fees, honoraria, and paid authorship.

Research: 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 Policy, 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, except that it does not include Phase I grants under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

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Senior/Key Personnel: The PD/PI and any other person identified as senior/key personnel by EIP in the grant application, progress report, or any other report submitted to the PHS by EIP under the Regulation. Such individuals among those considered Investigators under this Policy.

Significant Financial Interest (SFI):
(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, an SFI 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.

(ii) With regard to any non-publicly traded entity, an SFI 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.

(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 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. EIP's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with EIP's FCOI policy, the designated official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term SFI does not include the following types of financial interests: salary, royalties, or other remuneration paid by EIP to the Investigator if the Investigator is currently employed or otherwise appointed by EIP, including intellectual property rights assigned to EIP and agreements to share in royalties related to such rights; any ownership interest in EIP held by the Investigator, as EIP is a for-profit organization; 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; 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 income from 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.

III. Policy and Management

An FCOI related to EIP's PHS-funded research may occur when an Investigator has an SFI that compromises, or appears to compromise, that individual's independence and

objectivity in the discharge of his/her institutional responsibilities in the design, conduct, or reporting of EIP's research. Investigators should avoid conflicts and the potential for conflicts resulting from financial arrangements with third parties that could have a special interest in the outcome of EIP's research. Additionally, all employees of EIP are restricted from having any such financial arrangements with third parties, for example with a contract research organization (CRO) engaged to manage EIP's research.

When EIP's PHS-funded research is conducted through a subrecipient (e.g., subcontractors or consortium members), Investigators may be required to comply with either EIP's FCOI policy or that of the subrecipient, under conditions further described in Section V. Subrecipients.

Disclosure: Investigators are required to disclose SFIs (and those of the Investigators' immediate families). During the award period of PHS funding, this disclosure will be made at least annually [to include any information that was not disclosed initially to EIP or updated information regarding any previously disclosed SFI] and within 30 days of discovering or acquiring a new SFI (such as through purchase, marriage or inheritance).

EIP will name "Designated Official(s)" to manage the FCOI policy. The designated official(s) will take action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

If it is determined that an FCOI exists, EIP's Designated Official(s) will recommend a suitable management plan to eliminate or manage the FCOI consistent with the objectives of this Policy.

The management plan shall provide for its periodic review and updating at least annually. If there is no reasonable way to manage an FCOI, the Investigator may be prohibited from participating in the related Research until such a time as the FCOI is eliminated. For EIP employees, the usual course would be to eliminate the FCOI. For example, stock ownership in a CRO that could potentially be engaged or has been engaged to conduct EIP research would need be sold.

For all Investigators, examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

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

(ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

(iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;

(iv) Modification of the research plan;

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

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

(vii) Severance of relationships that create financial conflicts.

EIP shall review the proposed management plan and can approve or modify. Final review and determination must be completed prior to the expenditure of any PHS funds for the applicable Research.

A FCOI should be managed, reduced, or eliminated within sixty (60) days of its identification by EIP's Designated Official(s). EIP's Designated Official(s) shall be responsible for monitoring and enforcing any management plan.

This shall also apply when, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses an SFI or an existing Investigator discloses a new SFI to EIP.

While salary or other renumeration by EIP and ownership interest in EIP is not considered an SFI by this Policy or by the FCOI Regulation, Investigators employed or otherwise appointed by EIP must disclose such renumeration/ownership interest when publicly presenting or publishing results of EIP's research.

Enforcement: If an Investigator fails to comply with EIP's FCOI policy, within 120 days of discovery by EIP, EIP shall complete a retrospective review of the Investigator's activities to determine potential bias.

If a bias is found, EIP shall submit a mitigation report to the PHS Awarding Component, in accordance with the Regulation, that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias.

EIP will work with the Investigator to implement an FCOI management plan to address the situation.

EIP will mandate that Investigators disclose the FCOI in each public presentation of research results. In extreme cases of bias, an Investigator may be removed from their institutional responsibilities.

IV. Training, Reporting, and Records Management

Training: All persons subject to the EIP FCOI policy will be required to train on the policy by reading and affirming their understanding of, and intent to comply with the FCOI policy at times specified below.

EIP's Investigators may demonstrate understanding of FCOI by using the NIH web-based training which can be accessed online.

Unless otherwise covered by a third-party FCOI Policy as agreed upon with EIP (Section V. Subrecipients), each Investigator is required to complete training on EIP's FCOI

Policy by reading and affirming the policy or demonstrating training on the NIH web-based training on the following occasions:

- Prior to engaging in research related to EIP's PHS-funded grant,
- At least every 4 years, and
- Immediately if:
  1. EIP revises the FCOI Policy in a manner that affects requirements of Investigators,
  2. An Investigator is new to EIP's PHS-funded research, or
  3. An Investigator is not in compliance with EIP's FCOI Policy or management plan.

Reporting: As required by the Regulation, EIP shall file a report with PHS Awarding Component providing information on every identified FCOI and the manner in which the FCOI is being or has been managed, reduced, or eliminated. Reports shall include the elements required by the Regulation. EIP will notify NIH promptly if bias is found with the design, conduct, or reporting of PHS-funded research, and file a mitigation report in accordance with the Regulation.

EIP will send initial, annual (*i.e.* ongoing) and revised FCOI reports, to the PHS Awarding Component, as required by the Regulation and as follows:

- Prior to expenditure of PHS funds
- Within sixty (60) days of identification for an Investigator new to the PHS-funded project
- Wthin sixty (60) days for new or newly identified FCOIs for existing Investigators
- At least annually, with report to provide status of the FCOI and any changes to the management plan, until completion of the PHS-funded project.

In addition, EIP will notify the PHS Awarding Component of any bias or noncompliance by an Investigator as described in Section III, Enforcement.

Records Management: The records of all financial disclosures and all actions taken by EIP will be maintained for at least three (3) years from the date of submission of the final expenditures report for a PHS-funded award.

V. Subrecipients

If EIP carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), EIP will take reasonable steps to ensure that any subrecipient Investigator complies with the Regulation by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether EIP's FCOI policy or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with the Regulation. If the subrecipient cannot provide such certification, the

agreement shall state that subrecipient Investigators are subject to EIP's FCOI policy for disclosing SFIs that are directly related to the subrecipient's work for EIP;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified FCOIs to EIP. Such time period(s) shall be sufficient to enable EIP to provide timely FCOI reports, as necessary, to the PHS as required by the Regulation;

(iii) Alternatively, if the subrecipient's Investigators must comply with EIP's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to EIP. Such time period(s) shall be sufficient to enable EIP to comply timely with its review, management, and reporting obligations under the Regulation.

(2) Providing FCOI reports to the PHS Awarding Component regarding all FCOIs of all subrecipient Investigators consistent with the Regulation, *i.e.,* prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

VI. Public Accessibility

EIP's FCOI Policy shall be posted on the public portion of the EIP website. In addition, upon receipt of a written request for information concerning identified FCOIs by Senior/Key Personnel (as defined in this Policy and the Regulation), EIP will make that information available within five (5) business days of the request. The information shall include all elements required by the Regulation, updated through the date of the response.