Epigen Biosciences, Inc.

Conflict of Interest Policy for Investigators and Subrecipients on Public Health Service (Including NIH) Grants, Contracts, and Cooperative Agreements

Objective research is of paramount importance to Epigen and our subrecipients, to ensure public trust and meet scientific, program and ethical goals of our Department of Health and Human Services (DHHS), National Institutes Health (NIH) grant efforts. To address the increasing complexities related to financial interests held by biomedical researchers, the Public Health Services (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) has published their final rule (Part IV, Department of Health and Human Services, 42 CFR Part 50, 45 CFR Part 94, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors; Final Rule. https://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf). The following are key-term definitions and Epigen's policy guidance for principal or program investigators, collaborators, subrecipients, contractors, fee-for-service providers and/or consultants affiliated with Epigen. This policy is also available on the Epigen website (www.epigenbiosciences.com):

I. **Purpose.** This Policy has been established as of December 22, 2020 to comply with the requirements of 42 CFR Part 50 Subpart F federal regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors, commonly known as the Financial Conflict of Interest regulations (the "Regulations"). Epigen shall update this Policy periodically as needed to comply with changes in the Regulations.

II. **Applicability.** Except for Phase I SBIR and Phase I STTR grants ("Exempted Research"), this Policy applies to all Investigators and Subrecipients who participate in research funded by grants, contracts, and cooperative agreements with the Public Health Service (PHS), including the National Institutes of Health (NIH), and other research funded by a government contract that incorporates the Regulations in its terms (collectively, "Covered Research"). The term "Investigator" means an employee, consultant, collaborator, or agent of Epigen who, regardless of title or position, is responsible for the design, conduct, or reporting of research proposed for funding, or actually funded, under Covered Research. The term "senior/key personnel" means individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are

requested. The term "Subrecipient" means a grant subrecipient, subcontractor, or other person or entity who has responsibility for the design, conduct, or reporting of research proposed for funding, or actually funded, under Epigen Covered Research. Unless special circumstances apply, vendors of supplies and equipment to Epigen and vendors who provide routine testing services to Epigen without any significant knowledge of the Covered Research are not Subrecipients.

III. **Administration.** The Board of Directors of Epigen shall designate an employee of Epigen who is not an Investigator to administer this Policy. Such employee shall be referred to in this Policy as the "Administrator" and shall fulfill all obligations that are assigned to the Institutional Official under the Regulations.

IV. **Existence of Financial Conflict of Interest.** A financial interest exists if the Investigator or his or her spouse or dependent children:

(1) receives from an entity remuneration greater than $5,000 in the aggregate in the 12 months preceding the disclosure of such interest, including without limitation salary, consulting fees, and honoraria;

(2) holds equity with a value greater than $5,000 in a publicly traded company, including without limitation stock, options, and other forms of ownership;

(3) holds any equity interest (e.g., stock, stock option, or other ownership interest) in a private company;

(4) receives income related to intellectual property rights and interests (e.g., patents, copyrights). Royalties from and agreements to share in royalties related to intellectual property rights paid to an Investigator (or his/her spouse or dependent children) are covered by the regulation and are subject to the $5,000 threshold, or

(5) receives travel that is sponsored or reimbursed by an entity other than Epigen or the government or academic entity or affiliate to a threshold of $5,000;

(6) BUT EXCLUDING:

(i) salary, royalties, or other remuneration paid by Epigen;

(ii) any ownership interest in Epigen;

(iii) 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

(iv) income from government or academic sources for seminars, lectures, teaching, and service on review panels or advisory committees.

A financial interest becomes a "Significant Financial Interest" if the financial interest reasonably appears to be related to the responsibilities of the Investigator to Epigen. A Financial Conflict of Interest ("FCOI") is a Significant Financial Interest that the Administrator reasonably determines:

(i) is related to the Covered Research, i.e., could be affected by the Covered Research or is in an entity whose financial interest could be affected by the Covered Research and

(ii) could directly and significantly affect the design, conduct, or reporting of Covered Research.

(iii) the Investigator is required to disclose all financial interests received from a foreign Institution of higher education or the government of another country. The regulation refers to exclusions of Institutions of higher education as defined in 20 U.S.C. 1001(a) (Institution and Investigator).

V. **Reports.** All Investigators must submit to the Administrator a report that discloses all Significant Financial Interests in Covered Research:

(1) when planning to participate in the Covered Research, not later than the submission of the application for the Covered Research,

(2) annually if participating in Covered Research, on or about June 30, and

(3) as soon as possible, but not later than 30 days, after discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

The Administrator shall review each report promptly after submission by the Investigator and shall inform the Investigator if a FCOI exists. If the Investigator eliminates the FCOI (which is not always possible or desirable) and revises and resubmits the report to the Administrator, then no further action is needed. However, if the FCOI continues, then the Administrator shall take the actions described below in this Policy.

VI. **Conflict Management and Disclosure.** If a FCOI exists, then the Administrator shall take the following actions prior to any expenditure of funds under the Covered Research to which the FCOI relates or, if the Covered Research is in progress and the FCOI is newly disclosed, then not later than 60 days after the FCOI is disclosed:

1) Develop, implement, and administer a management plan that specifies the actions that have been taken, and shall be taken, to manage the FCOI during the

period of the Covered Research. The Regulations provide the following non-limiting examples of conditions or restrictions that might be imposed by the Administrator to manage a FCOI:

i. public disclosure of the FCOI (e.g., when presenting or publishing the research);

ii. for research projects involving human subjects research, disclosure of the FCOI 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 FCOI;

iv. modification of the research plan; or

v. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.

2) Provide to the appropriate PHS agency a report regarding the FCOI. The report shall include sufficient information to enable the PHS agency to understand the nature and extent of the financial conflict, and to assess the appropriateness of the management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

i. project number;
ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
iii. name of the Investigator with the FCOI;
iv. name of the entity with which the Investigator has a FCOI;
v. nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
vi. value of the financial interest (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 reference to to public prices or other reasonable measures of fair market;
vii. a description of how the financial interest relates to the Covered Research and the basis for Epigen's determination that the financial interest conflicts with such research; and
viii. a description of the key elements of Epigen's management plan, including: (A) role and principal duties of the conflicted Investigator in the Covered Research; (B) conditions of the management plan; (C) how the management plan is designed to safeguard objectivity in the Covered Research; (D) confirmation of the Investigator's agreement to the

management plan; (E) how the management plan will be monitored to ensure Investigator compliance; and (F) other information as needed.

In addition, for any FCOI previously reported by Epigen with regard to ongoing Covered Research, Epigen shall provide to the appropriate PHS agency an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the Covered Research. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Epigen shall provide annual FCOI reports to the appropriate PHS agency for the duration of the Covered Research (including extensions with or without funds) in the time and manner specified by the PHS agency.

VII. **Training Requirement.** Epigen shall inform each Investigator of this Policy, the Investigator's responsibilities regarding disclosure of Significant Financial Interests, and of the Regulations, and shall require each Investigator to complete training regarding this Policy prior to engaging in Covered Research and thereafter at least every four years, and immediately when any of the following circumstances apply:

1) Epigen revises this Policy or any procedures in a manner that affects the requirements of Investigators;
2) an Investigator is new to Epigen; or
3) Epigen finds that an Investigator is not in compliance with this Policy or a management plan instituted by the Administrator.

Information and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site (http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm).

VIII. **Procedures for Subrecipients.** If Epigen conducts Covered Research through a subrecipient (e.g., subcontractors), Epigen must take reasonable steps to ensure that any subrecipient Investigator complies with this Policy and the Regulations by incorporating as part of a written agreement with the subrecipient terms that establish:

1) that this Policy will apply to Investigators of the subrecipient,

2) time periods for the subrecipient to submit disclosures of Significant Financial Interests, which time periods shall allow sufficient time for Epigen to comply with its requirements under this Policy,

3) that the subrecipient will accept any determination by the Administrator that a FCOI exists and shall enforce on its Investigators any management plan established by the Administrator. Alternatively, at the discretion of the Administrator, Epigen may accept the FCOI policy of a subrecipient, provided that such policy complies with the Regulations, and that Epigen and the

subrecipient enter into a written agreement in which the subrecipient provides written certification that the policy complies with the Regulations, the subrecipient agrees to the other requirements set forth above, and the subrecipient agrees to any other terms and conditions required by the Administrator to ensure that Epigen complies with the Regulations.

IX. **Noncompliance.** If Epigen discovers that an Investigator has failed to disclose a Significant Conflict of Interest within the timelines set forth in this Policy, or if an Investigator fails to comply with a management plan established under this Policy, then Epigen shall, within 120 days of the Institution's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research. The Institution shall document the retrospective review which must include at least the following key elements:

1) Project number;
2) Project title;
3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
4) Name of the Investigator with the FCOI;
5) Name of the entity with which the Investigator has a financial conflict of interest
6) Reason(s) for the retrospective review;
7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
8) Findings of the review; and
9) Conclusions of the review.

X. **Enforcement.** Any violation of this Policy by an Investigator may result in disciplinary action by Epigen, up to and including termination of employment.

XI. **Public Disclosure and Records.** Epigen shall publicly disclose this Policy on its website, as required by the Regulations. Under the regulation, the Institution is required to keep all records of all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest), and all actions under the Institution's policy or retrospective review, if applicable, as follows:

1) Records of financial disclosures and any resulting action must be maintained by the Institution for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations.

Such records shall be available for audit by the PHS as set forth in the Regulations. If a FCOI exists, then the Administrator shall take the following actions prior to any expenditure of funds under the Covered Research to which the FCOI relates or, if the Covered Research is in progress and the FCOI is newly disclosed, then not later than 60 days after the FCOI is disclosed:

i. FCOIs of senior/key personnel publicly accessible on website or within 5 business days upon request;