PGXL Financial Conflict of Interest Policy

I. Purpose

PGxl Laboratories (herein referred to as "the Laboratory") receives funds from the National Institutes of Health (NIH) and other Public Health Service (PHS) agencies. All investigators (as defined below) applying for funds from the NIH or other PHS agencies are obliged to comply with the requirements of the Laboratory's Financial Conflict of Interest Policy (FCOI).

Specifically, all United States Public Health Service agencies (includes National Institutes of Health, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Food and Drug Administration and the Agency for Healthcare Research and Quality) require awardee institutions to ensure objectivity in research through compliance with its comprehensive regulations, "Promoting Objectivity in Research", 42 CFR Part 50, Subpart F (the "FCOI Regulations") and "Responsible Prospective Contractors", 45 CFR Part 94. For purposes of this FCOI Policy, all references to "PHS" shall be a reference to the respective PHS funding agency.

The FCOI Regulations covering PHS funded activities provide for a more comprehensive level of disclosure, together with compulsory reporting to the applicable PHS agency. Disclosure to the Laboratory is required of ALL "Significant Financial Interests" that reasonably appear related to the Investigator(s) "Institutional Responsibilities."

> "Institutional Responsibilities" means an Investigator's professional responsibilities on behalf of the Laboratory, and as defined by the Laboratory, including, but not limited to, activities such as research, research consultation, teaching, clinical or other professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
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> "Investigator(s)" means the Project Director or Principal Investigator (PD/PI) and 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, consultants, postdocs, and paid or unpaid collaborators.

II. Guidance for Implementation

The Laboratory is responsible for ensuring that each Investigator is informed about (i) the FCOI Regulations; (ii) the Laboratory's FCOI Policy; and (iii) the Investigator's responsibilities regarding disclosure of significant financial interests. The Laboratory requires each Investigator to complete training regarding items (i) – (iii) prior to engaging in research related to any PHS-funded grant, cooperative agreement or contract and at least every four (4) years thereafter, and immediately when any of the following applies: (1) this FCOI Policy or Laboratory procedures are revised in any manner that affects the requirements of the investigators; or, (2) an Investigator is new to the Laboratory; or, (3) the Laboratory finds that an Investigator is not in compliance with this FCOI Policy.

The Laboratory has defined a Compliance Officer to monitor implementation.

III. Disclosure Procedures

a. All investigators are required to disclose financial interests at the time any PHS application is submitted. The lead principal Investigator on a proposed PHS application for funding is responsible for obtaining a disclosure forms for all participating investigators.

b. The Investigator shall list all significant financial interests (including those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.

"Significant Financial Interest" is defined as anything of monetary value, including but not limited to:

salary or other payments for services (e.g., consulting fees or honoraria);

equity interests (e.g., stocks, stock options or other ownership interests);

intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

(1) Salary, royalties, or other remuneration from the Laboratory;

(2) Any ownership interests in the Laboratory, if the Laboratory is an applicant under the SBIR Program;

(3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

(4) Income from service on advisory committees or review panels for public or nonprofit entities;

(5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests:

(a) Does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and

(b) does not represent more than a five percent ownership interest in any single entity; or

(6) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed $10,000.

c. In addition, the Investigator must cooperate with all requests from the applicable PHS Awarding Component for additional information as needed. All such internal disclosures shall be treated as confidential personal information with all necessary precautions to protect any sensitive proprietary company or sponsor information.

d. The Investigator shall update the disclosure of significant financial interest during the period of the award, either on an annual basis or as new Significant Financial Interests are obtained (1) that would reasonably appear to be affected by the PHS-funded research; and (2) in entities whose financial interests would reasonably appear to be affected by the research. New Significant Financial Interests require the Investigator to submit an updated disclosure statement within thirty (30) calendar days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) the new Significant Financial Interest. One annual disclosure will suffice to cover all

on-going PHS awards. These disclosure requirements must be completed prior to expending any funds under a PHS funded grant, cooperative agreement or contract.

e. Transfers and new hires are required to disclose financial interests and complete the training specified herein within thirty (30) calendar days of assignment to a PHS-funded research project.

IV. Management of Financial Conflicts of Interests

a. A Compliance Officer shall be assigned to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

The following are examples of when an Investigator would be deemed to have a financial conflict of interest: (i) if the Investigator (together with Investigator's spouse or dependent children) has a significant financial interest in an entity that could be affected by the research results from a proposed PHS-funded contract based on an analysis of the scope and subject matter of the proposed project described in the application, or (ii) the Investigator (together with Investigator's spouse and dependent children) has a significant financial interest in an entity that licenses technology from the Laboratory which has resulted in license income and that technology is the subject of a proposed PHS-funded award. In making this determination, the designated institutional official(s) may consult with all appropriate institutional and governmental officials.

b. If the Compliance Officer determines that a conflict exist, the Compliance Officer may develop a Management Plan to manage the conflict of interest. The Management Plan may impose any or all of the following restrictions: (1) public disclosure of significant financial interests; (2) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest; (3) modification of the research plan; (4) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (5) reduction or elimination of the financial interest (e.g., sale of an equity interest); or (6) severance of relationships that create financial conflicts; (7) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants is required.

c. The Laboratory will be responsible for monitoring Investigator compliance with the Management Plan on an on-going basis until the completion of the PHS-funded research project.

V. Reporting Financial Conflicts of Interests to PHS

a. The Laboratory must file an annual report that conforms to the requirements of the FCOI Regulations for the duration of the research project in the time and manner specified by the applicable funding agency.

b. Prior to expending any funds under an PHS-funded grant or contract, the Laboratory must report to the applicable PHS funding agency the existence of any FCOI (but not the nature of the interest or other details) found by the Laboratory and ensure that the conflicting interest has been managed, reduced, or eliminated.

c. For any significant financial interest that the Laboratory identifies as being a FCOI subsequent to the Laboratory's initial FCOI report under the award, the report will be made to the applicable

funding agency and a management plan shall be implemented, at least on an interim basis, within sixty (60) days of that identification. Such a disclosure could include a new significant financial interest received by the Investigator during the on-going research project, or a significant financial interest held by an Investigator who is new to the research project. However, if that FCOI is one that was not timely made to the applicable funding agency, for whatever reason, the Laboratory is required under the FCOI Regulations to conduct a retrospective review of the Investigator's activities and the research project. If bias is found during the course of this review, a mitigation report is required to be submitted. These reviews and reports must be made in accordance with the requirements of the FCOI Regulations.

d. The elements of such a report shall include, at least, the items enumerated under the FCOI

VI. Subrecipient Compliance and Reporting

a. All proposed subrecipients under a PHS-funded research of the Laboratory shall have a financial conflicts of interest policy that conforms to the requirements of the FCOI Regulations. With respect to these subgrantees, subcontractors, and collaborators, the Laboratory requires these entities to enter into a written agreement and make a certification to the Laboratory at the time of award that its financial conflicts of interest policy complies with the FCOI Regulations. The written agreement shall include all of the terms required under the FCOI Regulations.

b. The Laboratory will report to the PHS funding agency any FCOI which are identified by any subgrantee, subcontractor, or collaborator to the Laboratory in the manner required under the FCOI Regulations, prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

VII. Remedies

a. If an Investigator fails to comply with this FCOI Policy or a management plan and the non-compliance appears to have biased the design, conduct or reporting of the PHS- funded research, the Laboratory, as required under the FCOI Regulations, shall promptly notify the agency of the corrective action taken or to be taken. In every respect, the Laboratory shall ensure compliance with the requirements for retrospective review and prepare a mitigation report, if needed, for submission to the applicable funding agency as required under the FCOI Regulations. The funding agency may take its own action as it deems appropriate, which may include suspension of funding, or require the Laboratory to take further action to maintain the objectivity of the research.

b. For clinical research projects supported by the PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with a FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the Laboratory requires the Investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts and oral presentations, including classroom materials) of the results of the research and to request an addendum to previously published presentations.

VIII. Enforcement and Sanctions

a. All persons subject to this FCOI Policy and other applicable Laboratory policies are expected to comply fully and promptly. Whenever an Investigator has violated the Laboratory's FCOI Policy, for example, by a failure to disclose a significant financial interest, the Laboratory may refer the matter to the appropriate Laboratory official or committee for disciplinary action or other appropriate action.

b. Violations of the Laboratory's FCOI Policy and the FCOI Regulations that constitute falsification in proposing, performing, reporting or reviewing research shall be handled in accordance with the respective Laboratory policy and procedures governing allegations of research misconduct.

IX. Records

The Laboratory is required pursuant to the FCOI Regulations to maintain records of all financial disclosures and all actions taken by the Laboratory with respect to each FCOI as follows: (1) in the case of grants or cooperative agreements, for at least three (3) years from the date of submission of the final expenditures report, or where applicable, from other dates specified in 45 CFR 74.53(b) for different situations; (2) in the case of research contracts, for three years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7.