Pure Green Pharmaceuticals, Inc.
Financial Conflict of Interest Policy

PURPOSE

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest (FCOI) to safeguard the integrity of NIH-related research conducted by **Pure Green Pharmaceuticals, Inc**. (Company) and to comply with federal regulations.

This policy has been developed to address and comply with the specific federal agency requirements as defined in the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F). These Regulations were developed to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring the design, conduct and reporting of research funded under certain National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

While our collaborations may be governed by the FCOI policies and processes of our collaborative research institutions, the purpose of this policy is to ensure when there is no institutional FCOI to rely upon, Company research will still be in compliance with the Regulations. Our research agreements with subawardees and/or subrecipients will establish if they will follow the Company's FCOI policy or that of their institution of employment.

The Company will certify, in each application for funding subject to the Regulations, that the Company (i) has an up-to-date, in-effect, written and enforced administrative process to identify and manage FCOI; (ii) promotes and enforces compliance with the Regulations by the individual investigator(s) ("Investigator(s)"); (iii) manages FCOI and provides initial and ongoing FCOI reports; (iv) agrees to make FCOI and Significant Financial Interests (SFI) information (including related Institutional reviews and determinations) available to HHS, promptly, upon request; and (v) fully complies with the Regulations.

This policy provides guidance to help personnel manage situations in their personal affairs, employment outside the Company, and financial activities that may appear to conflict with their responsibilities and to ensure the Company and its employees comply with applicable federal laws when participating in research funded by the Public Health Service (PHS). This policy applies to any Company member acting as an Investigator or as a Senior/Key personnel on any PHS research project and any Sub-recipient of that project. The Company's personnel will promptly disclose the circumstances of any situation that might be covered by this policy.

An electronic version of the Regulations is found at http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf.

SUMMARY OF PROCESS

Significant Financial Interests (SFI; as defined below) shall be disclosed on the Significant Financial Interest Disclosure Form (SFIDF) by an Investigator requesting government-

sponsored or company-sponsored funds for a research project or by an Investigator when an SFI arises during the course of research. Regardless of whether an SFI exists, all Investigators and key personnel are required to submit an SFI Disclosure Form annually.

It is the Principal Investigator's responsibility to ensure those with financial interests in research are identified and make the required disclosures in conjunction with the submission of a research proposal or application for human subjects' approval.

The Significant Financial Disclosure Form and supporting materials are forwarded to the Company's Chief Financial Officer (CFO) or designated authorized organization representative/administrator for review. The CFO/Financial Administrator or Finance Department, in consultation with the Company's CEO, will be responsible for evaluating and instituting a plan for managing any disclosed financial interests, for producing institutional reports and other required reports to external sponsors and governmental agencies, and for the general administration and enforcement of this policy.

Advance approval by the CFO or Financial Administrator is required prior to engaging in government-sponsored research. An SFI review must be completed before any expenses are incurred under an award. The CEO will provide approval as the signatory of the research agreement, simple agreement, or engagement contract, or provides written approval for the CFO/Financial Administrator (an AOR) or Company signatory to sign in their stead. Annual updates are required of all Investigators and key personnel participating in research. Any Investigator who has acquired a new or increased financial interest during the course of a research project shall report it immediately to the CFO/Financial Administrator. Annual updates and newly acquired interests are reported using the Significant Financial Interest Disclosure Form. This process is meant to inform each Investigator of the (i) Institutional policy, (ii) Investigator's disclosure responsibilities, and (iii) Regulations (42 CFR 50.604(b)).

TRAINING

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes financial conflict of interest. This course is required for anyone involved with an NIH funded project, which includes all Investigators, consultants and employees of Pure Green Pharmaceuticals engaged in NIH-funded research or its compliance.

The course is accessible at http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm. Upon completion of the training, a certificate of completion must be turned in to the CFO/Financial Administrator. The Company and respective Investigator will retain a copy for their records. This training is required (i) prior to engaging in research relating to any NIH-funded grant or as deemed necessary by the Company due to changes in the FCOI policy, (ii) immediately upon a) the Company revising its FCOI policy or management plan (42 CFR 50.604(b)) that affects requirements of Investigators, b) non-compliance of the Investigator/Key Personnel or c) new to the Company, and (iii) tol be taken every three (3) years, at a minimum.

KEY DEFINITIONS

The following definitions are provided as a reference and are considered key definitions in understanding the federal regulations of FCOI. A complete list of official definitions can be found at 42 CFR 50.603.

Institution – means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS/HHS research funding..

Investigator – means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS/HHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Institutional responsibilities – means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, including but not limited to, 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.

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

Financial conflict of interest (FCOI) – means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS/HHS-funded research.

FCOI Report – means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

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). 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.

Manage – means taking 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.

Senior/Key Personnel – means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS/HHS by the Institution under the regulation.

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 United States Department of Health and Human Services (HHS) and the National Institutes of Health (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 significant financial interest 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. 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, a significant financial interest 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) Upon receipt of income related to intellectual property rights and interests (e.g., patents, copyrights)

(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 excluded sources provided in the regulation. For example, if a PI/Key Personnel travels to a scientific seminar but does not pay or receive reimbursement from the Company directly (i.e., the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Company relating to the trip, such as purpose of the trip, identify of the payer/sponsor, destination and duration. In accordance with the Company's FCOI policy, company official(s) will determine if additional information is needed, including a determination or disclosure of monetary value, and whether the travel constitutes an FCOI with the PHS/HHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests:

(i) salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;

(ii) intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;

(iii) any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;

(iv) 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;

(v) 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

(vi) income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education as defied 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.

PROCEDURES

The Company CFO/Financial Administrator or other Designated Official or his/her designee shall be responsible for the following:

A. Identification of Persons Required to Disclose a Significant Financial Interest - It shall be the responsibility of the Principal Investigator and the CFO/Financial Administrator of a Research project to identify all Investigators who have an SFI requiring disclosure under this policy and to ensure that an SFI Disclosure Form (SFIDF) is prepared and submitted. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed. To assist PIs with this responsibility, the CRO/Financial Administrator will send out reporting reminders, SFIDF forms, and receive completed SFIDFs, and send for review. Reporting will occur yearly and just prior to application submissions. PIs are responsible for reporting SFIs that occur between these reporting timelines.

This process is established to require each Investigator to disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigators institutional responsibilities that meets or exceeds the regulatory definition of SFI (42 CFR 50.03): (i) no later than at the time of application for PHS-funded research; (ii) at least annually during the period of award; and (iii) within 30 days of discovering or acquiring a new SFI (42 CFR 50.604(e)(1)-(3)).

B. Submission and Review of Significant Financial Interest Disclosure Form (SFIDF) - Every individual having an SFI requiring disclosure under this policy shall prepare a fully-completed SFIDF that shall be submitted to the CFO/Financial Administrator. An initial review of the SFIDF will be conducted by the CFO/Financial Administrator using a Review of Conflicts Form (RCF) to determine whether a potential for conflict of interest exists. The RCF analyzes the focus, contractual involvements, and research goals of the research project against the SFIDF provided by the researcher(s). If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to address the SFI identified in the SFIDF. A management plan may be required to outline the terms, conditions, and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:

- Public disclosure of significant financial interests;
- Review of research protocols by independent reviewers;
- Monitoring of research by independent reviewers;
- Modification of research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divesture of significant financial interests;
- Severance of relationships that create actual or potential conflicts

All management plans are required to be signed by the Investigator and the Chief Financial Officer/Financial Administrator (in consultation with the Company's CEO). Compliance of the management plan shall be monitored by the Company's Finance Department. The CFO/Financial Adminstrator solicits and review disclosures of SFIs of the Investigator(s) (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities (4s CFR 50.604(d)). This process provides adequate guidelines

consistent with the Regulations for the designated Institutional officials to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI , and if so, implement management plans, as needed to manage FCOIs (4s CFR 50.605(a)(1)).

This process reviews the disclosures for SFIs and relevance to PHS-funded research (4s CFR 50.604(f)), makes determinations of FCOIs, and implements a management plan within sixty days whenever an Institution identifies an SFI that was not disclosed timely by an Investigator, not previously reviewed by the Institution (42 CFR 50.605(a)(3) and (i)-(iii)), or for an existing Investigator who discloses a new SFI (42 CFR 50.605(a)(2)). This process identifies and implements actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project (42 CFR 50.604(g) and 42 CFR 50.605(a)(4)).

C. Annual Reporting and After-Acquired Significant Financial Interests – All Investigators shall provide annual SFI Disclosure Form reports or more frequently if required by the management plan. Any Investigator who acquires a new or increased SFI shall promptly submit a new SFIDF within 30 days of discovering or acquiring the new SFI. It is the Principal Investigator's responsibility to ensure that any newly acquired Investigator on a research project submits the required SFI report to the CFO/Financial Administrator.

The CFO/Finance Administrator must report to PHS/HHS/NIH any FCOIs within 10 days of notification of new SFIs identified by the PI on either notification report, or annual report, and immediately upon review and determination of any bias found with the design, conduct, or reporting of NIH-funded research and to include the requirement to submit a Mitigation Report in accordance with the Regulations. The Mitigation Report includes the following FCOI reporting items:

(i) the name of the Investigator with the FCOI;
(ii) The name of the entity with which the Investigator has an FCOI;
(iii) the nature of the Significant Financial Interest (SFI);
(iv) the value of the financial interest;
(v) the description of how the financial interest relates to the NIH-funded research and why the institution determined that the financial interest conflicts with such research; and the
(vi) description of the key elements of the Company's management plan, including other required information

This process defines the reporting steps to send initial, annual (i.e., ongoing) and revised FCOI reports, including reporting elements required by the Regulations to the NIH for the Institution and its subrecipients, if applicable, as required by the Regulations (42 CFR 50.604(h) and 42 CFR 50.605(b)) (i) prior to the expenditure of funds; (ii) within 60 days of identification for an Investigator who is newly participating gin the project; (iii) within 60 days for new, or newly identified, FCOIs for existing Investigators; (iv) at least annually (at the same time as when the Institution is required to submit the annual progress report, multiyear progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and (vi) following a retrospective review to update a previously submitted report, if appropriate (42 CFR 50.605(a)(3)(iii)).

D. Violations of Conflict of Interest Policy – Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the CFO/Financial Administrator shall make recommendations to the CEO regarding the impositions of sanctions or disciplinary proceedings against the violating individual. The CFO/Financial Administrator and CEO will review together with the employee(s)/Investigator(s) the specific behaviors and consequences that are determined relevant based upon review, and any other administrative actions to assure Investigator compliance, including but not limited to supervised research activities. The CFO/Financial Administrator and CEO must conduct retrospective reviews within 120 days of the Institution determining noncompliance for SFIs not disclosed in a timely manner or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the Regulations.

In addition, the Company shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved. In any case in which the PHS/HHS determines that a funded research project of clinical research whose purpose is to evaluation the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an Investigator with an FCOI that was not compliantly managed or reported, the Investigator involved will be required to:

(i) disclose the FCOI in each public presentation of the results of the research, and
(ii) request an addendum to previously published presentations of the same. Investigator will provide evidence of these disclosures to the Company.

This policy establishes adequate enforcement mechanisms and provides for employee sanctions or other administrative actions to ensure Investigator compliance (42 CFR 50.604(i)).

E. Record Keeping – Records of Investigator SFIDF, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the CFO/Finance Department for three (3) years from the date the final expenditure report is submitted to the PHS (NIH), or as required by 45 CFR 74.53(b) and 92.42(b) for different situations, where applicable (42 CFR 50.604(i)).

F. Sub-recipient Requirements – Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy, *2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F)* and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. Prior to Notice of Award, Company and sub-awards will establish in written agreement which FCOI policy will be followed by which Investigator, and if applicable, certification that the sub-award policy complies with the Regulations, requirement to report identified FCOIs in a timeframe that permits Company to report identified FCOIs to PHS/NIH as required by the Regulations, or that Company will solicit and review sub-recipient Investigator disclosures to enable identification, management and reporting of FCOIs as required by NIH. If an SFI is identified by the sub-award recipient, they are required to notify the Company's CFO/Financial Administrator of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with federal regulations (42 CFR 50.604(c).

G. Federal Reporting – The Finance Department is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the PHS/NIH:

(i) Initial report – prior to the Company's expenditure of any funds under an NIH-funded research project, the Company must provide to the NIH an FCOI report regarding any Investigator SFI found by the Company to be a financial conflict of interest in accordance with the Regulations.

(ii) During on-going NIH-funded research projects – the Company shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If an FCOI was not disclosed timely, the Company shall submit an FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.

(iii) Annual FCOI report – For any FCOI previously reported to the NIH, the Company shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

H. Public Accessibility Requirements – The Company will provide public access to this policy on publicly accessible page of https://pgpharma.co. This policy establishes a process to make available information concerning identified FCOIs held by senior/key personnel (as defined by the Regulations), publicly accessible prior to the expenditure of funds. The CFO/Financial Administrator will ensure that any updated versions of this policy are provided for updated posting immediately upon implementation. In addition, and FCOI determined to exist for any Investigator or Senior Key Personnel will be posted to this same webpage in compliance with the Regulations, including the date of posting and

(i) the minimum elements as provided in the Regulations;

(ii) posting within 5 days of a written request;

(iii) annual updates, unless written requests are made which should continue to be available;

(iv) any updates within 60 days of newly identified FCOI; and

(v) remain available for three years from the date the information was most recently updated.

This policy makes the Institution FCOI policy publicly accessible on the Institution website (42 CFR 50.604(a) and NIH GPS 4.1.10).