

Company Financial Conflict of Interest Policy (FCOI) January 1, 2017 (Version 1.0)

Objective research is of paramount importance to Company (“Company”), our affiliates, our subgrantees, and our vendors, to ensure public trust and meet scientific, program and ethical goals of our National Institutes Health (NIH) grant efforts. To address the increasing complexities related to financial interests held by researchers, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) has published regulations governing researcher’s financial interests as they impact federally funded research. The Company is instituting this Financial Conflict of Interest (FCOI) Policy in accordance with PHS’ and HHS’s regulations. Company shall update this policy as needed, particularly in response to any changes in personnel FCOI issues or upon further government guidance.

Effective January 1, 2017, Company policy requires that each investigator, sub recipient, sub grantee and collaborator affiliated with the Company, by NIH or any other applicable grant or contract, be in compliance with 42 CFR Part 50, Subpart F for grants and cooperative agreements, and 45 CFR Part 94 for contracts. In addition, these regulations reflect NIH’s commitment to preserving the public’s trust that the research NIH supports is conducted without bias and with the highest scientific and ethical standards. The Company will use this FCOI Policy for all other Federal agency grant and contract efforts, as tailored or amended as needed.

The following are key term definitions and Company policy guidance for principal or program investigators, subrecipients, subgrantees and collaborators affiliated with Company

Funded Research

Funded Research is a project governed by PHS regulations including NIH Small Business Innovation Research (SBIR) grants and contracts. Excluded are applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Investigator

An Investigator is any person (including subrecipients, subgrantees and collaborators) who is responsible for the design, conduct or reporting of Funded Research.

Training Requirement

Company investigators and all applicable sub-level vendors are required to complete training related to FCOI. If any conflicts of interest are found or known, they must be disclosed. The training must be updated no-less than every four years or as designated based on grant or role and change in circumstances.

Information and other resources developed by NIH will be updated as appropriate and can be accessed through the [NIH Web site](#).

PHS Awarding Component

The PHS awarding component is any sub-agency of the Public Health Service or Department of Health and Human Services.

Significant Financial Interest (SFI)

Significant Financial Interest is defined by the regulations as:

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. For the 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 in stock, stock options or other ownership interest, as determined through reference to public prices and 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 remunerations 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 interests (e.g. stock, stock options, 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, medical center, or research institute that is affiliated with an Institution of higher education. Investigators must disclose to Company's designated Institutional Official the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institutional Official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the funded

research. Investigators must disclose any additional information requested by the institutional official regarding the travel.

3. The term Significant Financial Interest does not include the following types of financial interests: salaries, royalties or other remuneration paid by the institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights; any ownership interest in Company held by the investigator; income from investment vehicles, such as mutual funds and retirements 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, 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.

A Financial Conflict of Interest exists when the Company reasonably determines that a Significant Financial Interest (defined above) could directly and significantly affect the design, conduct or reporting of Funded Research.

Disclosures/Reporting Process

Each Investigator who is planning to participate in Funded Research must disclose to the Designated Official, all of the Investigator's Significant Financial Interests and those of the Investigator's spouse and dependent children at least 30 days prior to the application for the Funded Research.

Each Investigator who is participating in Funded Research must disclose to the Designated Official no later than December 1st of each year all of the Investigator's Significant Financial Interests and those of the Investigator's spouse and dependent children.

Each Investigator who is participating in Funded Research must disclose to the Designated Official all of the Investigator's new Significant Financial Interests and those of the Investigator's spouse and dependent children within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) the new Significant Financial Interest.

The Designated Official will promptly review all disclosures from Investigators and evaluate whether any Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the Funded Research, which will be designated as FCOIs. If no FCOI is identified the disclosure form will be filed. If an FCOI is identified it will be put on the FCOI report through the eRA Commons FCOI module prior to expending any funds. Company will then report the FCOI to the PHS Awarding Component that has issued the award within 60 days for current funded research, or at the time of application for new Funded Research, as applicable. If Funded Research is conducted by an Investigator with an FCOI that was not

disclosed or managed, Company shall disclose the FCOI in each public presentation related to the results of the research.

Management of a FCOI

The Company will take necessary measures to manage any FCOI in accordance with 42 CFR 50.605 or 45 CFR 94.5, as applicable, 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.

Compliance and Penalties for Non-Performance

If an Investigator fails to comply with Company FCOI policy, within 120 days, the Company shall complete a retrospective review of the Investigator's activities to determine bias. If a bias is found, the Company shall submit a mitigation report to the NIH, in accordance with 42 CFR 50.605(b) (3) or 45 CFR 94.5(b)(3), as applicable. The mitigation report shall address the impact of the bias on the research project and the actions the Company has taken to mitigate the bias. The Company will work with the Investigator to set up an FCOI management plan to mitigate the situation. The Company shall require the Investigator to disclose the FCOI in each public presentation with research results if the FCOI was not reported initially. In cases of extreme bias, the Investigator may lose the right to work on the project or any future federally funded projects.

Records Management

The records of all financial disclosures and all actions taken by Company will be maintained for at least three years from the date of submission of the final expenditures report.

READ AND ACCEPTED:

Name: _____

Signature: _____

Date: _____