Financial Conflicts of Interest Policy

I. INTRODUCTION

A. Purpose

This policy implements U.S. federal requirements pertaining to "Objectivity in Research" promulgated by the Public Health System ("PHS") of the U.S. Department of Health and Human Services ("HHS"), which includes the U.S. National Institutes of Health ("NIH"), the Biomedical Advanced Research and Development Authority ("BARDA"), the Center for Disease Control and Prevention, and the Agency for Healthcare Research and Quality ("FCOI Policy"). Financial Conflict of Interest ("FCOI") requirements, related to PHS Organization-funded research, are published in U.S. regulations 42 CFR Part 50, Subpart F and 45 CFR Part 94.

The intent of this FCOI Policy is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of research performed under grants or contracts with PHS Organizations will be biased by any conflicting financial interest. To apply for funding with PHS Organizations, Promiliad Biopharma must be able to certify, in each application for funding, that the Promiliad Biopharma:

- has in effect, an up-to-date, written and enforced administrative process to identify and manage FCOI
- will promote and enforce Covered Individual compliance with the regulation
- will manage FCOI and provide initial and ongoing FCOI reports
- will make FCOI and significant financial interest information available to the PHS Organization, promptly, upon request; and
- will fully comply with the regulation's requirements.

Promiliad's FCOI process addresses training requirements; disclosure, review, and monitoring requirements; reporting requirements; maintenance of records; enforcement mechanisms and remedies for noncompliance; sub-recipient requirements; and public accessibility requirements.

B. Scope

A Promiliad Biopharma employee or contractor who submits a grant or contract proposal or conducts research under a PHS Organization's funding grants or contracts must adhere to the applicable requirements of the PHS Organization, including those involving the disclosure and regulation of outside activities and financial interests. Specific FCOI laws and regulations are applicable to all project directors and principal investigators, whether employees or contractors, who are responsible for the design, conduct and reporting of research work under grants and contracts with PHS Organizations.

A number of non-PHS organizations have adopted the PHS regulations. These include, but are not limited to, the American Cancer Society, the American Heart Association, and the Juvenile Diabetes Research Foundation. FCOI disclosure process could be implemented on a case-by-case basis for non-PHS, non-profit organizational funded grants requiring similar disclosure, but this Policy does not require it.

II. DEFINITIONS

A. Covered Individual ("CI"): Any Promiliad Biopharma employee or contractor who is responsible for the design, conduct or reporting of a PHS-Funded Research project or proposed for such project, including any project director, principal investigator and any other key personnel designated as such in a PHS-Funded grant application or contract.

B. Covered Individual Responsibilities: A Covered Individual's professional responsibilities performed on behalf of an entity that proposes to undertake or undertakes PHS-Funded Research.

C. 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.

D. Financial Conflict of Interest ("FCOI"): A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.

E. Financial Interest: Any interest of monetary value, whether or not the value is readily ascertainable.

F. Immediate Family: A Covered Individual's spouse or domestic partner and dependent children.

G. Non-Significant Financial Interests ("Non-SFI"): include the following types of Financial Interests:

(i) remuneration paid by an entity to which a CI owes Covered Individual Responsibilities, if the CI is currently employed or otherwise appointed by such entity, including intellectual property rights assigned to such entity and any agreement to share in royalties related to such rights; or

(ii) any ownership interest in an entity held by the CI or income from investment vehicles, such as mutual funds and retirement accounts, as long as the CI does not directly control the investment decisions made in these vehicles; or

(iii) income from seminars, lectures, or teaching engagements sponsored by a US 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

(iv) income from service on advisory committees or review panels for a US 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.

I. PHS: 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, among others, the NIH. A listing of the PHS agencies and their offices may be located on the U.S. Department of Health and Human Services Organizational Chart.

J. PHS-Funded Research: any Research funded by way of a grant from, or a contract with, a PHS Organization.

K. PHS Organization: (i) an agency that is part of the PHS or (ii) an organization that has adopted the PHS Regulations, but not a non-governmental non-profit organization.

L. PHS Regulations: U.S. 42 CFR Part 50, Subpart F and 45 CFR Part 94

M. Remuneration: (i) salary and any payment for services including consulting fees and honoraria; (ii) any Equity Interest; and (iii) travel reimbursement related to the Covered Individual Responsibilities.

N. 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, including basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

O. Significant Financial Interest ("SFI"): A Financial Interest consisting of one or more of the following interests of a Covered Individual (and those of the Covered Individual's Immediate Family) that reasonably appear to be related to Covered Individual Responsibilities, but specifically excludes any Non-SFI:

(i) any Remuneration received from any publicly traded entity in the twelve months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure, when aggregated, exceeds $5,000; or

(ii) any Remuneration received from any non-publicly traded entity in the twelve months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure, when aggregated, exceeds $5,000; or

(iii) intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

III. TRAINING REQUIREMENTS

Promiliad Biopharma must establish a process to inform each Covered Individual of the Promiliad's FCOI Policy, the Covered Individual Responsibilities, and the PHS Regulations. In addition, Promiliad Biopharma must establish a process to require each Covered Individual to

complete FCOI training prior to engaging in PHS-Funded Research, at least every four years, and immediately, if Promiliad Biopharma revises the FCOI Policy that affects requirements of Covered Individuals, a Covered Individual is new to the Promiliad Biopharma or a Covered Individual is not in compliance with the FCOI Policy or of a management plan.

IV. DISCLOSURE, REVIEW AND MONITORING REQUIREMENTS

Promiliad Biopharma must establish a process to require each Covered Individual to disclose SFIs (and those of the Covered Individual's Immediate Family) related to the Covered Individual Responsibilities that meet or exceed the definition of SFI. This disclosure must occur no later than at the time of application for PHS-Funded Research, at least annually during the period of the award, and within 30 days of discovering or acquiring a new SFI.

Promiliad Biopharma must designate individual(s) to solicit and review disclosures of SFIs of the Covered Individual (and those of the Covered Individual's Immediate Family) related to a Covered Individual Responsibilities. Adequate guidelines must be created for the designated individual or committee to determine whether a Covered Individual's SFI is related to PHS-Funded Research and, if so related, whether the SFI is an FCOI.

Promiliad Biopharma must establish a process to require the designated individual or committee, prior to the Promiliad Biopharma expenditure of award funds, to review all Covered Individual SFI disclosures, determine if any SFIs relate to PHS-Funded Research, determine if an FCOI exists (i.e. SFI that could directly and significantly affect the design, conduct, or reporting of the PHS-Funded Research), and develop and implement management action plans, as needed, to manage FCOIs.

Promiliad Biopharma must establish a process to review disclosure of SFIs, make determination of FCOIs, and implement a management plan:

- when required for a Covered Individual who is new to participating in a PHS-Funded Research project or for an existing Covered Individual, who discloses a new SFI

- within sixty days whenever the Promiliad Biopharma identifies an SFI that was not disclosed by a Covered Individual or not previously reviewed by Promiliad Biopharma.

Promiliad Biopharma must also establish a process to take such actions, as necessary, to manage FCOIs, including any financial conflicts of a Subcontractor, if applicable, and monitor Covered Individual compliance with management plans until completion of the PHS-Funded Research project.

V. REPORTING REQUIREMENTS

Promiliad Biopharma must establish a process to send initial, annual (i.e. ongoing) and revised FCOI reports to the PHS Organization including all reporting elements required by the regulation

for the Promiliad Biopharma and its sub-recipients, if applicable, as required by PHS Regulations:

- Prior to expenditure of funds
- Within 60 days of identification of an FCOI for a Covered Individual who is newly participating in the project
- Within 30 days for new, or newly identified, FCOIs, for existing Covered Individuals
- At least annually (at the same time as when the Promiliad Biopharma is required to submit the annual progress report, multi-year progress report, if applicable, or at the 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
- Following a retrospective review to update a previously submitted report, if appropriate.

Whenever Promiliad Biopharma identifies an SFI that was not disclosed, identified, reviewed, or managed in a timely manner (as required by the PHS Regulations and described above), Promiliad Biopharma shall, within 60 days, review and make the determination of whether an FCOI exists, and report the FCOI if it exists, to the PHS Organization. If an FCOI exists, Promiliad Biopharma shall, within 120 days of Promiliad Biopharma's determination of noncompliance, complete a retrospective review of the Covered Individual's activities and PHS-Funded Research to determine whether any of the funded research, or a portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct or reporting of such research. During the time the retrospective review is being conducted, Promiliad Biopharma must implement, on at least an interim basis, a management plan that will specify the actions that have been, and will be, taken to manage the FCOI going forward. Subsequent to the retrospective review, if applicable, Promiliad Biopharma will update the existing FCOI report and if bias is found, Promiliad Biopharma must notify the PHS Organization promptly and submit a mitigation report.

Promiliad Biopharma must establish a policy and procedure to notify the PHS Organization promptly if a Covered Individual's failure to comply with the FCOI Policy or if an FCOI management plan appears to have biased the design, conduct or reporting of the PHS-Funded Research, and, in such an instance, inform the PHS Organization of the corrective action taken or to be taken.

VI. MAINTENANCE OF RECORDS

Promiliad Biopharma must establish a procedure to maintain all FCOI-related records:

- For at least 3 years from the date the final expenditure report is submitted to the PHS Organization.
- From other dates specified in 45 CFR 74.53(b) and 92.42(b) where applicable.

VII. ENFORCEMENT MECHANISM AND REMEDIES FOR NONCOMPLIANCE

Promiliad Biopharma must ensure the existence of adequate enforcement mechanisms and provide for corrective action to ensure Covered Individual compliance.

In any case in which HHS determines that a PHS-Funded Research project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment, has been designed, conducted or reported by a Covered Individual with an FCOI that was not managed or reported by Promiliad Biopharma as required, Promiliad Biopharma shall require the Covered Individual to disclose the FCOI in each public presentation of the results of the research, and request an addendum to previously published presentations and publications.

VIII. THIRD PARTY REQUIREMENTS

Promiliad Biopharma must have a process in place to assure that any contractor or collaborator who carries out PHS-Funded Research with Promiliad Biopharma ("Subcontractor") certifies, via written agreement, that it will follow this FCOI Policy or the Subcontractor's own FCOI policy.

If the Subcontractor certifies that it will comply with this FCOI Policy, the agreement shall specify the time periods for the Subcontractor to report all SFI to Promiliad Biopharma. Such time periods shall be sufficient to enable Promiliad Biopharma to comply with timely review, management and reporting obligations required by this FCOI Policy.

If the Subcontractor certifies that it will comply with its own FCOI policy, the written agreement with the Subcontractor shall include:

- A copy of the Subcontractor FCOI policy
- A certification by the Subcontractor that its policy complies with all applicable laws, regulations, and rules (including, but not limited to the PHS Regulations; and
- Time periods for the Subcontractor to report any identified FCOI to Promiliad Biopharma defined to permit sufficient time to enable Promiliad Biopharma to provide timely FCOI reports under this FCOI Policy, as necessary, to the PHS Organization.

IX. ACCESSIBILITY OF DISCLOSURE DOCUMENTATION

Promiliad Biopharma must make the FCOI policy publicly accessible by ensuring the most recent version of this FCOI Policy is accessible to the public on Promiliad Biopharma website.

Prior to the expenditure of funds, Promiliad Biopharma shall establish a process to make information concerning identified FCOIs available within 5 business days to any requesting PHS organization. The information will be updated by CIs at least annually, be updated within 60

days of a newly identified FCOI, and all records should remain available for three years from the date of the last payment by PHS Organization.