

## CONFLICT OF INTEREST

### INTRODUCTION

This policy of PreCyte Inc (the “Company” governing financial conflict of interest applies to all PHS-sponsored research of PreCyte Inc (the “Company”) except Phase I SBIR grants<sup>1</sup>. For purposes of this FCOI Policy, all references to “PHS” shall be a reference to the respective PHS funding agency. This policy shall be made available on the Company’s website.

The PHS financial conflict of interest regulations have unique financial conflict of interest reporting and conflict management requirements. Specifically, PHS awardee institutions, including business corporations or companies, must ensure objectivity in research through compliance with the regulations set forth at 42 C.F.R. Part 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” (hereafter the “FCOI Regulations”).

The purpose of the FCOI Regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by the PHS under grants, cooperative agreements or contracts will be free from bias resulting from the financial conflicts of interest of an Investigator (as defined in Section II below). The NIH Office of Extramural Research Conflict of Interest website contains helpful information and resources about the FCOI Regulations.<sup>2</sup> The FCOI Regulations provide for a comprehensive level of disclosure, together with compulsory reporting to the applicable PHS agency. Disclosure to the Company is required of ALL “Significant Financial Interests” that reasonably appear related to the Investigator(s) As more precisely defined below, “Significant Financial Interests” include all travel reimbursements of any amount, any equity interest in a privately-held entity other than the Company and all other financial interests having a value in excess of \$5,000. Financial interests of a lesser amount do not require handling under this FCOI Policy.

This policy is for the purpose of ensuring compliance with these important regulations. All Investigators applying for funds from the NIH or other PHS agencies are required to comply with the requirements of this FCOI Policy. The Company shall designate an individual to solicit and review the disclosures required under this policy (hereafter referred to as the “Designated Official” or “DO”).

### DEFINITIONS

*Family* means any member of the Investigator’s immediate family, specifically, any dependent children and spouse.

*Financial Interest* means anything of monetary value received or held by an Investigator or an Investigator’s Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

*Financial Interest* does NOT include:

- a) salary, royalties, or other remuneration from the Company;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. Institutions of higher education; research institutes affiliated with Institutions of higher education, academic teaching hospitals, and medical centers; or

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<sup>1</sup> Funding under Phase I SBIR grant is not subject to this Policy.

- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.
- e) equity interests in the Company,
- f) salary, royalties, or other remuneration paid by the Company 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

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her Company responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. Institutions of higher education, research institutes affiliated with Institutions of higher education, academic teaching hospitals, and medical centers.

*Significant Financial Interest* means a Financial Interest that reasonably appears to be related to the Investigator's Company Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Company,
- e) is reimbursed or sponsored travel related to their Company responsibilities, or

*Financial Conflict of Interest* means a Significant Financial Interest (or, where the DO requires disclosure of other Financial Interests, a Financial Interest) that the Company reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

*DO* means the individual within the Company that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's Company responsibilities. The DO is initially the CEO.

*Company responsibilities* means the Investigator's professional responsibilities associated with his or her Company appointment or position, such as research, teaching, clinical activities, administration, and Company, internal and external professional committee service.

*Investigator* means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

*Public Health Service* or *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 of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

*Research* means a systematic investigation, study, or experiment designed to 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).

## **CONFLICT OF INTEREST:**

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Company to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the DO.

### **1) DISCLOSURE OF FINANCIAL INTERESTS**

All Investigators are required to disclose their outside financial interests as defined above to the Company on an annual and on an ad hoc basis, as described below. The DO is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

#### **a) Annual Disclosures**

All Investigators must disclose their Significant Financial Interests that are related to the investigator's Company responsibilities to the Company, through the DO, on an annual basis. All forms should be submitted to the DO or designee by March 1 for the previous calendar year.

#### **b) Ad hoc Disclosures**

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Company, through the DO, within 30 days of their initial appointment or employment.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the DO an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Company will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the DO an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

#### **c) Travel**

Investigators must also disclose reimbursed or sponsored travel related to their Company responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The DO will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

## 2) REVIEW AND DECISION OF THE DO

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the DO or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the DO will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate. DO

A Financial Conflict of Interest will exist when the DO or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the DO determines that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

The DO will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

## 3) SUBRECIPIENT COMPLIANCE

### a) Research

Non-PHS-Funded Research: 1) Company subrecipients shall provide appropriate assurances that policies and procedures no less stringent than this Policy are in place and enforced in connection with subcontracts or sub-award agreements. 2) Subrecipients shall confirm that Investigators employed by subrecipients including sub-grantees, contractors, subcontractors, and collaborators are subject to conflict of interest rules and procedures that are no less stringent than this Policy.

PHS-Funded Research: PHS-Funded subrecipients shall provide appropriate assurances that they comply with this Policy or their conflict of interest policy if such policy complies with all applicable PHS and federal FCOI rules and requirements.

### b) Agreements

Written agreements with subrecipients shall specify periods for reporting FCOIs to the Company, which are sufficient to allow the Company to perform the review, management and reporting required by this Policy.

## 4) CLINICAL TRIALS

### Review of Significant Financial Interests Related to Clinical Trials

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

- a) In the event of non-compliance with reporting and/or management of a financial conflict of interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the investigator must

disclose the financial conflicts of interest in each public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

## 5) REPORTING TO PHS

The DO will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.

## 6) INVESTIGATOR NON-COMPLIANCE

### a) **Disciplinary Action**

In the event of an Investigator's failure to comply with this Policy, the DO may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the DO is implemented.

A DO's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the DO, will be described in a written explanation of the decision to the investigator, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. The Company will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

### b) **Retrospective Review**

In addition, if the DO determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the DO will complete a retrospective review of the Investigator's activities and the PHS-sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The DO will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the Company will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

## 7) TRAINING

Each Investigator must complete training on this Policy, the investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS, and at least every four

years thereafter. They must also complete training within a reasonable period of time as determined by the DO in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the investigator is new to the Company, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

## **8) RECORD RETENTION**

The DO will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

## **9) CONFIDENTIALITY**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Company may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Company, if requested or required. If the Company is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

## **10) PUBLIC ACCESSIBILITY**

Prior to the expenditure of funds, the Company will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation. Any information posted on the Company's website shall be (1) updated at least annually; (2) updated within sixty (60) days of a newly identified FCOI; and (3) remain available for three (3) years from the date the information was most recently updated.

## **11) REGULATORY AUTHORITY**

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.