

## **POLICY FOR MANAGING CONFLICTS OF SIGNIFICANT FINANCIAL INTERESTS**

### **General Policy for *Financial Conflict of Interest* (“FCOI”)**

The principles articulated herein are intended to provide guidance in the management of formal relationships between employees of Cohere-Med, Inc. (“Cohere-Med”, “Company”) and their external constituencies in order to ensure that the design, conduct, and reporting of sponsored research will not be biased by any conflicting financial interests.

Under the Public Health Service (PHS) and National Science Foundation (NSF) final rules on Objectivity in Research (Federal Register, July 11, 1995 and modified in the Federal Register on August 25, 2011), each investigator is required to disclose a listing of his/her significant financial interests, as well as those of his/her spouse and dependent children, that would reasonably appear to be affected by the research proposed for funding by the PHS or the NSF.

If, after review of these disclosures, it is determined that the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research, the Company will report the existence of such conflicting interests to the sponsor and act to protect the resulting research from bias owing to the conflict of interest.

This policy statement is intended to satisfy current Federal rules for disclosure with regard to projects funded by the PHS or the NSF.

### **SCOPE**

This policy and the associated procedures are applicable immediately to all sponsored program activity at Cohere-Med carried out by Company employees, consultants, scientists, trainees, technicians and other agents or research collaborators (“Company employees”). The policy and the associated procedures are derived from the final rules on Objectivity in Research promulgated by the PHS and the NSF that were published in the Federal Register of July 11, 1995 and modified in the Federal Register on August 25, 2011.

These procedures will be followed whenever Cohere-Med’s employees submit a request for funding from any external agency, whether it is the PHS, the NSF or another Federal or State agency.

#### **I. RESPONSIBILITY:**

It is the Company's responsibility to assure the integrity of all aspects of sponsored research while, simultaneously, taking care not to discourage the development of external funding opportunities. The purpose of this document is to identify situations where potential conflicts of significant financial interest are likely to arise and to establish a process whereby such conflicts are either avoided or at least managed equitably to the satisfaction of all concerned parties.

### **MANAGING CONFLICTS OF SIGNIFICANT FINANCIAL INTEREST**

This document articulates Company policy on the management or elimination of conflicts of significant financial interest between outside constituencies and the associated funded activities carried out by Company. While this policy focuses upon avoiding, or at least managing conflicts of

significant financial interest, its primary purpose is to promote compliance with the standards of Objectivity in Research.

## II. DEFINITIONS

- A. *Conflict of Significant Financial Interest* is considered to occur whenever a Company employee, or a family member of the Company employee, has an existing or potential financial or other material interest that impairs, or appears to impair, the Company employee's independence and objectivity in the discharge of his/her responsibilities to and/or for the Company; or, alternatively, conflict of significant financial interest is considered to occur whenever a Company employee receives financial or other material benefit through inappropriate use of knowledge or information confidential to the Company.
- B. *COIC*: In order to review and manage conflict of interest, a committee will be established that includes at least one member who is not employed by Company as well as senior Company employees.
- C. *Company Employee* is any individual employed on a full- or part-time basis by Cohere-Med and is receiving, or will receive, compensation for such employment. (Includes Consultants, Agents and Research Collaborators of the Company).
- D. *Investigator* is the principal investigator, co-principal investigators, or any other Company employee responsible for the design, conduct, or reporting of externally funded scientific research activities.

Individuals participating in a study that are employees of a subrecipient with significant experience in managing conflicts of interest for PHS, the NSF or another Federal or State agency related programs, then such individuals may be covered by FCOI policy of that subrecipient and are not included in this definition if the subrecipient certifies that all their employees participating in the study comply with its FCOI policy.

- E. *Family member* includes the Company employee's spouse and children or other adults who qualify as dependents under the Internal Revenue Code definitions.
- F. *Project* implies any externally funded activity such as basic, applied, or developmental research, or other activity conducted by Company employees on behalf of the Company.
- G. *Significant Financial Interest*:
  - (1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependents) 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 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 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 dependents) holds any equity interest (e.g., stock, stock option, 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) 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, a medical center, or a research institute that is affiliated with an Institution of higher education.
- (3) The term significant financial interest does not include the following types of financial interests: 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; any ownership interest in the Institution held by the Company; 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; 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 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.

H. *Negative Finding* means a determination that no Conflict of Significant Financial Interest exists that could jeopardize the objectivity of design, conduct or results of Project.

I. *Positive Finding* means a determination that a Conflict of Significant Financial Interest exists and, therefore, appropriate administrative action will be required.

### III. POLICY STATEMENT

#### A. TRAINING

All Investigators must complete FCOI training.

Proof of completion of FCOI training (E.g. a training completion certificate) will be placed in Company records for a period of Ten (10) years and must be available before any Company Employee begins, or continues to, work as an Investigator.

FCOI training must be completed within Thirty (30) days by Investigator the sooner of

- a. every four (4) years,
- b. upon any change to this FCOI policy, or
- c. upon being found to be non-compliant with this FCOI policy

## **B. MANDATORY DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS**

In accord with relevant Federal and State regulations, Company will manage, eliminate, or reduce any potential conflicts due to Significant Financial Interest of Investigators.

Every Investigator must disclose to the Company their Significant Financial Interest which would reasonably appear to be affected by the project being funded by external government agencies. Investigators are required to provide updated disclosure information during the time period in which the proposal is pending, annually during the time period of an award, or absolutely within Thirty (30) days of any new Significant Financial Interest acquired by the investigator.

Any sponsored travel must be a part of the Significant Financial Interest. In disclosing sponsored travel for which monetary value is not available, Investigator shall disclose the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Company shall have the right to seek additional information for such sponsored travel, if required, to determine Conflict of Significant Interest.

The CEO is responsible for securing disclosures of Significant Financial Interest from all Investigators in a timely manner. All Significant Financial Interest disclosures will be reviewed by COIC within sixty (60) days of receipt by Company to determine Conflict of Significant Financial Interest.

## **C. IDENTIFICATION OF CONFLICTS OF SIGNIFICANT FINANCIAL INTEREST**

COIC will review Significant Financial Interest disclosures within Forty-five (45) days of its receipt by Company. COIC will evaluate whether it will generate Conflict of Significant Financial Interest (that could affect Investigator's objectivity in their conduct of the research study.)

Each determination by COIC will be filed in Company's records for Ten (10) years.

For Negative Finding no further review is required.

## **D. MANAGING POSITIVE FINDINGS OF SIGNIFICANT FINANCIAL INTEREST**

Following determination of Positive Finding in a disclosure, COIC along with the management team of Company shall make a final determination involving one of the administrative actions:

- 1) Accepting the sponsored project award;
- 2) Not accepting the sponsored project award; or

3) Accepting the sponsored project award subject to suitable modifications in the award documentation or in the investigator's, or his/her family's, affiliation with the external constituencies involved.

Two or more of the following actions will be required for (3) above:

- 1) Requiring that public disclosure of the identified financial interests be made;
- 2) Requiring that the data and research results be reviewed by independent reviewers who are not Company Employees;
- 3) Requiring that the research plan be modified;
- 4) Requiring that the investigator be disqualified from participation in a portion of the research;
- 5) Requiring that the investigator and/or her/his family member(s) divest certain significant financial interests related to the positive finding; or
- 6) Requiring that the investigator and/or his/her family members(s) sever relationships that create the conflict of significant financial interest.
- 7) Monthly review of this Investigator's work performed (such as computer code used or output files generated) by a Company Employee who does not have Significant Financial Interest. This Company Employee will generate monthly reports of the review to be presented to the COIC and management team who shall together determine on a monthly basis if objectivity of the study is compromised as long as the Investigator continues to remain part of the research study.

#### E. COMPLIANCE

Investigator who is required under this policy to disclose Significant Financial Interest disclosure and fails to do within Thirty (30) days of being informed of such failure may be subject to reprimand, removal from the research study and legal procedures.

If an unreported Significant Financial Interest involves a research project administered by the Company, appropriate administrative action required by the funding agency will also be taken.

Company will promptly notify the funding agency if it is determined that the company is unable to manage satisfactorily any Conflict of Significant Financial Interest. Intentional disregard for this policy, including non-adherence to the agreed upon management plan to mitigate Conflict of Significant Financial Interest, shall constitute serious misconduct and may be the basis for termination and other legal recourses.

Any non-compliance by any Investigator will require them to re-complete FCOI training. Within 120 days of determination of non-compliance, a retrospective review will be conducted by the COIC to determine if actions taken by management have removed the reasons of the non-compliance and/or bias in the conduct of the research study.

#### F. REPORTING TO NIH

For any study related to NIH, company shall send FCOI reports prior to expenditure of funds, within Sixty (60) days of identification of new Investigator in the study and within Sixty (60) days of new or newly identified FCOIs for existing Investigators.

At the very least, FCOI reports will be sent annually to NIH to provide status of FCOI and any changes to the management plan for the study.

Any Positive Finding for a study related to PHS/NIH where a bias is determined to exist will be reported to PHS/NIH along with the specific mitigation action taken to remove such bias. Follow up report will also be sent with results of the mitigation action until any bias is corrected.

**G. SUBRECIPIENT REQUIREMENTS**

Investigators from subrecipients with significant experience in managing conflicts of interest for PHS, the NSF or another Federal or State agency related programs, will be covered by the FCOI policy of that subrecipient if that subrecipient agrees to provide certification to Company that all their investigators participating in Company study comply with its FCOI policy. If such a subrecipient fails to provide such a certification, its Investigators will be subject to Company's FCOI policy.

Any subrecipient that does not have significant experience in managing conflicts of interest for PHS, the NSF or another Federal or State agency related programs, will be covered by Company's FCOI policy.

**H. PUBLIC ACCESSIBILITY REQUIREMENTS**

Company website will have a public link to request Company's FCOI policy. Upon receiving such a request from a legitimate entity or individual, Company shall send the FCOI policy to the recipient within Five (5) business days of such a request being submitted.