

Policy for Managing Conflicts of Significant Financial Interests for Government Grants

I. INTRODUCTION

A. GENERAL POLICY

The principles articulated herein are intended to provide guidance in the management of formal relationships between employees of Entegriion, Inc. (“Entegriion” or “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 Department of Health and Human Services (“DHS”) Promoting Objectivity in Research that were published in the *Federal Register* of August 25, 2011 (“Objectivity in Research”), 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 under Public Health Service (PHS) grants or cooperative agreements. 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.

B. SCOPE

This policy and the associated procedures are applicable immediately to all sponsored program activity at Entegriion 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 rules on Objectivity in Research promulgated by the PHS that were published in the *Federal Register* of August 25, 2011. These procedures will be followed whenever Entegriion or its employees submit a request for funding from any external agency, whether it is the PHS or another Federal agency.

C. RESEARCH STATEMENT

Entegriion’s research is facilitated and/or made possible through external funding from private as well as public sources. It is the Company’s responsibility to assure the integrity of all aspects of such 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.

D. 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 the 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. *Company Employee* is any individual employed on a full-time or part-time basis by Entegriion and is receiving, or will receive, compensation for such employment. (Includes Consultants, Agents and Research Collaborators of Company)
- C. *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.
- D. *Family Member* includes the Company employee's spouse and children or other adults who qualify as dependents under the Internal Revenue Code definitions.
- E. *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.
- F. *Significant Financial Interest* is 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 (stock, stock option, or other ownership interest); or intellectual property rights and interest (e.g. patents, copyrights), upon receipt of income related to such rights and interest. *Significant Financial Interest* does not include: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator; income from investment vehicles, income from seminars, lectures, or teaching engagements.
- G. *Negative Finding* means a determination has been made that no conflict of significant financial interest exists.
- H. *Positive Finding* means a determination has been made that a conflict of significant financial interest does exist and, therefore, appropriate administrative action will be required as given under III. D. below.

III. POLICY STATEMENT

- A. **MANDATORY DISCLOSURE OF SIGNIFICANT INTERESTS**
In accord with relevant Federal regulations, the Company is required to manage, eliminate, or reduce any potential conflicts of significant financial interest that may be inherent in the personal financial interests of an investigator. Company, therefore,

requires investigators to disclose to the Company, any significant financial interest, including those of his/her family members, 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 whenever new significant financial interests are obtained by the investigator.

B. IDENTIFICATION OF CONFLICTS OF SIGNIFICANT FINANCIAL INTEREST

In conjunction with the administrative review of applications for grants, the Chief Executive Officer (“CEO”) in conjunction with the Chief Financial Officer (“CFO”) will review each Financial Disclosure submitted and shall make the determination of whether or not a conflict of significant financial interest exists. If the CEO and the CFO determine that no conflict of significant financial interest exists, the resulting negative finding will be filed in the Company’s Human Resource files. For negative findings no further review is required.

C. APPEAL OF POSITIVE FINDINGS

Investigators may appeal a resulting positive finding to the Chairman for a review of the conflict of significant financial interest determination reached by the CEO and the CFO. The review of an appealed positive finding must be completed prior to the expenditure of any funds under any award. In reviewing positive findings, the President will be guided by the following principles: 1) assure adherence to all relevant Company policies; 2) give full consideration to the nature and extent of the financial interest in the relationship of the investigator, and/or the investigator’s family members, with external constituencies; 3) give special consideration to the terms and conditions of sponsored project agreements that mitigate or complicate the given situation; and 4) consult fully with the investigator and obtain additional information from the investigator, as deemed appropriate to the management of the apparent conflict of significant financial interest.

D. MANAGING POSITIVE FINDINGS OF SIGNIFICANT FINANCIAL INTEREST

Following the determination of a positive finding, or upon receipt of the review by the CEO and the CFO shall make a final determination involving one of the following 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. Reasonable modifications under option 3 above might include one or more of the following actions: 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 identified by the President and the investigator; 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 his/her family member(s) divest certain significant financial interests related to the positive finding; or 6) requiring that the investigator and/or his/her family member(s) sever relationships that create the conflict of significant financial interest.

E. COMPLIANCE

If an investigator who is required under this policy to file a conflict of significant financial interest disclosure fails to do so or fails to disclose a significant financial interest on the disclosure form, the investigator may be subject to company 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. Entegriion 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, shall constitute serious misconduct and may be the basis for further administrative or legal inquiry.

