

Zenalux Biomedical, Inc. Policy for Managing Conflicts of Significant Financial Interests

1) INTRODUCTION

a) General Policy

The principles articulated herein are intended to provide guidance in the management of formal relationships between Zenalux Biotechnology, Inc. ("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), 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 purposed 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 as well as State of California statutes involving conflict of interest situations.

b) Scope

This policy and the associated procedures are applicable immediately to all sponsored program activity 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. These procedures will be followed whenever Company or its employees submit a request for funding from any external agency, whether it is the PHS, the NSF or another Federal agency.

c) Research and the Mission Statement

The Mission Statement for Company states: Zenalux develops novel biophotonic-based tools to aid in the diagnosis and treatment of cancer as well as other disease states.

Such company 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 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.

2) 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- or part-time basis by Company 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 any item of monetary value including, but not limited to:
 - i) salary or other payments for services rendered such as consulting fees;
 - ii) equity interests such as stocks, stock options, or other ownership interest; and
 - iii) intellectual property rights such as patents, copyrights, and royalties from such intellectual property rights.

Significant Financial Interest does not include:

 - i) Company remuneration such as salary or royalties;
 - ii) consulting fees from service on advisory committees or review panels for public or nonprofit entities; or
 - iii) financial interest in business enterprises or entities where the value of such interests would not be anticipated to exceed \$10,000 per annum or represent more than a five per cent (5%) ownership interest. The value of such equity interests is to be determined on the basis of public prices or other reasonable measures of fair market value.
- 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 3.d. below.

3) POLICY STATEMENT

- a) Mandatory Disclosure of Significant Financial Interests

In accord with relevant Federal and State of California regulations, the Company is required to manage, eliminate, or reduce any potential conflicts of significant financial interests that may be inherent in the personal financial interest 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 Interests

In conjunction with the administrative review of applications for grants, the Vice President of Research, in conjunction with the Vice President of Operations and Legal Counsel will review each Financial Disclosure submitted and shall make the determination of whether or not a conflict of significant financial interest exists. If the Vice President of Research, Vice President of Operations and Legal Counsel determines that no conflict of significant financial interest exists, the resulting negative finding will be filed in the Company's Legal and 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 CEO for a review of the conflict of significant financial interest determination reached by the Vice President of Research, Vice President of Operations and Legal Counsel. The review of an appealed positive finding must be completed prior to the expenditure of any funds under an award. In reviewing positive findings, the CEO will be guided by the following principles: 1) Assure adherence to all relevant Company policies; 2) Give full considerations to the nature and extent of the financial interests in the relationship of the investigator, and/or the investigator's family members, with the 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 Interests

Following the determination of a positive finding, or upon receipt of the review by the CEO, Vice President of Research, Vice President of Operations and Legal Counsel 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. 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 CEO 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 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 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.

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, shall constitute serious misconduct and may be the basis for further administrative or legal inquiry.

ZENALUX BIOMEDICAL, INC. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS FORM

Name _____ Department _____

Title _____

Grant Proposal Title _____

Intended Government Funding Agency _____

Name of Constituent Organization/Institution in which you claim a Significant Financial Interest:

Name

Address

City, State Zip

Describe in detail the nature of your financial interest or role in the Constituent Organization or institution with respect to the following:

1. Describe your significant financial interest in the organization (other than _____) that is directly related to your research interest (or would be affected by your research) or directly relates to a business decision you are participating in:

Significant Financial Interest is any item of monetary value including, but not limited to: a) salary or other payments for services rendered (e.g. consulting fees or honoraria) b) equity interests (e.g. stocks, stock options, or other ownership interest) c) intellectual property rights (e.g. patents, copyrights, and royalties from such rights)

Significant Financial Interest does not include:

- a) salary, royalties, or other remuneration from the applicant institution
- b) any ownership interest in the institution, if the institution is an applicant under the SBIR Program

- c) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- d) income from service on advisory committees or review panels for public or nonprofit entities;
- e) an equality interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than five percent ownership interest in any single entity;
- f) salary, royalties or other payments that when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months, are not reasonable expected to exceed \$10,000.

2. Describe your involvement or financial interest that is, or could be perceived to be, in conflict with the discharge or your duties
