

## **Emory University**

### **Policies and Procedures for Faculty Members Involved in Sponsored Research and Technology Transfer (Conflict of Interest in Research Policy)**

#### **Purpose**

This document deals with certain aspects of sponsored research of University together with related technology transfer activities. It complies with federal regulations issued by the Public Health Service and the National Science Foundation.

#### **Background**

Collaboration between Emory investigators and industry is a component of Emory's research and technology transfer program. Through such collaborations Emory investigators obtain support for their research and access to expertise and materials uniquely available in industry. Such collaborations form the foundation for Emory's technology transfer activities. Technology transfer serves to: (I) make significant innovations, such as new and improved diagnostic and therapeutic technology available to the public; (II) stimulate regional economic development and national competitiveness; and (III) provide funding for research and other University programs. These policies and procedures seek to foster sponsored research and technology transfer by (I) providing guidelines and mechanisms for resolving perceived or actual conflicts of interest and (II) safeguarding Emory's and Emory investigators' reputation for academic integrity. These policies and procedures comply with Federal Regulations pertaining to sponsored research. For grants and cooperative agreements, the Public Health Service (PHS) Regulations are set forth in 42 CFR Part 50, Subpart F Section 50.601 through Section 50.607. For contracts, the PHS Regulations are set forth in 42 CFR Subpart 94, Section 94.1 through Section 94.3 and Section 50.604 through Section 50.606. The National Science Foundation (NSF) Regulations are published in the Federal Register, Volume 60, No. 32, July 11, 1995, pages 35822-35823.

Emory investigators may, under appropriate circumstances, maintain one or more of the following relationships with research sponsors or licensees of Emory technology: (I) equity participation; (II) service on a governing board or as an officer; (III) service on a scientific advisory board; and (IV) principal investigator for sponsored research. Emory investigators may also share in "Net Revenues" received from licensees in accordance with Emory's Patent Policy.

Emory University may accept equity and other forms of consideration from licensees in accordance with the Emory University Patent Policy. Individual Emory investigators who wish to receive equity from any licensee of Emory technology shall fully disclose the proposed terms of such arrangement to the Dean. No part of the proceeds from Emory University's equity interest shall be distributed to Emory investigators who hold equity interests in licensees of Emory technology.

Multifaceted relationships between research sponsors or licensees catalyze research and technology transfer activities. However, on occasion, such relationships may present Emory investigators and administrators with issues regarding perceived, potential or actual conflicts of commitment or interest. These policies and procedures are intended to assist Emory investigators and administrators in identifying

and resolving such issues.

## **Definitions**

The following terms as used in this Policy shall have the following meaning:

- a) Investigator shall mean the principal investigator, co-principal investigator and other Emory investigators, or any Emory research collaborator, including visiting scientists, responsible for the design, conduct or reporting of Research or educational activities or responsible for preparing a proposal for Research funding. For purposes of this Policy, "Investigator" shall include the Investigator's spouse and dependent children.
- b) Compensation shall mean anything of monetary value including, but not limited to, salary, consulting fees, honoraria or other payments for services.
- c) Equity Interest shall mean stocks, stock options, or other ownership interests.
- d) Research shall mean any systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences Research. The term encompasses basic and applied Research and product development. The term further includes any such activity for which funding is available from a PHS Awarding Component or through a grant or cooperative agreement whether authorized under the PHS Act or other statutory authority.

## **Conflict of Interest Statements**

ANY EMORY INVESTIGATOR ENGAGED IN SPONSORED RESEARCH, OR WHO WISHES TO BE ELIGIBLE TO ENGAGE IN RESEARCH, SHALL COMPLETE AND FILE A CONFLICT OF INTEREST STATEMENT IN THE FORM ATTACHED HERETO WITH HIS OR HER DEAN AND/OR DIRECTOR (HEREINAFTER "DEAN") AT LEAST ONCE EACH YEAR AS SPECIFIED BY THE INVESTIGATOR'S DEAN. (Each Dean may delegate any functions provided for the Dean under this Policy.)

## **Forms**

Copies of the Conflict of Interest Forms may be obtained from the Dean's Office or through the web at the following links:

Conflict of Interest Form General

Conflict of Interest Form - School of Medicine

## **General Requirements**

Arrangements for sponsored Research must meet the below described criteria and any other conditions deemed appropriate due to unique circumstances presented by a specific case, by the Investigator's Dean, or other University Officers charged with administering this Policy, or the Emory Conflict of Interest Panel:

- a. Safeguard the academic integrity of Emory Research and educational programs. This entails ensuring

that: (I) the nature and scope of the Research is appropriate and consistent with Investigators' academic and research interests; (II) any financial interests (i.e., Equity Interest or Compensation) of an Investigator which could affect the design, conduct, or reporting of Research or educational activities is disclosed and eliminated or managed as appropriate.

b. Ensure that graduate students, postdoctoral researchers and other Emory personnel are assigned appropriate duties consistent with their status or position.

c. Ensure that Research sponsors' access to university equipment, supplies and intellectual property rights is appropriate and consistent with Emory's legal, policy, financial and reputational interests.

### **Disclosure of Relationships between Investigators and Potential Research Sponsors and Licensees**

Proposals for sponsored Research involving any of the following arrangements shall be disclosed by each Investigator who intends to participate in the Research to his or her Dean prior to submitting a formal proposal to the Sponsor:

a. A proposal to a Research sponsor: (I) from which any Investigator receives, or anticipates receiving, Compensation in excess of \$10,000.00 during a calendar year; or (II) in which an Investigator has an Equity Interest greater than 1% or worth more than \$10,000.00; or (III) from which an Investigator is entitled to receive royalties under a license or assignment of an Investigator's intellectual property rights to such proposed sponsor.

b. A proposal to evaluate technology that is owned by a business: (I) from which the Investigator receives, or anticipates receiving Compensation in excess of \$10,000.00 during a calendar year; or (II) in which an Investigator has an Equity Interest greater than 1% or worth more than \$10,000.00.

c. A proposal to a Research sponsor involving a waiver or preferential reduction of University direct or indirect costs to benefit to such sponsor: (I) from which the Investigator receives, or anticipates receiving, Compensation in excess of \$10,000.00 during a calendar year; or (II) in which an Investigator has an Equity Interest greater than 1% or worth more than \$10,000.00.

d. A proposal involving the purchase of equipment or other materials from a vendor or supplier: (I) from which the Investigator receives, or anticipates receiving, Compensation in excess of \$10,000.00 during a calendar year; or (II) in which an Investigator has an Equity Interest greater than 1% or worth more than \$10,000.00.

In cases where Investigators are not aware of the existence of such arrangements at the time of the proposal, or such arrangements arise after submission of a proposal, Investigators shall notify the Dean within (3) business days of learning of such arrangement. An Investigator who is the person to whom disclosure would normally be made shall disclose such an arrangement to the next superior official.

A "company" shall not include the interest of a diversified mutual fund in which an Investigator is an investor.

Emory Investigators involved in technology transfer activities shall disclose in writing any relationship with a prospective licensee to the Dean and to Emory's Director of Licensing, before Emory or the

Investigator commences negotiations with such party.

### **Review by the Dean or Director**

If the Dean determines that a proposal, as initially disclosed, or as modified with the agreement of the Investigators and the Dean, complies with this policy, the proposal may go forward. Alternatively, the Dean may refer a proposal to the Conflict of Interest Panel for further review. A finding by the Dean that the proposal does not comply with this Policy may be appealed to the next superior official, including the Vice President for Health Affairs or Vice President for Academic Affairs as applicable, which official shall seek the advice of the Conflict of Interest Panel.

Upon receipt of a proposal for external funding, the Dean will review the proposal to determine if the Principal Investigator has certified on the Sponsored Programs Approval Form (SPAF) that there is or is not a financial interest that could be a potential and/or real conflict of interest.

### **Review of Proposals with Potential Conflicts of Interest**

Proposals involving the following arrangements shall be reviewed by the Dean to determine whether a financial interest poses a potential or real conflict of interest. A conflict of interest exists when the reviewer(s) reasonably determines that a financial interest will directly and significantly affect the design, conduct, or reporting of the sponsored research or educational activities.

- a) A proposal to a sponsor to perform Research involving a technology that has been licensed, or offered under an option to the sponsor or other commercial entity, under an arrangement that will result in the Investigator receiving royalties or other Compensation from the commercial exploitation of the technology.
- b) A proposal for Research support from a sponsor in which the Investigator holds equity in excess of 1%.
- c) A proposal for Research support from a sponsor in which an Investigator's immediate supervisor, co-investigator on that project, or any laboratory staff, or students who are directly supervised by that Investigator and who would be engaged in the proposed project or their immediate family individually or collectively hold equity in excess of 1%.
- d) Proposals for external Research support involving non-faculty employees or students to whom the circumstances described in "a" through "c" apply.

If a conflict is determined, the Dean shall determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflict of interest (see Conditions the Dean and/ or the Conflict of Interest Panel May Impose).

If the Dean cannot determine the action to be taken to manage, reduce, or eliminate the conflict of interest, the matter will be referred to the University's Conflict of Interest Panel for review and recommendations.

The Conflict of Interest Panel shall consist of not fewer than six nor more than ten members who shall be

appointed by the Provost with the approval of the Dean of the School of Medicine and the Dean of Graduate Studies.

Any proposals to license Emory technology to a company in which an Emory inventor of the technology holds equity shall also be referred by Emory's Director of Licensing to the Conflict of Interest Panel for review and recommendations.

Service by an Investigator on the governing board or as an officer of any sponsor of the Investigator's Research shall require the prior approval of Conflict of Interest Panel or the Investigator's Dean.

### **Clinical Research**

Special precautions must be taken to avoid the appearance of or actual with respect to clinical Research involving the evaluation of therapeutic strategies or products, the commercial success of which may enure to the benefit of Emory or Emory Investigators. An Emory Investigator shall not ordinarily participate in any clinical trial of a therapeutic strategy or product if the Investigator is in a position to receive royalties or other Compensation as a result of the commercial success of such strategy or product. Emory will not ordinarily participate in any clinical trial of a therapeutic strategy or product if Emory has, as a part of a licensing arrangement, acquired equity in the company sponsoring such trial. If Emory, or the Investigator, or both, hold equity in a sponsoring company, and Emory is also the preferred or only feasible site for a clinical trial, the Conflict of Interest Panel may, with the approval of the appropriate Academic Vice President and the Dean, allow such trial to proceed. In such situations, the Conflict of Interest Panel may establish an ad hoc committee including at least one individual having no affiliation with Emory to review, approve and oversee the clinical trial.

### **Conditions the Dean and/or the Conflict of Interest Panel May Impose**

Conditions that the Dean and/or the Conflict of Interest Panel may impose to manage potential or actual conflicts of interest involving sponsored Research shall include, but not be limited to:

- a) public disclosure of any financial interest of an Investigator in a Research sponsor or the commercial success of any therapeutic strategy or product that is the subject of any Research results being reported; or
- b) monitoring of any Research project by independent reviewers; or
- c) modification of any Research proposal or plan; or
- d) disqualification of any Investigator from participating in all or a portion of any sponsored Research; or
- e) divestiture by an Investigator of any financial interest in any Research sponsor or severance of any relationship between an Investigator and a Research sponsor which may create actual or potential conflicts of interest.

The Dean and/or Conflict of Interest Panel will be responsible for ensuring that the Investigator complies with the recommended action.

### **Fiscal Matters**

Fiscal matters pertaining to a sponsored Research or license arrangement that is subject to review by the Dean and/or the Conflict of Interest Panel shall be approved by the appropriate Academic Vice President and the Executive Vice President.

### **Compliance with this Policy and Relevant Law**

The Dean and/or the Conflict of Interest Panel shall be responsible for investigating and resolving any alleged violations of this Policy and shall take appropriate action to enforce this Policy, including, not but limited to, imposing sanctions upon Investigators in violation of the Policy. The Dean and/or the Conflict of Interest Panel shall promptly notify the Office of Sponsored Programs (hereinafter "OSP") of any conflicts not resolved to the satisfaction of Emory. OSP shall notify the federal sponsor of unresolved conflicts.

Emory Investigators involved in sponsored Research or technology transfer are expected to comply with all federal regulations and laws pertaining to the conduct of Research and the sale and purchase of securities.

### **Reporting Conflicts of Interest; Maintenance of Records**

Unless circumstances warrant otherwise, the review of a proposal for any potential conflict of interest by the Dean, and when necessary by the Conflict of Interest Panel, will occur within ninety (90) days after the proposal is submitted to the sponsor. When a conflict of interest is determined, the Dean and/or the Conflict of Interest Panel will inform the Principal Investigator that a conflict has been determined and implement an action for managing, reducing, or eliminating the conflict.

The Dean will notify OSP that a conflict has been determined and that an action has been implemented. OSP will inform those sponsors that require notification of the conflict and action. The Dean shall be responsible for maintaining records, identifiable to each award, of all disclosures of relationships between Investigators and potential Research sponsors and all actions taken by the Dean and/or the Conflict of Interest Panel to manage any actual or potential conflicts of interests for at least three (3) years beyond the termination or completion of the award or until resolution of any action by any federal agency involving the records, whichever is longer.

### **Certification**

The Dean and/or the Conflict of Interest Panel shall certify those elements enumerated in Title 42, Section 50.604 (7) of the Code of Federal Regulations for all PHS applications for Research funding.

William M. Chace  
September 27, 1995