EXTERNAL CONTRIBUTOR CONFLICT OF INTEREST DISCLOSURE FORM

A conflict of interest disclosure must be completed annually. This disclosure form contains a brief training module. The training module contains helpful definitions and guidelines for understanding conflict of interest, your responsibilities and completing your disclosure.

TRAINING MODULE

CONFLICT OF INTEREST (COI)

The Conflict of Interest Office serves in partnership with researchers, educators, administrators and patient care providers to promote an environment of quality and integrity in which to advance biomedical research and patient care.

The environment of academic medicine and healthcare has transformed significantly over the past decade. Healthcare providers and scientists are making advances in the field of medicine and human health at a record pace. Many of the successes achieved in healthcare outcomes are the result of public institutions collaborating with private industry. The relationships that exist between government, academia and industry are seen as essential to developing entrepreneurial and innovative approaches to delivering the highest quality healthcare in a rapidly changing world, not only today but in the future. MUSC embraces and is advancing its belief in these collaborations as stated in the 2010-2015 strategic plan.

In order for these types of collaborations to be successful, MUSC has to identify and manage conflicts of interest. By doing so, the institution ensures that objectivity surrounding education, research and patient care is protected. Conflict of interest occurs when an employee or a family member receives personal financial benefit or an economic interest from the employee's position in a manner that may influence the employee's judgment, compromises the employee's ability to carry out his or her institutional responsibilities or is a detriment to the institution's integrity.

The COI Disclosure is the initial step in understanding relationships that exist between employees of sub recipient organizations and outside entities and the nature of these relationships. It is important to understand that a COI does not imply wrong doing; rather the disclosure process is designed to identify relationships and determine if a conflict exists. MUSC will work to manage or eliminate COI so that collaborations that are valuable to advancing biomedical research and patient care are strengthened.

INDIVIDUAL RESPONSIBILITIES

Each employee of the sub recipient organization participating in a research project has certain responsibilities pertaining to conflict of interest. As described in the MUSC COI Policy, each employee participating in a research project must disclose on an annual basis any financial interests with an entity that does **business with the MUSC Enterprise** or **relates to their job duties.**

The university has a policy on Conflict of Interest; each employee should read and understand this policy. The Conflict of Interest Policy can be accessed by clicking here:

MUSC/MUHA COI Policy

The NIH has regulations on Conflict of Interest. Each person who is responsible for the design, conduct or reporting of research should read and understand the regulations. This disclosure contains questions that will comply with the NIH regulations on "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought."

The NIH regulations can be found by clicking here:

42 CFR Part 50 Subpart F (Grants): Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought

45 CFR Part 94 (Contracts): Responsible Prospective Contractors

Please remember that if any business or financial relationship <u>changes or develops</u> during the calendar year, you are required to modify this disclosure within 30 days.

DEFINITIONS AND TERMS

The following definitions should be used when considering the disclosure questions. These definitions and terms are important because they are used to determine if a relationship with an outside entity exists and the nature of the relationship.

<u>Family Member</u>: The Board of Trustees' COI Policy defines a family member to include the employee's parents, spouse, siblings, children, stepchildren, and grandchildren. In responding to the disclosure questions, "you" and "your family" include both you individually and your family as defined above.

Role: A role in an entity may include any of the following:

- Being employed
- Ownership of stock (publicly traded)
- Equity interest (privately owned)
- Intellectual property rights
- Participation on a speakers' bureau
- Serving as consultant, advisor or expert witness
- Serving as an officer in the entity
- Any other relationship that relates to your institutional responsibilities
- Serving as a board member (governing, scientific or advisory)

<u>Financial Relationship</u>: A financial relationship is defined as anything of current or future monetary value to you or a family member from an entity.

<u>Entity</u>: An entity is any organization engaging in business, such as a proprietorship, partnership, or corporation. It also includes professional and trade associations, non-profit organizations, foundations or other similar organizations.

<u>Institution</u>: Means any domestic or foreign, public or private, entity or organization that is applying for or that receives PHS research funding.

<u>MUSC Enterprise</u>: The enterprise includes the Medical University of South Carolina (MUSC), Medical University Hospital Authority (MUHA), as well as the MUSC Affiliates, e.g., MUSC Physicians (formerly UMA), and the Foundation for Research Development.

The questions included in this disclosure are designed to allow external contributors to disclose their conflicts of interest and the nature and extent of the conflict.

DISCLOSURE REQUIREMENTS

Do Not Report the Following Items:

- Any salary or any other compensation paid by the institution to the employee.
- Income from investment accounts, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these accounts.
- ➢ Income, reimbursed or sponsored travel from seminars, lectures, teaching engagements, service on advisory 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.
- Research funding awarded to the institution or the MUSC Enterprise.

DISCLOSURE

The COI Disclosure that follows has been designed to assess whether or not you have a relationship with an entity that **does business with the MUSC Enterprise** or **relates to your job duties**, and if a relationship exists, the nature of that relationship. All questions are based on the definitions on the preceding pages; please refer back to the definitions as you complete the disclosure.

If you are completing your annual disclosure, the information that should be disclosed is for the preceding 12 months. If any business or financial relationship <u>changes or develops</u> in the current calendar year, you are required to modify this disclosure within 30 days.

If you answer "YES" to one or both of the questions in Part A, you will be directed to an additional set of more specific questions in Part B. When all required questions have been answered, you will have completed your annual COI Disclosure.

COI DISCLOSURE

Name (last, first, middle initial)	Name	(last,	first,	middle	initial):
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PART A

The following two questions refer to entities that **conduct business with MUSC** or **are associated with your job duties.**

A.1 Do you or a family member have a role or a financial relationship with an entity?

Yes No

A.2 Have travel expenses been reimbursed to you or a family member or have travel expenses been sponsored for you or a family member by an entity?

Yes No

If you answered "No" to both questions in Part A, <u>skip</u> Part B and proceed to Part C. If you answered yes to either question in Part A, please complete both Part B and Part C.

PART B

Name of Entity:

B.1 Do you or a family member own publicly traded stock in this entity?

Yes No If yes, please provide approximate value \$

B.2 Do you or a family member have a private equity/ownership interest in this entity?

Yes No If yes, please provide approximate value \$

B.3 Do you or a family member have intellectual property rights (patents or trademarks) that are held, or have been licensed to or optioned to this entity?

Yes No

B.4 Do you or a family member receive royalties from this entity?

Yes No If yes, please provide approximate value \$

B.5 Do you or a family member receive payments from this entity for speaking or presenting?

Yes No If yes, please provide approximate value \$

B.6 Do you or a family member receive payments for serving as a consultant or advisor to this entity?

Yes No If yes, please provide approximate value \$

B.7 Do you or a family member receive payments from this entity for serving as a board member (Governing, Scientific, or Advisory Boards)?

Yes No If yes, please provide approximate value \$

B.8 Do you or Yes	a family memb	• •	s for serving as an officer in this entity? de approximate value \$
B.9 Has this e	ntity reimburse No	•	rel for you or a family member? de approximate value \$
described wit	hin this disclos	ure which is related MUSC Enterprise fo	ner role or financial relationship not to your institutional responsibilities (including or research, education or clinical purposes)? de approximate value \$
		e support for any of ch Agreement or cor	f the research in which you may be involved ntract)?
•	•	•	nduct or reporting on any research project all device or treatment) made by this entity?
decisions reg	arding this ent	ity's products? This	olved in purchasing or procurement may be by providing advice or consultation ucts, goods or services.
B.14 Do you p Yes	orescribe, use o No	or implant products,	e.g. drugs or devices, made by this entity?
Please use th with this entit	• •	ovide comments or	additional information about your relationship
			d and understand the COI training module and the disclosure requirements.
Signature		 Date	