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.

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.

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 subrecipient 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 investigator of the subrecipient organization participating in a research project has certain responsibilities pertaining to conflict of interest. As required by the PHS (NIH) FCOI regulations, each investigator 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 that relates to his/her area of professional expertise.

MUSC has a policy on Conflict of Interest. The MUSC/MUHA 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

Details regarding MUSC's procedures and guidelines for compliance with the federal regulations noted above can be found here: Research Conflict of Interest Definitions and Guidelines

Please remember that if any business or financial relationship <u>changes or develops</u>, you are required to update 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 companies)
- Equity interest (privately held companies)
- Intellectual property rights
- Speaking or presenting on behalf of an entity
- Serving as consultant, advisor or expert witness
- Serving as a governing board member
- Serving as an officer in the entity
- Any other relationship that relates to your institutional responsibilities

<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 MUSC Foundation for Research Development.

The questions included in this disclosure are designed to allow external contributors to disclose their financial interests and the nature and extent of these relationships.

DISCLOSURE REQUIREMENTS

Do Not Report the Following Items:

- Any salary or any other compensation paid by the institution to the employee. *The exception is that royalties distributed through the institution should be reported on your disclosure.
- 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, or 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 or Contract funding awarded to the institution.

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 that relates to your area of professional expertise, 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.

The information that should be disclosed is for the preceding 12 months. If any business or financial relationship changes or develops, 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):

PART A

The following two questions refer to entities that <u>conduct business with MUSC</u> or are related to your area of professional expertise.

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 paid on behalf of 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, trademarks, copyright) 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 \$

Please include royalties distributed to you through your institution.

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	er receive payments for serving as an officer in this entity? If yes, please provide approximate value \$
B.9 Has this e	ntity reimburse	d or sponsored travel for you or a family member?
Yes	No	If yes, please provide approximate value \$
Please describ	oe the details o	f each trip, which must include the purpose, destination and duration
	eady described	mber have any other role or financial relationship with this within this disclosure which is related to your institutional
Yes	No	If yes, please provide approximate value \$
		e support for any of the research in which you may be involved the charact state of the support for contract.
		for the design, conduct or reporting on any research project ments being developed, produced or sold by this entity?
regarding this	entity's produ	uties, are you involved in purchasing or procurement decisions cts? This may be by providing advice or consultation regarding n of products, goods or services.
B.14 Do you p Yes	orescribe, use c No	r implant products, e.g. drugs or devices, made by this entity?
Please use th with this entit	•	vide comments or additional information about your relationship
		rtify that I have read and understand the COI training module and re in accordance with the disclosure requirements.
Signature		 Date