

Charleston Research Institute Policy Memorandum

Title: Research Conflict of Interest Policy

Reviewed by: Board of Directors

Implementation Date: February 11, 2013

Revision Date: April 26, 2016, April 24, 2019

Next Scheduled Review Date: April 24, 2022

Approval: Amanda C. LaRue, Ph.D., Chairperson

Policy Statement:

To satisfy the Public Health Service (PHS) financial conflict of interest (FCOI) in research requirements for PHS-funded researchers, Charleston Research Institute and its Investigators will follow the Conflict of Interest policy established and enforced by the Medical University of South Carolina for all non-corporate funded grants or contracts. For all other grants or contracts, CRI will follow Ralph H. Johnson Department of Veterans Affairs Medical Center (RHJMC) Center Policy Memorandum No. 151-11-09 dated October 11, 2011 Conflict of Interest in Research Policy. The consequence of following MUSC's policy is adhering to the disclosure requirements.

Background:

The Department of Health and Human Services mandated implementation of "Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors" by August 24, 2012. The regulation includes implementation of new policies, procedures and training on financial conflict of interest.

The regulation is applicable to:

Each Institution that is applying for, or that receives, Public Health Service (PHS) research funding by means of a grant or cooperative agreement including subaward recipients.

Each Investigator who is planning to participate in, or is participating in, such research.

The regulation is for purposes of financial disclosure only and it covers the Investigator's spouse and dependent children.

RHJMC has adopted conflict of interest disclosure forms used by the Medical University of South Carolina (MUSC). The forms solicit the disclosure of all information required by the VA. (RHJMC Center Policy Memorandum No. 151-11-09 dated October 11, 2011 Conflict of Interest in Research Policy Section II. Part D).

The CPM also states that thresholds for disclosure of financial conflicts of interest in all cases will conform at least to the federal guidelines for Public Health Service (PHS) grants. (RHJMC Center Policy Memorandum No. 151-11-09 dated October 11, 2011 Conflict of Interest in Research Policy Section II. Part E. 2.)

Guidelines:

CRI Investigators are required to have a current (not older than 1 year) FCOI disclosure on file with the MUSC Conflict of Interest Office which also satisfies the PHS training requirement. MUSC employees will complete an online disclosure and non-MUSC employees will complete a paper disclosure.

Principal Investigators will also be required to acknowledge they understand all External Contributors to a proposed project must be in full compliance with the PHS FCOI regulations.

Definitions for Purposes of FCOI:

Institution: Any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for, or that receives, PHS research funding.

Investigator: The project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Financial Conflict of Interest: A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a PHS-funded research project and could directly and significantly affect the design, conduct or reporting of the PHS-funded research.

Significant Financial Interest (SFI):

In excess of \$5,000 – in aggregate over 12 months preceding disclosure

Remuneration received (consulting fees, paid authorship, pay outs from equity interests)

Equity interest in publically or non-publically traded entity (stock, stock options)

Intellectual property rights and interests (patents, copyrights)