MUSC
Medical University of South Carolina

I. Policy

A. Responsibilities and Ethical Principles

MUSC Institutional Review Boards for Human Research (IRB) shall provide ethical and scientific review and continuing oversight of the human subject's research of the MUSC and the VAMC. The IRBs shall operate in full compliance with all applicable federal, state, and local laws and regulations.

Research at MUSC is guided by the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, generally known as the "Belmont Report". Research with humans conducted at MUSC is subject to prospective IRB review and approval when the institution's employees or agents intervene or interact with human subjects; when the institution's employees or agents obtain individually identifiable private information about human subjects for the purposes of research and/or when the institution is the recipient of a federal award to conduct human research even if all human research activities are performed elsewhere.

The responsibility for the protection of the rights and welfare of human subjects is shared both by the institutions and the investigators who conduct the research.

B. Authority and Independence

1. Scope of Authority

The Medical University of South Carolina's (MUSC) Institutional Review Boards were established and empowered by the President of MUSC to act as the Institutional Review Boards (IRBs) for MUSC and the Ralph H. Johnson Veterans Medical Center (VAMC).

Specifically, the Institutional Review Boards have the authority to:

(a) Decide whether research submitted for review is human subjects research as defined by and subject to federal regulations;

(b) Review, and have the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research;

(c) Review and determine exempt status from 45 CFR 46.101 and 21 CRF 56.104;

(d) Suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants and report such violation and suspension to organizational officials;

(e) Conduct initial review and continuing review of approved research (not less than once per year), and reporting IRB findings to the investigator and the Institution;

(f) Determine which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review;

(g) Request audit by the University Compliance Office;

(h) Monitor the consent process;

(i) Require timely progress reports from investigators; and

(j) Report to the Office of Human Research Protections (OHRP) and, if applicable, the local district Food and Drug Administration (FDA) (21 CFR 56.108b) any significant or material finding or action, including:

1. Unanticipated problems involving risks to subjects or others;

2. Serious or continuing noncompliance with federal regulations or IRB requirements; and

3. Suspension or termination of IRB approval.

In exercising this authority, the MUSC IRBs shall communicate all decisions regarding human-subjects research and clinical investigations to investigators and to the Institution through the MUSC Office of Research Integrity (ORI) and the VAMC Research and Development Office.

2. Independence

The MUSC IRBs shall exercise independence as the entities authorized to oversee human-subjects research for MUSC and

VAMC. Consistent with federal regulation (45 CFR 46.112 and 21 CFR 56.112), research that has been reviewed and approved by the IRB may be subject to further review and disapproval by organizational officials. As well, the VA Associate Chief of Staff for Research may choose to undertake additional review of any or all VA associated studies as they come through the IRB review process. The Associate Chief of Staff or the VA Research and Development Committee may disapprove any VA associated study, even if the IRB has granted approval. No one, however, may approve research if it has been disapproved by the IRB.

Ralph H. Johnson VAMC Research and Development administrative officials including, but not limited to the Associate Chief of Staff for Research and development (ACOS) and the Administrative Officer to the Associate Chief of Staff for Research (AO/ACOS) are prohibited from serving as voting members of the IRB.

Principal Investigators have the right to appeal the IRB's decision in writing to the Chair; the Administrator will place the item on the next available agenda for full Board discussion and vote. The PI will be asked to attend the meeting to provide information and address the Board's concerns.

3. Undue Influence

Anyone who has concerns about undue influence or coercion (e.g., someone outside of the IRB seeks to influence the outcome of the IRB review of a research activity) should report these concerns to the IRB Program Director, IRB Chair, the Organizational Officials or to the University Compliance Officer. If the concern is related to the IRB Program Director, IRB Chair, or Organizational Officials, the reports should go to the University Compliance Officer. Concerns regarding the University Compliance Officer should be reported directly to the University General Counsel. Anonymous concerns may also be reported to the University Compliance Hotline.

Concerns regarding undue influence or coercion shall be documented. Appropriate University Officials will promptly investigate any reports and report their findings to the ORI Director, IRB Program Director, and/or other Organizational Officials. Immediate steps shall be taken, as necessary, to remedy any concerns or to take remedial actions as necessary based on the findings.

C. Memorandum of Understanding

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current “Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina’s Institutional Review Boards”.