

**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**

Effective Date: 4/26/05

PURPOSE

1. This Memorandum of Understanding (MOU) sets forth the agreement between the Ralph H. Johnson VA Medical Center (VAMC) and the Medical University of South Carolina (MUSC) concerning the Ralph H. Johnson VAMC's utilization of MUSC's Institutional Review Board(s) (IRB).
2. No other divisions or services of the Ralph H. Johnson VAMC or MUSC are otherwise modified pursuant to this MOU.

SHARED INSTITUTIONAL REVIEW BOARD

1. Under this MOU, the Ralph H. Johnson VAMC shall be granted the full use of MUSC's IRB until such time as this MOU may be rescinded. The research activities of the Ralph H. Johnson VAMC shall be supported through MUSC's IRB.
2. For purposes of filing human subjects protection assurances with the Office of Human Research Protections (OHRP), Department of Health and Human Services (DHHS), each institution shall file its own Federal Wide Assurance (FWA). The MUSC IRB(s) shall be registered with OHRP. The Ralph H. Johnson VAMC shall designate the MUSC IRB(s) as the "IRB(s) of record" on their FWA.

GENERAL PROCEDURES

1. The MUSC IRB(s) shall perform all the functions required under 38 CFR 16 (Common Rule) for reviewing and approving human subjects research conducted under the auspices of the Ralph H. Johnson VAMC's FWA. This includes but is not limited to, research supported by the VA or conducted at a VAMC facility, and research involving VA patients as research subjects [hereafter "VA research"].
2. MUSC's IRB Standard Operating Procedures (SOP) shall incorporate either through inclusion or reference, every VA procedure applicable to reviewing and approving VA research protocols. Relevant VA documents shall be readily available to the MUSC IRB for guidance. The Ralph H. Johnson VAMC shall

follow MUSC SOP's regarding the protection of human subjects in research except where noted in the VA R&D SOP's.

3. All human research conducted by the Ralph H. Johnson VAMC will receive approval or exemption from review by MUSC IRB(s) and the Ralph H. Johnson VAMC R&D Committee prior to enrolling subjects.
4. Representatives of the MUSC Dean's Committee will sit on the Ralph H. Johnson VAMC R&D Committee as required by VHA Handbook 1200.5 and M-3, Part 1, Chapter 2.02.
5. MUSC IRB(s) agrees to assist, as requested, in the accreditation of the Ralph H. Johnson VAMC Human Research Protection Program (HRPP) with the National Committee for Quality Assurance (NCQA).

COMPOSITION AND EDUCATION

1. MUSC IRB(s) voting membership shall adequately represent VA interests, by the inclusion of at least two (2) Ralph H. Johnson VAMC employees per board, as required by VHA Handbook 1200.5
2. The Ralph H. Johnson VAMC employee members of the MUSC IRB(s) shall meet all training and certification requirements for IRB membership. Training and educational opportunities normally offered to IRB members by MUSC shall be made available to the VA employee members of the IRB.
3. The Ralph H. Johnson VAMC staff shall provide continuing education about VA-specific requirements for human subject protection to all MUSC IRB members as needed.

IRB REVIEW

1. MUSC IRB(s) review and approval of VA research shall be conducted in accordance with 38 CFR 16, 45 CFR 46 Subparts A through D, 21 CFR 50 and 56 (where applicable), and all relevant academic affiliate policies and VA rules and policies as set forth in writing within VHA Handbook 1200.5 and M-3, Part 1.
2. All VA research protocols must include a VA- specific consent form (Form 10-1086). The consent form must conform to all VA requirements, including a VA-specific indemnification and notification clause. The consent forms must have the MUSC IRB(s) approval stamp on each page.

DOCUMENTATION

1. MUSC's Office of Research Integrity shall maintain all documents reviewed by its IRB(s) in connection with VA research protocols, including any communication with investigators, and make such documents available to the Ralph H. Johnson VAMC R&D Office upon request.

2. The MUSC IRB(s) minutes shall be forwarded to the Ralph H. Johnson VAMC R&D committee for consideration at the monthly meeting as required by VHA Handbook 1200.5.
3. Upon request, the MUSC IRB(s) shall make available to the Ralph H. Johnson VAMC R&D Office all research related materials, i.e. databases used to track study related materials, training information, etc., concerning VA research.
4. The Ralph H. Johnson VAMC R&D Office will cooperate and make available to the MUSC IRB(s) any documents or data needed in regards to activities of this joint HRPP.

REPORTING

1. MUSC's Office of Research Integrity and the Ralph H. Johnson VAMC R&D Office shall immediately report to the reciprocal office any noncompliance issues involving VA research of which it becomes aware, including but not limited to human subjects protection violations. Each office should notify the reciprocal office if and when an oversight agency or organization initiates any action regarding such noncompliance.
2. MUSC's Office of Research Integrity and the Ralph H. Johnson VAMC R&D Office shall immediately report to the reciprocal office any serious adverse event in research involving a VA patient of which it becomes aware. This reporting mechanism is in addition to, and does not replace, the investigator's duty to report adverse events as required by regulation, policy and procedure.
3. The VA/IRB Liaison will provide a report to the Ralph H. Johnson VAMC R&D Committee summarizing the decisions/actions associated with VA research activities for each convened IRB meeting.
4. The Ralph H. Johnson VAMC R&D Committee will inform the MUSC IRB(s) of any actions taken on active VA IRB protocols.
5. The Chair of the Ralph H. Johnson VAMC R&D Committee and the Chair(s) of the MUSC IRB(s) will communicate issues of mutual importance on a timely basis.
6. The VA/IRB Liaison shall make a separate report to the Ralph H. Johnson VAMC R&D Committee on an annual basis as required by VA regulations outlined in M-3, Part 1, Chapter 3. This report should summarize the functioning of the MUSC IRB(s) with respect to VA research and delineate any problems or potential problems therewith. A copy of this report shall be submitted to the MUSC IRB Chair(s).

OVERSIGHT

1. The Ralph H. Johnson VAMC Director is ultimately responsible for the HRPP afforded to the subjects at the Ralph H. Johnson VAMC.
2. MUSC IRB(s) will cooperate fully with the Ralph H. Johnson VAMC and make appropriate records available to regulatory and accrediting entities at such time as the HRPP of the Ralph H. Johnson VAMC is under review.
3. The Ralph H. Johnson VAMC reserves the right to revoke this MOU if the MUSC IRB(s) does not fulfill its obligations. MUSC also reserves the right to revoke this MOU. Six months written notice to the Ralph H. Johnson VAMC Director and/or the MUSC Provost must be provided to revoke this MOU.

The undersigned have read and agreed to all terms above. Full concurrence is required for this MOU to have legal effect.

William A. Mountcastle, CHE Date
Director
Ralph H. Johnson VAMC

John R. Raymond, MD Date
Vice President for Academic
Affairs and Provost, MUSC

M. Rita Young, PhD Date
ACOS/R
Ralph H. Johnson VAMC

Patricia Arford, PhD Date
Chair, IRB(s) I & II
MUSC

Robert J. Malcolm, MD Date
Chair, IRB III
MUSC