

**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: October 2, 2017

Purpose:

1. This Memorandum of Understanding (MOU) sets forth the agreement between the Ralph H. Johnson VA Medical Center (RHJVAMC) and the Medical University of South Carolina (MUSC) (collectively "the Parties"), concerning the agreed upon arrangements between the Parties for the use of MUSC's Registered Institutional Review Board(s) (IRB00000027, IRB00000028, & IRB00001377) (MUSC IRB) under the auspices of the RHJVAMC Federal Wide Assurance FWA00001591. MUSC functions under FWA00001888.
2. No other divisions or services of the Ralph H. Johnson VAMC or MUSC are otherwise modified pursuant to this MOU.

General Agreement:

1. The MUSC Federalwide Assurance (FWA) indicates that the institution does not apply federal requirements to all human research conducted under the auspices of the MUSC. The MUSC IRB agrees that all VA research is federally conducted or supported and that the IRB must apply all VA and federal requirements in review and oversight of all VA research.
2. The Parties have and will maintain Office for Human Research Protections ("OHRP") approved FWAs. The Parties agree to abide by the Health Insurance Portability and Accountability Act ("HIPAA") and its implementing regulations, and any additional VA specific regulations and policies consistent with the Code of Federal Regulations ("CFR") as are published in VA Directives and Handbooks. The areas in which VA specific regulations and policies impose these additional requirements or guidelines are generally referenced in the body of this MOU.
3. The Parties acknowledge that the VA Facility Director (Institutional Official) (IO) is the individual legally authorized as Signatory Official to commit an institution to an Assurance. The IO serves as the official representative of the institution to

external agencies and oversight bodies, and provides all written communication with external departments, agencies, and oversight bodies. MUSC IRB agrees to provide sufficient information to allow the VA Facility Director to report promptly to external agencies concerning VA research events.

4. The IRB will perform regulatory oversight required under 38 CFR Parts 16 and 17, The Common Rule in 45 CFR Part 46 Subparts A-E; 21 CFR Parts 50 and 56; any other pertinent federal regulations and guidance; and VA Handbook 1200.05 and VHA Handbook 1058.01 for human subjects research conducted under the RHJVAMC FWA. This includes research:
 - a. Utilizing VA resources or facilities including space leased or used by VA under written sharing agreements;
 - b. Involving VA patients, including use or disclosure of their medical information or PHI; or
 - c. Conducted by VA employees on VA time, including part-time staff, without compensation employees (WOC), and/or Intergovernmental Personnel Appointees (IPAs).
5. The Parties will each have and maintain a current FWA and promptly notify the other of any modifications to, or changes in, the status of the FWA. VA will prohibit involvement of VA investigators in any collaborative effort with any institution that does not have an FWA or other assurance acceptable to the Executive Director, Office of Research Oversight (ORO).
6. Where the RHJVAMC uses the services of the VHA Central Office IRB, or other external IRB for oversight of selected human research, the MUSC IRB acknowledges that it has no jurisdiction or oversight of such VA research.

RHJVAMC Agrees:

1. To adhere to the federal regulations as codified in the Common Rule 38 CFR Parts 16 and 17, 21 CFR Parts 50 and 56, 45 CFR 46 subparts B-E if applicable to VA research, HIPAA regulations in 45 CFR Parts 160 and 164, and any other pertinent federal regulations and guidance. All VA policies apply, and the VA cannot waive any policy requirements.
2. To grant authority to the MUSC IRB to review, approve, require modifications to secure approval, disapprove, suspend, or terminate approval of research, and to observe, or designate a third party to observe, the informed consent process.
3. To ensure that the Research and Development ("R&D") Committee considers the MUSC IRB review, prior to granting final approval in the conduct of VA human subjects research and that no such research will be conducted without R&D Committee and MUSC IRB approval, or determination by MUSC IRB that the

activity is exempt from IRB review. All research approved by the R&D Committee is considered VA Research.

4. To supply to MUSC IRB copies of any new documents pertaining to new VA requirements described in Veteran's Administration ("VA") directives or handbooks concerning human subjects protections.
5. To notify MUSC IRB promptly of any report of complaints from subjects or others, serious adverse events (whether anticipated or unanticipated, whether related or unrelated to the research), unanticipated problems involving risks to subjects or others, suspensions or terminations pertaining to VA research; and apparent serious or continuing noncompliance encountered in VA research.
6. To notify MUSC IRB of the results of any regulatory actions and/or inspections conducted by any oversight agency involving the Human Research Protection Program ("HRPP") at the RHJVAMC conducted by the Office of Research Oversight ("ORO"), OHRP, Food and Drug Administration ("FDA"), or other federal research oversight entities.
7. To cooperate fully with MUSC IRB, to the extent permitted by applicable law, in the event that MUSC IRB or RHJVAMC is subject to an audit, inspection, or evaluation by any authorized oversight agency or accrediting organization involving human research subjects issues including without limitation OHRP, ORO, FDA, and the VA Office of Inspector General (OIG).
8. To develop and maintain Standard Operating Procedures (SOPs) that detail how compliance monitoring, audits, and reporting to appropriate regulatory authorities will be handled by administrative official(s), compliance officers, and MUSC IRB and its administrators, and to provide the results of any external monitoring or audits of research activity to MUSC IRB. To work with MUSC IRB to develop and maintain mutually acceptable policies for monitoring human subjects research, and for providing regular communication of results of this monitoring, and other documentation of human subjects research, and to establish a description of the method and frequency of providing information including minutes, correspondence, and reports of quality improvement activities to the R&D Committee.
9. To assure MUSC IRB that all key VA personnel engaged in research meet both the VA and IRB training requirements and to maintain an adequate system for tracking such training.
10. To appoint at least two designated VA primary members to each MUSC IRB that reviews VA research, and alternates where possible. The VA representatives:
 - a. Must have a VA-salaried appointment (not Without Compensation (WOC) or Intergovernmental Appointment (IPA));

- b. At least one must have scientific expertise, per board;
 - c. Must be full voting MUSC IRB members on all full board reviewed protocols; and
 - d. At least one must be present during full board review of VA human subjects research.
11. To submit IRB membership changes to ORO within 30 days of a change. Work with MUSC to ensure VA alternates serve as required by VHA Handbook 1200.05.
12. The RHJ VAMC R&D Manager will provide a report to the RHJ VAMC R&D Committee monthly summarizing the decisions/actions associated with VA research activities for each convened MUSC IRB.
13. The VAMC R&D Manager, VA Research Compliance Officer, in conjunction with the Director of the MUSC Office of Research Integrity, will make a separate report to the RHJVAMC R&D Committee on an annual basis as part of the R&D Committee assessment of the MUSC IRB as required in VA Handbook 1200.01. The MUSC IRB will receive a copy of this report. The report will assess the following:
- a. The qualifications and experience of a new MUSC IRB Chair.
 - b. The appropriateness of MUSC IRB and IRB membership, given the research being reviewed, and compliance with 38 CFR 16.107 concerning IRB membership.
 - c. That MUSC IRB includes representatives, either as members or ad hoc consultants, interested in or who have experience with vulnerable populations involved in research and to supplement MUSC IRB's expertise in specific research areas.
 - d. The adequacy of MUSC IRB's policies and procedures.
 - e. Volume and type of human subject research reviewed.
14. To track all research disclosures in accordance with HIPAA regulations, 45 CFR 164.528 and to ensure that research is conducted in compliance with HIPAA regulations. Authorizes MUSC IRB to review HIPAA authorizations for use and disclosure of protected health information (PHI) and requests for waiver of authorization.
15. To provide information to MUSC IRB about significant issues discussed during the VA approval process that might affect the conduct of a protocol.
16. To provide access and training to MUSC IRB members regarding VA policies and procedures that govern the VA HRPP processes and determinations.
17. To provide and facilitate the use of the VA Form 10-1086 for obtaining and documenting informed consent for all VA Research, and to ensure that no human

subjects are involved in research prior to obtaining consent. To assure that VA specific language for indemnification and notification is used.

18. VHA employees conducting or reviewing research are subject to the Federal Criminal Code and the Standards of Ethical Conduct for Executive Branch Employees. The obligation to act in accordance with ethics laws and regulations applies to all individuals while acting under a VA appointment, including full and part-time employees, without compensation (WOC) employees, and employees under the Intergovernmental Personnel Act (IPA) of 1970. Ethics officials in the VA Office of General Counsel are available to provide guidance on dealing with actual or potential conflicts of interest. RHJVAMC will establish a documented process to identify and manage conflicts of interest for RHJVAMC investigators and to advise MUSC of that process and will adhere to MUSC IRB requirements regarding reporting conflicts of interest for MUSC IRB members and investigators.
19. To notify MUSC IRB regarding the scheduling of, and participation in, the HRPP Accreditation Program sponsored by the VA and the outcome of the accreditation.
20. To provide MUSC IRB with complete and timely notification of information needed to support the HRPP for accreditation, including an agreement about scheduling the application submission and on-site survey, and specifying the appropriate communication channels.
21. To provide the IRB access to all relevant investigator records (including data files, regulatory files/binders, case report forms, sponsor queries, internal and external monitoring reports, and audit reports); research subjects' clinical and research records or case files; and facility research records (including sponsor agreements), as required for oversight and monitoring of research activity. This access will be provided to any individual(s) designated by the IRB.
22. To actively cooperate with MUSC IRB in resolving any problems encountered in either HRPP.
23. VA will comply with the provisions of, VHA Handbook 1605.01 §13, and VA Handbook 6500 with respect to reporting to the VAMC Privacy Officer of any unauthorized use, loss, or disclosure of individually-identifiable patient information of which it becomes aware. Collaborate with MUSC IRB to establish written procedures.
24. VA will comply with the provisions of VA Handbook 6500.2 with respect to reporting to the VAMC Information Security Officer of any violations of VA information security requirements of which it becomes aware. Collaborate with Affiliate IRB to establish written procedures.

MUSC Agrees:

1. To provide MUSC IRB services for review and regulatory oversight of human subjects research protocols to be conducted at the RHJVAMC to include the review of VA Form 10-1086 Consent Form. The only exception to this will be for VA human subjects research protocols conducted under the oversight of the VHA Central Office IRB or other external IRBs used by RHJVAMC.
2. That MUSC may not delegate or assign IRB review of VA research to any MUSC IRB panel or external IRB used by MUSC not designated on the VA FWA or that has no VA membership.
3. To adhere to MUSC IRB membership requirements as described in their policy and procedure manual and to appoint and maintain on each MUSC IRB two or more RHJVAMC salaried employees that RHJVAMC has designated as its primary MUSC IRB delegates and alternates if possible. The VA representatives:
 - a. Must have a VA-salaried appointment (not Without Compensation (WOC) or Intergovernmental Appointment (IPA));
 - b. At least one must have scientific expertise, per board;
 - c. Must be full voting MUSC IRB primary members on all full board reviewed protocols; and
 - d. At least one must be present during full board review of VA human subjects research.
4. To provide VA facility and VHA Office of Research Oversight (ORO) access for review and copying to any IRB or other records, documents, or reports relevant to compliance reviews of research conducted or supported by VA, approved by the VA facility's R&D Committee, or involving individuals with VA appointments. Provide hard copy and other access to electronic database records to approved VA representatives for purposes of tracking ongoing VA research.
5. To develop and maintain mutually acceptable policies for monitoring human subjects research, and for regular communication of results of this monitoring, and other documentation of human subjects research to the R&D Committee; and to work with RHJVAMC to establish a description of the method and frequency of MUSC IRB providing information including minutes, correspondence, and reports of quality improvement activities to the R&D Committee.
6. To provide copies of essential communications with investigators concerning RHJVAMC approved protocols to the R&D Committee, including approval and renewal letters, and suspension letters.
7. To develop and maintain a mutually acceptable MUSC IRB Policies and Procedures ("P&P") Manual where federal, and RHJVAMC-specific human subject protection documents and SOPs are referenced and are made available.

The P&P Manual shall incorporate, either by inclusion or reference, VA policies and procedures applicable to reviewing and conducting oversight of VA human subject research.

8. To cooperate fully, to the extent permitted by applicable law, in the event that MUSC IRB or RHJVAMC is subject to an audit, inspection, or evaluation by any authorized oversight agency involving human research subjects issues including without limitation OHRP, ORO, VHA Office of Research and Development (ORD), FDA, and VA OIG.
9. To develop and maintain P&Ps that detail how compliance monitoring, audit, and reporting to appropriate regulatory authorities will be handled by administrative official(s), compliance officers, and MUSC IRB and its administrators, and to report the results of any external monitoring or audits of research activity at MUSC that involve any unanticipated problems involving risk to subjects or any serious or continuing non-compliance and impact upon VA research or the status of the RHJVAMC HRPP. This includes visits by sponsors and regulatory/compliance bodies.
10. To review VAMC HIPAA authorizations for use and disclosure of protected health information (PHI) and waivers for the requirement of authorization in accordance with HIPAA regulations, 45 CFR 164.512(l), and to ensure that VA research is conducted in compliance with the HIPAA regulations. The IRB will ensure the VA HIPAA authorizations contain the VA required language (use of VA Form 10-0493, HIPAA authorization). The VA ISO and PO will provide their feedback at this point.
11. To maintain RHJVAMC human subject research records as required by VA RCS 10-1 records management policy following project termination, to provide RHJVAMC ready access to these records for reviewing and/or copying, and to consult with RHJVAMC and transfer such records to the facility if requested, before destruction of any records maintained by MUSC IRB.
12. To promptly inform RHJVAMC of any complaints from subjects or others; unanticipated problems involving risks to subjects or to others; serious adverse events (whether anticipated or unanticipated; whether related or unrelated to research); suspension or termination of activities; or continuing noncompliance encountered in VA human subjects research. Provide the VA with information needed to fulfill the facility's reporting requirements under VHA Handbook 1058.01.
13. To ensure that all MUSC IRB members have received the appropriate training as outlined in the P&P Manual and to facilitate training on applicable VA policy.

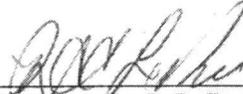
14. To provide training to VA staff and investigators as appropriate for compliance with MUSC IRB policies and submission procedures as they apply to VA submissions.
15. To maintain a current IRB Registration with OHRP. MUSC will notify the RHJVAMC of changes to the IRB rosters to allow RHJVAMC to comply with reporting requirements in VHA Handbook 1058.03 for reporting IRB membership to ORO within 30 days of a change. MUSC also agrees to maintain FDA-required information in the IRB Registration as mandated by 21 CFR 56.106 .
16. To be aware that RHJVAMC may not collaborate with institutions that do not have FWAs or other assurances acceptable to the Executive Director, VHA Office of Research Oversight.
17. To require the use of VA Form 10-1086 as the informed consent form for all VA human subjects research that includes VA specific language for indemnification and notification of subjects.
18. To advise RHJVAMC of requirements for reporting conflict of interest for MUSC IRB members and investigators. To advise the RHJVAMC of any issues that occur. To work with the RHJVAMC to ensure that both VA and MUSC requirements for investigator or IRB member reporting of financial conflict of interest are addressed, and to advise the RHJVAMC of any issues that occur.
19. To allow RHJVAMC R&D Committee access as required by VHA Handbook 1200.01 for review of the MUSC IRB. Assessment includes but is not limited to:
 - a. The qualifications and experience of a (new or existing) MUSC IRB Chair.
 - b. The appropriateness of MUSC IRB and IRB membership, given the research being reviewed for the RHJVAMC and the MUSC.
 - c. That MUSC IRB includes representatives, either as members or ad hoc consultants, interested in or who have experience with vulnerable populations involved in research and to supplement MUSC IRB's expertise in specific research areas.
 - d. The adequacy of MUSC IRB's policies and procedures.
 - e. Volume and type of human research reviewed.
20. To notify the VAMC of any changes to the status of the MUSC IRB accreditation.
21. To actively cooperate and provide timely access to staff, MUSC IRB members, files and records needed by the accrediting body to support RHJVAMC accreditation application submission and on-site survey.

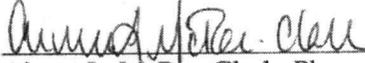
22. To actively cooperate with RHJVAMC in resolving any problems encountered in either HRPP.
23. To comply with the provisions of VHA Handbook 1200.05, VHA Handbook 1605.1 and VHA Handbook 6500 with respect to reporting to the RHJVAMC Privacy Officer of any unauthorized use, loss, or disclosure of individually-identifiable patient information of which it becomes aware. MUSC further agrees to establish written procedures for such reporting.
24. To comply with the provision of VHA Handbook 1200.05 with respect to reporting to the RHJVAMC Information Security Officer of any violations of VA information security requirements of which it becomes aware. MUSC further agrees to establish written procedures for such reporting.

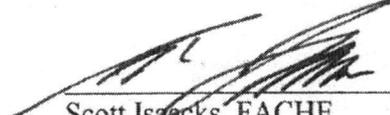
Term of Agreement:

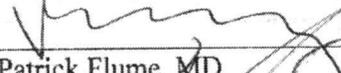
The term of this Agreement shall be three (3) years from the effective date of this Agreement and must be renewed timely to avoid lapse. This Agreement may be modified or amended with a written amendment signed by both parties. Either institution may terminate this Agreement at any time on 60 days written notice of intent to terminate the agreement to the other, delivered by hand or registered mail to the Institutional Official signing this agreement or such other individual as specified in writing. In the event a decision is made to terminate this agreement, MUSC agrees that MUSC IRB oversight of VA research will continue until all research is transferred to the oversight of another IRB or safely terminated so as not to harm human subjects or put them at risk. This MOU may be modified to describe the process and timetable for such transfer of oversight.

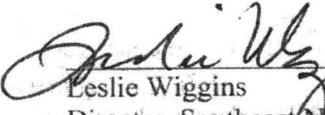
The undersigned have read and agree to all terms of this Agreement. Full concurrence is required for this Agreement to have legal effect.


 R. Amanda C. LaRue, PhD Date 09/18/17
 ACOS/R, Ralph H. Johnson VAMC


 Aimee L. McRae-Clark, PharmD, BCPP Date 9/20/17
 Director, Office of Research Integrity,
 MUSC


 Scott Isaacks, FACHE Date 9/25/17
 Director, Ralph H. Johnson VAMC


 Patrick Flume, MD, Date 9/27/17
 Associate Provost for Research, MUSC


 Leslie Wiggins Date 10/6/17
 Director, Southeast Network VISN 7


 Kathleen Brady, MD, PhD Date 9/23/17
 Vice President for Research, MUSC

References:

- VHA Handbook 1200.01 – Research and Development Committee
 - VHA Handbook 1200.05 – Requirements for Protection of Human Subjects in Research
 - VHA Handbook 1058.03 – Assurance of Protection for Human Subjects in Research
 - VHA Handbook 1058.01 –Research Compliance Reporting Requirements
 - VHA Directive 1605.01 – Privacy and Release of Information
 - VHA Handbook 6500 – Risk Management Framework for VA Information Systems –Tier 3: VA Information Security Program
 - RHJVAMC HRPP CPM 151-11-07
 - RHJVAMC Research Quality Manual
 - MUSC IRB/VA Investigator’s Manual
 - MUSC IRB Policies and Procedures
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