



Policy Name: Description, Principles and Authority for MUSC HRPP			
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I. OVERVIEW

The mission of the Medical University South Carolina (MUSC) is to achieve excellence in patient care, education, and research, in an environment that is respectful of others, adaptive to change and accountable for outcomes. Human subjects research is an important element in meeting this mission. The University has established policies, procedures, and programs for the review of human subject research to promote the ethical conduct of research, safeguard the integrity of and protect human subjects and maintain strict compliance with regulatory standards. MUSC investigators are granted the privilege of using human subjects under assurance to the government that research conducted at MUSC complies with all federal and local regulations protecting individuals involved in human subjects research.

MUSC operations abide by the Federal Policy for the Protection of Human Subjects (the Common Rule) and the principles outlined in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Declaration of Helsinki, the Nuremberg Code, and the VA Handbook 1200.5. The ethical conduct of research on human subjects is an essential component of our research mission and the rights and welfare of all persons participating in research are vigorously protected.

MUSC has a long-standing human research protection program and human subjects research program that includes our General Clinical Research Center (GCRC) first funded by the National Institutes of Health in 1977. The GCRC has long been a focal point for stimulating, facilitating and conducting multidisciplinary clinical and translational research.

All human research studies operate under the auspices of a campus-wide Human Research Protection Program (HRPP) with oversight and management from the Office of the President of MUSC through the Associate Provost and the Vice President for Academic Affairs/Provost as the responsible organizational officials for its operation. Individual elements of HRPP operation include the following:

- a) education and training of all personnel involved in human subject research (Researchers and research staff, IRB members and IRB staff);

- b) submission and review of human subject research protocols by independent review committees (Institutional Review Boards) with required expertise and community representatives;
- c) human subject outreach, communication and education;
- d) financial management and review;
- e) risk management;
- f) research integrity;
- g) conflict of interest disclosure and management;
- h) clinical services and investigational drug pharmacy;
- i) community outreach and engagement;
- j) monitoring of all approved human subject research; and
- k) quality improvement programs.

We have a number of programs in place to educate and reach out to the community on human subjects research and mechanisms are in place to allow human subjects to voice complaints, issues, concerns and suggestions providing ongoing connectivity and mechanisms for quality improvement (see HRPP Program Guide Section 6.4 – Subject Complaints, Issues, Concerns and Suggestions Policy and Procedures and Section 9.3 – Quality Improvement Initiatives)

These individual elements blend to form a system that is robust, interactive and constantly improving with the ability to adapt and address any issue in a prompt and transparent process.

MUSC is committed to providing the best possible program for protection of human research subjects under the auspices of our institutional wide HRPP to ensure the allocation of necessary resources, continued oversight and compliance and to nurture these programs for the benefit of human subject participants and society.

II. TYPES OF HUMAN SUBJECTS RESEARCH CONDUCTED AT MUSC

MUSC has 1060 active research projects involving human subjects in the biomedical, behavioral sciences, social sciences and medical economics and may encompass Phase 1 through Phase IV Medication Trials. These studies are conducted by one of approximately 456 active principal investigators (MD, PhD, PharmD, DDS and/or RN). Surgical studies involving innovative therapies, device trials, and organ transplantation are also conducted at MUSC. The MUSC Tissue Bank also serves as a repository for human samples for various research projects.

Funding Source	Review Type			
	Full	Expedited	Exempt	Not Human Research Determination
Federal	210	90	36	Funding Information Not Required
Foundation Philanthropy	38	57	6	
Health Agency	2	0	0	
Industry	250	37	6	
MUSC	26	30	54	
No Sponsor	92	148	181	
State	67	44	73	
Other	4	4	1	
Total Initial Review Protocols	689	410	357	

In FY08, total extramural research funding to MUSC was \$202M with \$101M from the National Institutes of Health. Of the \$202M, ~72% is federal funding and ~16% is corporate funding. ~25% of federal funding and ~87% of corporate funding involves human research protocols submitted to the IRB. The majority of human research studies operate under the oversight of the Department of Health and Human Services and the Food and Drug Administration.

The categories of study participants include adults with normal decision-making capacity, adults with impaired decision making capacity, pregnant subjects, children, prisoners, employees and students. No categories of human subjects are specifically excluded. Special oversight mechanisms are in place for the review and monitoring of studies with vulnerable populations (Section 3.2 – Vulnerable Subject Populations).

III. REGULATORY GUIDELINES AND ASSURANCES

The MUSC human subjects research program operates under a Federal Wide Assurance (FWA #00001888) from the Office for Human Research Protections (OHRP).

MUSC becomes engaged in human research whenever (a) the Institution’s employees or agents intervene or interact with human subjects for purposes of federally-conducted or –supported research; (b) the Institution’s employees or agents obtain individually identifiable private information about human subjects for purposes of federally-conducted or –supported research; or (c) the Institution receives a direct federal award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

MUSC is the University Affiliate IRB for the Ralph H. Johnson Veterans Affairs Medical Center (VAMC). The VA operates under FWA #00001591. The specific guidelines and governance articulating the operational agreement are described

in the Memorandum of Understanding between MUSC and Ralph H. Johnson VAMC concerning the Utilization of MUSC's Institutional Review Boards.

All research involving human subjects at MUSC must comply with all Federal Regulations and requirements that address the protection of human subjects, including Regulations and requirements that address the protection of human subjects, including 21 Code of Federal Regulations (CFR) Parts 45, 50, 56 and all related policy and procedural documents (45 CFR) in accordance with the regulations and expectations of the Department of Health and Human Services and other organizations such as the Food and Drug Administration, the Veterans Administration (38 CFR, VA Handbook 1200.5) and the State of South Carolina as applicable. These regulations and requirements, along with approval of our Institutional Review Board, must be met before any research involving human subjects is initiated and adherence must be sustained throughout the conduct of research. The regulations specific for the Veterans Administration (38 CFR 16 and VHA Handbook 1200.5) guide all studies conducted at the Ralph H. Johnson VA Medical Center in Charleston for which MUSC serves as the University Affiliate for the IRB.

All individuals involved with human subjects research at MUSC are required to complete training prior to initiating any such research. MUSC is registered for training through the Miami Collaborative Institutional Training Initiative or CITI (<http://www6.miami.edu/citireg/>). All individuals involved in human research must complete the initial 17 basic modules focused on biomedical or social/behavioral research when commencing such research. Beginning in 2008, all individuals involved in human research must also complete the MIAMI CITI COURSE REFRESHER MODULE 101 every three years providing a mechanism of continuing education. Additional training requirements are in place for VA investigators through the federal regulations described in the VA Handbook 1200.5.

IRB approval is required before commencing any human subjects research protocol and several mechanisms (see below) are in place to assure that this policy is followed.

Education and outreach

- 053 HRPP Guide Section 4.1 Principal Investigator Responsibilities - The section entitled "Supervision of Staff and Protection of Subjects" states that "No research will be initiated without prospective IRB review and approval".
- Human Subject Regulations Decision Charts are provided to assist investigators in determining whether an activity is research that must be reviewed and approved by the IRB.
- The IRB manager presents to research groups and research support teams on campus providing information on IRB operations and the requirement for IRB approval for human subject research.

- All investigators and staff involved in human subject research must complete specific training modules before commencing research.
- Core Clinical Research Training – A two week course for investigative teams that covers human research policies and procedures Including the requirement for IRB approval before commencing any human subjects research protocol.
- Mentoring - Students and trainees involved in human subject research are assigned mentors familiar with IRB operations.
- Faculty Research Orientation - Provides information to new faculty on policies and procedures for human subject research.
- South Carolina Clinical and Translational Research Center - Staff with experience in human subject research policies and procedures provide support and guidance for research teams.

Operational

- The Principal Investigator, the Department Chair and the Mentor if applicable must all sign the human research protocol submitted to the IRB before it is reviewed.
- The General Clinical Research Center requires IRB approval on all human subjects research protocols prior to beginning research.
- The signature of the Associate Provost for Research is required for non-funded human subject research studies.
- For industry-sponsored human subjects research, the Office of Research and Sponsored Programs and the Office of Research Integrity review the IRB-approved informed consent and the contract to validate consistency prior to release of funds for expenditure.
- IRB approval is required for expenditure of research funds awarded in support of human subjects research.
- Investigative Drug Services requires IRB approval prior to releasing the study drug.
- Human subjects research involving cancer requires approval by Hollings Cancer Center Protocol Review Committee prior to release of IRB approval.
- For human subjects research involving non-routine radiation, approval by the Office of Radiation Safety approval is required prior to release of IRB approval.
- For human subjects research involving biohazardous material, approval by the Institutional Biosafety Office is required prior to release of IRB approval.
- The Research and Development Committee of the Ralph H. Johnson VA Medical Center, which reviews all human subjects research at the VA, requires IRB approval prior to commencing research.
- The University provides whistle-blowing protection to anyone who reports an activity that violates any regulations or policies related to human subjects research.

IV. AUTHORITY AND ORGANIZATIONAL STRUCTURE

The HRPP program involves all aspects of our operations at MUSC including research teams and their staff, the Office of Research Integrity, Institutional Review Boards, Office of Sponsored Research, Office of Grants and Contracts, Clinical Services, University General Counsel, the Office of Compliance and many other aspects of our organization. The overall organizational structure for these offices is indicated in the organizational charts provided as MUSC Organizational Charts (HRPP Program Guide Section 1.2).

President Ray Greenberg is recorded as the Institutional Official on the FWA and he has appointed the Associate Provost (Stephen M. Lanier, Ph.D.) and the Vice President for Academic Affairs/Provost (John R. Raymond, M.D.) as the responsible organizational officials for the operation of the MUSC HRPP. These three individuals form the leadership core for the University and have offices adjacent to each other facilitating communication. The active involvement of senior administration ensures that adequate resources are provided to operate an effective HRPP. The description of the Individual elements of the HRPP and their interaction is described in the following text.

Associate Provost for Research and Vice President of Academic Affairs and Provost - Serve as the Responsible Institutional Officials for administration and oversight of the HRPP. The Associate Provost for Research serves as the coordinating individual for the HRPP and meets regularly with Directors of each component of the HRPP. In the office of the Associate Provost for Research, Loretta Lynch-Reichert, M.S. and Lynn M. Veatch, Ph.D. facilitate connectivity among the multiple components of the HRPP program.

Office of Research Integrity - Responsible for review of all human research protocols for the Medical University of South Carolina and the Ralph H. Johnson VA Medical Center. This office serves as the administrative unit for the Institutional Review Board, the Institutional Biosafety Committee, the Institutional Animal Care and Use Committee and the Research Integrity Officer for scientific misconduct. The Office of Research Integrity developed a course "Core Clinical Research Training" that is now offered through our General Clinical Research Center for all research teams and coordinators involved in human research. Robert Malcolm, M.D. serves as the Director of this office and reports to the Associate Provost for Research. Dr. Malcolm meets weekly with the Associate Provost for Research.

Office of Research and Sponsored Programs – Responsible and institutional signatory authority for submission of sponsored research proposals. R. Darren McCants, MPA serves as the Director of this office and reports to the Associate Provost for Research. Mr. McCants meets weekly with the Associate Provost for Research.

Office of Grants and Contracting – Responsible for monitoring and reporting

financial information related to the University's externally sponsored grants and contracts. Velma G. Stamp, BS, serves as the Director of this office and reports to the Vice President of Finance and Administration. Velma Stamp meets monthly with the Associate Provost for Research.

University Compliance Office – Provides a proactive program to ensure full compliance with all applicable policies, procedures, laws and regulations while promoting ethical behavior in accordance with MUSC's core values as expressed in the MUSC Mission Statement and Code of Conduct. Reece H. Smith, MBA serves as the Director of this office and reports to the Vice President of Academic Affairs and Provost. Ms. Smith meets regularly with the Associate Provost for Research.

Investigative Drug Services – Supports clinical investigations conducted by scientists affiliated with MUSC by 1) randomization and blinding of study drug, 2) controlling drug inventory including performance of routine audits, 3) preparation and dispensing of oral and parenteral admixture study drugs, 4) in-service training for patients and staff. Kimberly Porter, R.PH is the lead Pharmacist and also serves on the IRB providing added connectivity.

South Carolina Clinical and Translational Research Institute (SCTR) – Facilitates cross-disciplinary research in translational research including support for development and management of human subjects research. SCTR includes the General Clinical Research Center, a specialized, JCAHO-accredited patient unit facilitating investigator-initiated, peer-reviewed, clinical research projects within the institution. Kathleen Brady, MD, Ph.D. serves as the Director of SCTR and the General Clinical Research Center and meets regularly with the Associate Provost for Research.

Office of Risk Management – Responsible for the prevention of harm, protection of assets and the financial resources of MUSC by affirming and assuring compliance with applicable statutory and regulatory codes. Wayne Brannan, CPHRM, CHSP, CBCP, ARM serves as the Director of this office and reports to the Vice President for Finance and Administration. Mr. Brannan meets regularly with the Associate Provost for Research.

Office of the General Council – Joseph C. Good, Esq. serves as General Counsel and reports to the President. Mr. Good also serves on the Research Conflict of Interest Review Committee and meets regularly with the Associate Provost for Research.

Community Outreach - In 1997, the Medical University of South Carolina launched a significant new effort referred to as the Healthy South Carolina Initiative with the goal of improving the health and well being of the community. Under this broad banner, 28 separate projects were funded to address particular health concerns with an emphasis on vulnerable populations. The Healthy South

Carolina Initiative (<http://www.musc.edu/hsci/index.html>) is under the direction of Marilyn A. Laken, Ph.D. R.N.

Research Conflict of Interest Committee - This committee reviews all conflict of interest disclosures related to research and is under the direction of Tom Higerd, Ph.D., Associate Provost for Institutional Planning. Dr. Higerd meets regularly with the Associate Provost for Research.

Research Subject Ethics and Advocacy - A number of resources are available for ethical issues related to patient advocacy are accessed through the Institute for Human Values at MUSC under the direction of Dr. Robert Sade (MUSC Institute on Human Values in Health Care) and the Research Subject Advocate program (Section 3.12 – Research Advocacy Policy and Procedures). As Director of the Office of Research Integrity and as a participant in the South Carolina Clinical and Translational Research Institute (SCTR), Dr. Robert Malcolm interacts with both initiatives. These areas of subject advocacy are also covered in the “Core Clinical Research Training” offered through SCTR.

Ralph H. Johnson VAMC - MUSC has a longstanding, close working partnership with the Ralph H. Johnson VAMC, which is adjacent to campus, with many of our physicians serving as VA staff. MUSC and the VAMC also share a ~100,000 sq ft research building and an increasing partnership on healthcare delivery. The VAMC research program is led by the Director John Barilich, MSW, MBA (Institutional Official for the VAMC FWA) and the Associate Chief of Staff/Research and Development M. Rita I. Young, Ph.D.

The current Vice President for Academic Affairs/Provost at MUSC is the former Associate Chief of Staff/Research and Development at the VAMC. The Associate Provost for Research at MUSC also serves on the board of the VAMC non-profit entity Charleston Research Institute and regularly interacts with Dr. Young for program development. MUSC is the University Affiliate IRB for the Ralph H. Johnson Veterans Affairs Medical Center (VAMC) and the two institutions run a joint Animal Laboratory Program. Additional connectivity within the context of the HRPP is also present through cross-training of staff in compliance and review at the two institutions.

V. HUMAN SUBJECTS RESEARCH REVIEW AND MONITORING

The Institutional Review Boards (IRBs) provide the primary review of all human research protocols and are organized under the Office of Research Integrity directed by Robert Malcolm, M.D, whom reports to the Associate Provost for Research. The Office of Research Integrity includes the Institutional Animal Care and Use Committee, the Institutional Biosafety Committee and the Research Integrity Committee. Additional internal review mechanisms are provided through Department Chairs, various mentoring groups, the Hollings Cancer Center Clinical Trials Office, our NIH-Supported General Clinical

Research Center and the South Carolina Clinical and Translational Research Institute.

Research involving Human Subjects must be reviewed by the MUSC IRB where one or more of the following apply:

- i. The research is sponsored by this institution, or
- ii. The research is conducted by or under the direction of an individual in connection with his/her institutional responsibilities, or
- iii. The research is conducted by or under the direction of an individual who is receiving remuneration from the institution, or
- iv. The research is conducted by or under the direction of an individual using any property or facility of this institution, or
- v. The research involves the use of this institution's non-public information to identify or contact human research subjects for prospective subjects, or
- vi. The institution's name is used in any way in connection with the study including procurement of sponsorship, announcement or advertisement or other recruitment of subjects.

The IRB(s) review, and have the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research. The decisions of the IRB in all matters relating to the protection of humans involved in research shall not be influenced by any outside entity, including institutional officials. Research that has been reviewed and approved by the IRB may be subject to further review and disapproved by officials of the institution. Institutional officials may not, however, approve research if it has been disapproved by the IRB.

There are currently three IRBs, each under the direction of a Chair and Vice-Chair, that focus on different areas of research and consists of faculty with appropriate expertise, community representatives and staff support as detailed in our governance document (see HRPP Program Guide Section 1.6 – IRB Governance and Operating Procedures Policy and Procedures). It is the responsibility of the IRB to safeguard the rights and welfare of human subjects who participate in research at MUSC including special protection for vulnerable participants. Procedures are in place to review the quality of human subjects research protocols (see HRPP Program Guide Section 1.4 – Scientific/Scholarly Review of Protocols Policy and Procedures) and these procedures include the review by the Department Chair, external peer review and various internal review mechanisms offered through individual units such as the General Clinical Research Center, the Hollings Cancer Center and the Clinical and Translational Research Program.

The three Institutional Review Boards focus on different areas of research within their scope of work. All three IRBs may review studies involving investigational drugs and devices, questionnaires and surveys or behavioral modification. Each of the IRBs may have expedited studies that include retrospective chart reviews,

blood draws, prospective collection of biological samples by non-invasive procedures, and research involving materials collected for nonresearch purposes.

IRB-I - IRB-I currently has approximately 626 active protocols involving human subjects (427 Full Board and Expedited, 199 Exempt). IRB-I reviews protocols from Biostatistics, Bioinformatics & Epidemiology, Cell Biology and Anatomy, Cell and Molecular Pharmacology & Experimental Therapeutics, Clinical Services, College of Health Professions, College of Nursing, College of Pharmacy, Harper Student Life Center, Dermatology, Medical Lab Sciences, Otolaryngology, Pathology and Laboratory Medicine, Pediatrics, Pharmaceutical Sciences, Pharmacy Practice, Physical Therapy, Physiology, Psychiatry and Behavioral Sciences, Radiology, and Urology.

Psychiatry protocols may involve cognitively impaired subjects, subjects with addictions to alcohol, illegal drugs and/or nicotine, schizophrenic, and depressed subjects. The second largest volume of work for IRB-I involves pediatric studies related to cancer, cardiology or neonatology. IRB-I also has active protocols involving the prisoner population. Such protocols receive review by the prisoner representative on the IRB membership roster and follow the certification procedures outlined in the federal regulations.

IRB-II - IRB-II has approximately 543 active protocols (389 - Full Board and Expedited, 154 - Exempt) from Anesthesiology, Biochemistry and Molecular Biology, the Center For Health Care Research, College of Graduate Studies, Experimental Oncology, Family Medicine, General Dentistry, Materials Science, Medicine, Microbiology and Immunology, Molecular and Structural Biology, Neuroscience, Obstetrics and Gynecology, Ophthalmology, Oral & Maxillofacial Surgery, Orthopedic Surgery, Pediatric Dentistry/Orthodontics, Physical Medicine & Rehabilitation, Prosthodontics, Radiation Oncology, Stomatology, and Surgery.

Human subject research protocols include investigational drug cancer trials, digestive disease studies and transplant surgery. Protocols may include vulnerable populations (i.e. pregnant subjects, cognitively impaired from stroke).

IRB-III - IRB III has approximately 287 active protocols (283 - Full Board and Expedited, 4 - Exempt) and reviews all corporate sponsored studies. Protocols may include vulnerable populations (i.e. children, pregnant women, cognitively impaired).

The MUSC FWA also includes the use of the National Cancer Institute Central IRB #1 (IRB00000781) for adult protocols, the National Cancer Institute Central IRB #2 (IRB00004296) for pediatric protocols and Western Institutional Review Board (IRB00000533) for selected multi-site clinical trials as needed or defined for specific studies. We currently have 39 protocols approved and 5 under review by the National Cancer Institute Central IRB #2. We also began using the

NCI Central IRB for adult Phase III clinical trials in the fall of 2008. VA studies reviewed by the MUSC IRBs cannot use a central IRB, although a central VA IRB is currently being developed.

The Policy and Procedures for Governance of the Institutional Review Board (IRB) (see HRPP Program Guide Section 1.6 – IRB Governance and Operating Procedures Policy and Procedures) detail operational elements so crucial for an effective review and management of human subjects research. Records and documentation of all activities indicate the implementation of the policies and procedures and ensure effective operation of review and management process. HRPP Program Guide Section 1.3 – Definitions of Terms, defines all terminology used throughout the MUSC HRPP, ensuring consistency of application throughout the various components of the plan.

The principal investigator (PI) is the ultimate protector of the human subjects who participate in his/her research and is expected to abide by the highest ethical standards (see HRPP Program Guide Section 4.1 – Principal Investigator Responsibilities – Supervision of Staff and Protection of Subjects). The PI is responsible for developing a protocol that incorporates the principals of the Belmont Report. He or she is expected to conduct the research in accordance with the approved protocol and to oversee all aspects of the research, including supervision of the research support staff, students, post-doctoral fellows, residents, and other staff involved in the project. The PI is responsible for ensuring that all subjects give true informed consent and for establishing and maintaining an open line of communication with his or her research subjects. The PI is expected to comply with the institutional policies and administrative requirements for conducting research and is accountable for compliance with institutional policies and administrative requirements.

Appropriate mechanisms are in place for the IRBs and any individual to inform appropriate institutional officials of any unanticipated problems involving risks to subjects or others and/or serious or continuing noncompliance with federal regulations or IRB requirements. Mechanisms are in place to act upon such information and to suspend or terminate research studies upon review of the problems or noncompliance. Findings and actions taken by all IRBs at each of their meetings are on file and made available at the IRB office for examination by University Compliance and any delegated representatives of the Institutional and Organizational Officials.

The Institution provides legal protection for members of the IRB and to principal investigators granted approval to conduct research, provided they have met their obligations in good faith. The Institution provides whistle-blowing protection to anyone who reports an activity that violates any regulations or policies on the use of human subjects. The University Compliance Officer and/or designated representative conducts a regular review of the HRPP and this may be conducted together with the MUSC Office of Internal Auditing and report their

results to the senior leadership and the MUSC Board of Trustees. The Institution is responsible for investigating incidents or allegations of misconduct pertaining to the use of human subjects in research.

Outreach, education and post review monitoring form the foundation of initiatives to maximize compliance with policies and procedures. These activities include the items listed above related to education and outreach regarding IRB approval as well as the following items.

- Continuing education on human research protocol regulations is provided through special training sessions, visiting scholars and HRPP program directors.
- Updates on regulations and compliance awareness are communicated to investigators and research staff by the Associate Provost for Research and the Director of the Office of Research Integrity by a list serve email platform.
- The HRPP web site describes the components of the program (<http://academicdepartments.musc.edu/hrpp/index.htm>) and highlights updates on regulations and compliance.
- Distribution of Human Research Participant Brochure in English and Spanish.
- Regular communication with departmental business managers on compliance monitoring.
- Mechanism for reporting compliance issues via a Compliance hotline (011 Confidential Hotline Posters). The University provides whistle-blowing protection to anyone who reports an activity that violates any regulations or policies on the use of human subjects.
- Post-review random audits conducted by the University Compliance Office.
- Posting and distribution of Guidelines for Ethical Conduct of Research (091 MUSC Guidelines for the Ethical Conduct of Research).

VI. PROGRAM REVIEW AND QUALITY IMPROVEMENT

The MUSC Institutional Review Board was most recently a component of the accreditation process through the National Committee for Quality Assurance (NCQA) in July 2005 as the University Affiliate of the Ralph H. Johnson Veterans Administration Medical Center (VAMC). The IRB Structure and Operations Category of the NCQA review received a score of 95.9%.

In 2007, MUSC's Accreditation by the Southern Association of Colleges and Schools was reaffirmed with an exemplary recommendation that cited many achievements and the creativity of initiatives in inter-professional education.

MUSC has been proactive in providing the operational structure required for an effective HRPP and its oversight. Leadership places high priority on compliance and regulatory monitoring to ensure that all aspects of research integrity are valued and that the proper mechanisms are in place for education, training and continuing review. While the Associate Chief of Staff/Research and

Development at the VAMC, the current Vice President for Academic Affairs/Provost at MUSC appointed a monitor for post-approval review of all human subjects research, which made the Ralph H. Johnson VAMC among the first in the country to do so. Monitoring by the Office of Compliance includes validation of required training, annual review of each individual research protocol, internal audits and mechanisms to follow implementation of any required corrective action. A similar office was established at MUSC in 2002 under the Office of Compliance. This concept was expanded in 2007 to include post-approval review of animal research protocols and in 2008 for work involving recombinant DNA and infectious materials as reviewed by the Institutional Biosafety Committee.

An important indicator of the quality of our operations and the MUSC/VAMC partnership as well as our commitment to compliance and oversight is provided by the recent review of our Division of Laboratory Animal Resources by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). In July 2008 AAALAC granted MUSC/Ralph H. Johnson VA Medical Center full accreditation for three years. The site visit team and the AAALAC Council described our program as "exemplary", a description used for very few academic laboratory animal programs. This is the eighth consecutive "full accreditation" for our animal program since 1987, a record that may be unprecedented for academic institutions.

The ongoing improvement and quality of our HRPP is initiated through multiple mechanisms including post-review monitoring, education, quarterly visits from external advisors and consultants, ongoing monitoring by the Office of Compliance, ongoing review of best practices, regularly scheduled reviews of the IRB operations and weekly discussions among the multiple offices involved in our HRPP (see HRPP Program Guide Section 9.1 – Human Research Audit Policy and Procedures and Section 9.3 – Quality Improvement Initiatives). Visiting academicians and consultants meet with staff and consult with the institutional and organizational officials responsible for our HRPP. Consultants to date include Richard Marchase, Ph.D. (Vice President for Research at University of Alabama –Birmingham), Jeffrey Balser, M.D., Ph.D. (Associate Vice-Chancellor for Research at Vanderbilt University Medical Center), and Samuel J. Tilden, M.D. (Research Compliance Officer and former Deputy Provost for HRPP at University of Alabama -Birmingham).

We consider the ongoing review of educational and training requirements for all individuals involved in human research to be another important vehicle for quality improvement and have training requirements in place for individuals just beginning in research and for continuing education through the CITI. In addition, the Office of Research Integrity developed a course "Core Clinical Research Training" that is now offered through our General Clinical Research Center for all research teams and coordinators involved in human research. In addition, many centers and institutes on campus have training and mentoring opportunities in place to assist in education and awareness. Finally, we have active community-

based outreach and education programs to increase awareness in the community for human subjects' research, including a Human Research Participant Brochure ([English](#) and [Spanish](#) Versions) and [The Healthy South Carolina Initiative](#).

VII. MUSC HUMAN RESEARCH PROTECTION PROGRAM GUIDE

Many of the core aspects of our HRPP are captured in our MUSC Human Research Protection Program Guide that will be posted on the MUSC web site and freely available to guide both investigators and human research participants. The Guide provides an organizational scheme that serves as an important educational tool for all aspects of our HRPP.

MUSC Human Research Protection Program Guide

Section 1 – Overview of the MUSC Human Research Protection Program

- Section 1.1 – Description, Principles and Authority for MUSC HRPP
- Section 1.2 – Organizational Charts
- Section 1.3 – Definitions of Terms
- Section 1.4 – Scientific/Scholarly Review of Protocols Policy and Procedures
- Section 1.5 – State Laws Affecting Human Subjects Research

Section 2 – IRB Governance and Operations

- Section 2.1 – Responsibilities, Ethical Principles, Authority and Independence
- Section 2.2 – Functions of the IRB
- Section 2.3 – Membership of the IRB
- Section 2.4 – Approval of Research Activities by the IRB
- Section 2.5 – Convened Meetings of the IRB
- Section 2.6 – Retention of Review Activities Records by the IRB
- Section 2.7 – Management of the IRBs

Section 3 – IRB Review Process

- Section 3.1 – Human and Not Human Research Policy and Procedures
- Section 3.2 – Exempt Research Review Policy and Procedures
- Section 3.3 – Expedited Research Review Policy and Procedures
- Section 3.4 – Full Board Initial Review Policy and Procedures
- Section 3.5 – Full Board Continuing Review Policy and Procedures
- Section 3.6 – Full Board Amendment Policy and Procedures
- Section 3.7 – Case Reports Policy
- Section 3.8 – Quality Improvement Projects Policy and Procedures

Section 4 – Operational Guidelines for Human Research Protocols

- Section 4.1 – Review of Research Involving Drugs or Biological Drug Products
Policy and Procedures

- Section 4.2 – Single Emergency Use of an Investigational Drug Policy and Procedures
- Section 4.3 – Review of Research Involving Medical Devices Policy and Procedures
- Section 4.4 – Medical Devices Risk Determination Policy and Procedures
- Section 4.5 – Emergency Use of an Investigational Device Policy and Procedures
- Section 4.6 – Humanitarian Use Device Policy and Procedures
- Section 4.7 – Unanticipated Problems and Adverse Events Policy and Procedures
- Section 4.8 – Management of Non-Compliance Policy and Procedures
- Section 4.9 – Suspension or Termination of IRB-Approved Research
- Section 4.10 – Data and Safety Monitoring Plans
- Section 4.11 – Human Gene Transfer Studies Policies and Procedures
- Section 4.12 – Clinical Trials Registration Policy and Procedures
- Section 4.13 – Privacy and Confidentiality

Section 5 – The Research Team

- Section 5.1 – Principal Investigator Responsibilities – Supervision of Staff and Protection of Subjects
- Section 5.2 – Principal Investigator Responsibilities – Recordkeeping and Record Retention Requirements
- Section 5.3 – Education and Training Requirements for Individuals Involved in Human Research

Section 6 – Informed Consent

- Section 6.1 – Informed Consent to Participate in Research Policy and Procedures
- Section 6.2 – Hyperlinks to IRB Informed Consent Information and Guidance

Section 7 – Human Subject Participation

- Section 7.1 – Equitable Selection of Subjects
- Section 7.2 – Advertisements for Research Participants Policy and Procedures
- Section 7.3 – Payment for Participation Policies and Procedures
- Section 7.4 – Recruitment Incentives Policy and Procedures
- Section 7.5 – Research Involving Non-English-Speaking Subjects Policy and Procedures
- Section 7.6 – Research Subject Advocacy Policy and Procedures
- Section 7.7 – Subject Complaints, Issues, Concerns and Suggestions Policy and Procedures

Section 8 – Vulnerable Populations

- Section 8.1 – General Guidelines
- Section 8.2 – Research Involving Persons with Impaired Decision Making Capability (Cognitively Impaired)
- Section 8.3 – Research Involving Prisoners

- Section 8.4 – Research involving Pregnant Women, Fetuses, and Neonates
- Section 8.5 – Research Involving Children
- Section 8.6 – Research Involving MUSC Employees or MUSC Students

Section 9 – Human Subjects Research Conducted at Multiple Sites

- Section 9.1 – Multi-Site Research Studies Policy and Procedures
- Section 9.2 – Management of Reporting Events in Multi-Site Research Studies Policy and Procedures

Section 10 – Quality Assurance

- Section 10.1 – Human Research Audit Policy and Procedures
- Section 10.2 – Research Data Ownership and Record Retention Policy and Procedures
- Section 10.3 – Quality Improvement Initiatives within the Human Research Protection Program of MUSC