Policy Name: **Quality Improvement Initiatives within the Human Research Protection Program of MUSC**		
Approved		
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I. BACKGROUND

In December 2006, Dr. Stephen M. Lanier was named Associate Provost for Research at the Medical University of South Carolina. Dr. Lanier and his faculty and staff colleagues began a review of all the research offices with the goal of improving quality services to research participants, Principal Investigators, promoting communications and collaboration among offices and expanding shared resources is now far greater integration across all research endeavors. This initiative picked up further momentum with the appointment of Dr. Robert Malcolm as the Director of the Office of Research Integrity in September, 2007. From the human research prospective, the Office of Research Development, the Office of Research Integrity, the S.C. Clinical and Translational Research (SCTR) Institute and the Office of Research and Sponsored Programs developed close working relationships. Beginning in the fall of 2007, Dr. Lanier held a large development conference of these offices to develop grass roots support and a shared vision for research development over the next decade.

The initial AAHRPP self study process was an excellent quality improvement exercise. Old policies were examined in detail and revised to generate the Human Research Protection Guide. Resources needed to adequately conduct human research oversight were created. There is far greater harmonization of work effort and communication among research offices.

These initiatives culminated with AAHRPP accreditation in 2009. This process of quality improvement has continued over the past two years with notable accomplishments in operational seamlessness, educational outreach, workflow management and conflict of interest disclosure and management. The Designated Organizational Official for the MUSC HRPP and the Director of the MUSC AAHRPP accreditation team were invited to speak at the 2010 AAHRPP conference to review these accomplishments.

In 2009, MUSC was awarded a Clinical and Translational Sciences Award and also received National Cancer Institute designation of the Hollings Cancer Center. Both of these signature accomplishments provided an expanded platform for growth and overall operational quality improvement.

SPECIFIC QUALITY IMPROVEMENT PROJECTS

Annually, leadership meets to evaluate the effectiveness of compliance and quality improvement activities, and identifies at least one goal, an objective for

meeting that goal, and at least one way of measuring whether the objective is being met. Further information on the Program Review and Quality Improvements can be found in Section VI of HRPP 1.1 – Description Principles and Authority for MUSC HRPP. Examples of projects initiated to improve the quality of the MUSC HRPP are outlined below.

A. **Education Quality Improvement** Central to the HRPP is the concept of education, communication and awareness. This theme is nurtured by several mechanisms.

1. **The Core Clinical Research Training (CCRT) Course**, now offered through SCTR's Clinical and Translational Research Center (CTRC), was developed by the Office of Research Integrity several years ago to train research coordinators and new investigators. The course has now evolved to be an essential component of the clinical investigator and research staff toolkit. In addition to covering basic aspects of the HRPP operations and philosophy, this course is structured to allow the addition of new modules that can address specific evolving issues in the field. One example is provided by the addition of a module to train individuals for roles as research subject advocates. In addition to live training sessions, the CCRT course is now available as an online format, offering more flexibility with course attendance.

2. **Research Orientation** - In 2008, two initiatives were put in place to coordinate research support mechanisms. One is the development of a web portal (http://research.musc.edu/) that provides access to all aspects of the research process from idea development to grant development to grant submission to post-award monitoring. The second initiative was the establishment of a Research Orientation Session for new faculty and the broader research community with slides posted on our research web site. In 2009, the Research Toolkit, an online research guide, was developed (https://sctrweb2.musc.edu/research_toolkit/). The Toolkit assists MUSC research personnel in navigating the research enterprise, addresses steps involved with submitting, conducting, closing and disseminating results of a research study and includes links to institutional, state and federal resources and regulations. The research orientation is an annual event.

3. **The SUCCESS Center** - While we have several strong research support systems in place, there is often an educational and awareness gap for investigators entering into human subject research or for investigators new to MUSC on how to navigate their way through the various offices. The SUCCESS Center http://sctr.musc.edu) provides support for such investigators through a group of individuals with expertise in a variety of areas

related to human subjects research including the following: a) Research navigation to help with research processes and resources including Good Clinical Practice processes for research, study organization and conduct, study documentation, and research tools and templates; b) Regulatory processes and documentation, including areas such as IRB protocol submissions, IND and IDE applications and study quality improvement reviews; c) Subject recruitment, and d) Grant application process and budget development. The SUCCESS Center works closely with the Offices of Research Integrity and Associate Provost for research to identify, develop and disseminate educational resources to the research community. In addition, monthly educational sessions, seminars and webinars for the research community on a variety of research topics are hosted by SCTR and coordinated by the SUCCESS Center.

4. **Post-Audit Targeted Education** The University Compliance Office conducts an annual review of all human research audits conducted for that particular calendar year and submits a report to the Provost office. This report serves as a guide to initiate any focused educational efforts to increase awareness of common audit findings. For example, one annual report determined that documentation errors in the informed consent document and/or HIPAA authorization documents accounted for about 80% of discrepancies. Most of these errors were minor involving signature errors, initialing errors, dating errors or the use of obsolete forms of the informed consent document. A powerpoint educational module was developed to address this issue and outlined several courses of action including immediate review of HIPAA and informed consent documents by other staff members, verification of the informed consent process documentation by the Principal Investigators or his/her delegate and encouragement of self study audits. The continuing targeted education program also helps highlight federal regulations.

5. **Networking and Peer Engagement** – We maintain a program for leaders in various aspects of human subject research to network with staff in various offices, IRB Chairs and members, investigators and senior administration. These individuals may visit MUSC and present a seminar for the entire research community. This initiative provides an important mechanism for continuing education, awareness of best practices and connectivity.

B. IRB Workload Analysis

Beginning in the spring of 2008, the Office of Research Integrity Director, Senior IRB staff personnel and Chairman and Vice Chairman of IRB I and

II Committees (NIH funded human research committees) began evaluating work load between the two committees and assessing measures of turn-around time to hold reviews, new submissions, continuing reviews and adverse event reporting. A series of meetings were held to discuss the realignment of work effort and efficiency among the two committees to obtain grass root support for realignment of departments and colleges assigned to each committee. The data on this indicated that some departmental reassignments needed to be shifted to IRB II.

The Director of the Office of Research Integrity continues to meet with the IRB Chairs and staff on a regular basis to review work distribution. Another objective of these meetings between IRB chairs and staff is to establish harmonization of processes and procedures across the three IRBs.

The IRB Performance statistics continue to be monitored and maintained. The IRB competed a substantial report of the 2010 performance metrics and have continued to maintain the report into 2011. Comparisons regarding turn around time are being made between the older ERMA electronic system and the new eIRB system. The reporting capabilities of the new eIRB system are currently being developed to allow for a more robust analysis of numerous areas within the eIRB system. Once these reports are developed, the IRB and researchers will be able to better determine specific areas that need additional attention with regard to education and training.

C. CTSA Consortium

As a member of the consortium of institutions with NIH-supported Clinical and Translational Science Awards, we access a wealth of shared resources for performance statistics and peer networking.

D. Evaluation of alternative IRB Models

Under the direction of Dr. Stephen Lanier, we have begun a preliminary study of the use of central IRB's by other institutions within the southeast that have similar research profiles. A series of consultants have reviewed the work of our IRB's and have provided consultation through teleconferences or on-site visits to the University. As a result, in December 2010, IRB initiated a 12-month pilot project within 2 divisions of the Department of Medicine to evaluate a process of the potential use of Western Institutional Review Board (WIRB) for multi-site corporate-sponsored clinical trials. To facilitate this process, investigators were provided with guidelines on submission and two WIRB liaisons were designated within IRB to assist investigators with the research process. In July of 2011, this project was extended for one year and expanded to include all divisions within the College of Medicine. In November 2011,

the project was expended to all departments within the College of Medicine for new Phase III and Phase IV corporate sponsored research studies.

E. Upgrade of Automated Support Systems

A research support informatics team reviews current operations of our HRPP program and has focused on the research review unit. The goals of this group have been to provide seamless electronic, compliant processes for submission, review and monitoring of research involving human subjects to provide mechanisms to communicate among different reporting units in the HRPP program by cross-queries of data sources. We have gradually transitioned from our system "Electronic Research Management Applications" (ERMA), which was established in 2004, to incorporate next generation workflow systems into our research support services. One major example of this is illustrated by the transition of our ERMA-based IRB application submission and review process to a web-enabled workflow system.

Relative to our Research Review Unit, the research support informatics team worked with our partners in Health Sciences South Carolina to develop a statewide process for IRB submission and review through the "Click Commerce" management platform. This new electronic IRB (eIRB) system was implemented at MUSC in December 2010 and over 500 individuals have been introduced to the system, to date. Dedicated users, have also completed formal training in the computer labs, as well have available to them educational materials (http://research.musc.edu/ori/irb/eIRB.html) with instructions on how to submit protocols within the system.

The Offices of Associate Provost for Research, Research Integrity and SUCCESS Center also have staff available to assist users with system navigation. The new eIRB system allows a more robust monitoring of operations and oversight that will allow us to make another level of informed decisions for enhancement of our HRPP units. It is also far easier to track adverse events over time and develop new processes for intervening and reducing problems.

The new eIRB system has granted significant transparency for those departments, groups and committees needing to provide an ancillary review of research protocols. The eIRB system is programmed to automatically route the protocol to ancillary review areas such as: Hollings Protocol Review Committee, Departmental Approvers, VAMC, Office of Research and Sponsored Programs, Grants and Accounting, Investigational Drug Services. This ability easily increases awareness of the project as well as streamlines the entire ancillary review process minimizing traditional delays encountered with paper submission.

F. IRB Continuing Education

The IRB staff, chairs and Board members continue to take advantage of educational training opportunities. Regular meetings of staff and chairs cover various aspects of human subjects research protection. PRIM&R-sponsored webinars are accessed by the HRPP personnel. IRB staff and Chairs attend national PRIM&R conferences and/or the AAHRPP annual meeting.

The MUSC HRPP IRB serves on the 2012 OHRP South Atlantic National Conference Steering Committee to plan a regional conference in Raleigh, NC in March 2012. The focus of the conference is “Community Engaged Research”.

G. Outreach

Over the last couple of years, the IRB has increased the education and training provided to research groups. A big focus of this outreach has centered on students and new investigators. The IRB Administrators developed presentation materials and visited several departments to educate and inform researchers about the IRB process. These sessions have been incredibly popular and the IRB Administrators continue to receive invitations to return. The goals of this outreach are to provide enough information for the researchers and their teams to be aware of how, what and when to submit to the IRB, as well as providing the researcher with a specific individual to call upon when needing IRB assistance.

H. Communication

Communication and connection have become vitally important for the success of a strong human research protection program. Under the direction of the Associate Provost for Research, a number of groups hold regular meetings and sessions to stay connected and updated on all situations involving the protection of human subjects. These group meetings involve the Associate Provost for Research and all Directors of research support offices as well as IRB Staff and the SUCCESS Center.