



<b>Policy Name: Quality Improvement Initiatives within the Human Research Protection Program of MUSC</b>			
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**I. BACKGROUND**

In 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 Clinical and Translational Research Sciences Office 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. A series of smaller working groups have been held each month since then.

The AAHRPP self study process has been an excellent quality improvement exercise. Old policies have been examined in detail and revised. New policies that were originally based on convention history and oral lore have now been replaced with written policies. Resources needed to adequately conduct human research oversight have been created. There is far greater harmonization of work effort and communication among research offices. This is particularly true for the close cooperation of the Office of Research Integrity, Office of Research and Sponsored Programs, the Compliance Office and the Clinical and Translational Research Sciences Office. Senior and mid-level faculty and staff of these offices meet monthly and in some cases weekly to enhance joint human research efforts

**II. SPECIFIC QUALITY IMPROVEMENT PROJECTS**

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

1. **Post-Audit Targeted Education** For several years the University Compliance Office has conducted a review of all human research audits conducted for that particular calendar year and submitted a

report to the Provost office. Beginning with the audits for 2007, the Compliance Office developed a continuing education quality improvement PowerPoint module for all research faculty and staff. This is a mandatory course for research faculty and staff which will be offered as part of the annual overall compliance training courses (CATTs). This course reviews in detail the most common and most serious errors in the conduct of human research based on audit findings for the past twelve (12) months. In calendar year 2007 it was found that documentation errors in the informed consent document and/or HIPPA 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. Actions to reduce errors were placed in the continuing education CATTs guidance. These actions include immediate review of HIPPA 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 education program also helps highlight federal regulations. While occurring at a low rate, the report noted that protocol deviations were not always reported to the IRB (at about the rate of 1% of all studies audited). Also, at the rate of about 1% incorrect annual renewal information was provided to the IRB. With this continuing education course going into effect for 2008, we will closely monitor the annual report of audits and set a goal of a 10% reduction in the error rate of HIPPA and informed consent documentation. We will continue to monitor the protocol deviation reporting, annual renewal information and several other measures.

2. **The Core Clinical Training Course**, now offered through the General Clinical Research Center, 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 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.
3. **Visiting Scholars** - Over the past year we initiated a program for leaders in various aspects of human subjects research to visit on a quarterly basis and meet with staff in various offices, IRB Chairs and members, investigators and senior administration. These individuals often present a seminar for the entire research community and provide a very important mechanism for continuing

education, awareness of best practices and connectivity. This initiative is further enhanced by the seminar series sponsored by the South Carolina Clinical and Translational Research Center, where individuals speak on a variety of topics in the field.

4. **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.
5. **The SUCCESS Center** - The entry portal for the South Carolina Clinical and Translational Research (<http://www.sctrinstitute.org/>) Institute programs and services. While we have several strong research support systems in place, there is often an educational and awareness gap for investigators entering into human subjects research or for investigators new to MUSC on how to navigate their way through the various offices. The SUCCESS Center is one component helping to address this by providing 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 documentation including IRB protocol submissions and IND and IDE applications; c) Subject recruitment, and d) Grant application process and budget development.

## **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 have been 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. Preliminary analysis of the data on this indicates some departmental reassignments will need to be shifted to IRB II. Another task of these meeting between IRB I and II faculty and staff have been to establish greater harmonization of processes and procedures.

### **C. 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. Recently, Dr. Samuel Tilden spent several days reviewing our human research protection program and providing guidance for the improved quality of our research offices and guidance for our AAHRPP self study document.

### **D. Upgrade of Automated Support Systems**

A research support informatics team reviews current operations of our HRPP program and over the past year this group has focused on the research review unit. The goals of this group are to provide seamless electronic, compliant processes for submission, review and monitoring of human subjects research. Our current system has been in operation for several years and we have upgraded various aspects to enhance the submission and review of applications and to include additional regulatory-related queries as our programs have grown and evolved. A second goal of this group is to provide mechanisms to communicate among different reporting units in the HRPP program by cross-queries of data sources and this is part of a larger Data Warehouse Initiative for the Medical University being chaired by Dr. Lanier as Associate Provost for Research.

Relative to our Research Review Unit, the research support informatics team will also be working with our partners in Health Sciences South Carolina to develop a state-wide process for IRB submission and review through the "Click Commerce" management platform. The latter will allow 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 will also be far easier to track adverse events over time and develop new processes for intervening and reducing problems.

## **III. REFERENCES**