



## **I. BACKGROUND**

In February 2016, Dr. Kathleen Brady was named Vice President for Research (VPR) at the Medical University of South Carolina to lead a newly reorganized structure to lead the Human Research Protection Program at MUSC. Dr. Brady established a new position and named Dr. Patrick Flume the Assistant Provost for Research Compliance and Regulatory Affairs. More recently, Dr. Aimee McRae was named as the Director of the Office of Research Integrity. Under this leadership, there has been a close working relationship between the Office of Research Development, the Office of Research Integrity, the S.C. Clinical and Translational Research (SCTR) Institute, the Office of Research and Sponsored Programs, and the Office of Compliance.

Important milestones in the Quality Improvement Program in research include initial AAHRPP accreditation in 2009, renewal of the AAHRPP accreditation in 2012, the renewal of the Clinical and Translational Sciences Award in 2014, and the renewal of the National Cancer Institute designation of the Hollings Cancer Center in 2012. These signature accomplishments allowed for continued support for overall operational quality improvement.

Dr. Flume had led College of Medicine initiative, the Clinical Research Task Force, which ultimately led to the establishment of a standing committee, the Clinical and Translational Research Action Committee (CTRAC), which reports to the VPR and the University Research Council (URC). The charge of this committee is to identify opportunities for improvement in clinical and translational research. Included on this committee are representatives from all six colleges, investigators, research coordinators and administrators. Once the committee identifies a project of interest, a working group is established to develop a plan for improvement by identifying best practices as well as unique solutions for MUSC. These working groups include key stakeholders and ambassadors for change representing the IRB, SCTR, the Office of Compliance, and the MUSC legal office, among others.

### **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. In addition, there are multiple projects, some new while others considered of utmost importance to warrant continued attention, initiated to improve the quality of the MUSC HRPP with recent examples 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**, offered through SCTR's Clinical and Translational Research Center (CTRC), was developed by the Office of Research Integrity 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 ([http://academicdepartments.musc.edu/sctr/tools\\_links/toolkit\\_sitemap.html](http://academicdepartments.musc.edu/sctr/tools_links/toolkit_sitemap.html)). 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 Vice President 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 focused educational efforts to increase awareness of common audit findings. In addition, a collaboration between the Compliance Office, IRB and the SCTR Regulatory Knowledge and Support () core will review new federal regulations to develop new audit procedures and educational and support mechanisms to help investigators and their staff. For example, NCATS has placed a priority on investigational drug management, and this collaboration is developing the processes for this subject area. Previously, we had identified 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.
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 Performance and Workload Analysis**

The Director of the Office of Research Integrity meets regularly with the IRB Chairs and staff to review work distribution. In addition, IRB Performance statistics are monitored through the extensive capabilities of the eIRB system. We publish our metrics regarding turnaround time for all types of reviews on our institutional website. The reporting capabilities of the eIRB system allow us to identify opportunities for further improvement. Some recent examples are as follows:

1. **Not Ready for Review** – Many protocols submitted to the IRB are severely lacking in essential details that permit review. Rather than committing IRB staff time to the corrections required of the protocol, we have established a NRR category in which the protocol is referred back to the investigator with recommendation for consultation with the SUCCESS Center.

2. **ICF Library** – Consent forms often use the same elements that could be present in other ICFs. For example, study protocols frequently use the same procedures, and so would require explanation of these procedures in the consent forms. Rather than reviewing new language to describe procedures, we have created a library of terminology accepted by the IRB for a growing number of ICF elements that can be copied and pasted into consent forms to reduce review time.

3. **IRB retreats** – we have engaged the IRB leadership and staff to participate in an annual retreat in which key issues important to staff as well as to investigative teams can be discussed and solutions developed. As an example, the previous retreat included a discussion of harmonization of processes and procedures across the three IRBs. These retreats are important for continually driving improvement as well as enhancing the satisfaction of the staff.

## **C. CTSA Consortium**

As a member of the consortium of institutions with NIH-supported Clinical and Translational Science Awards, we have access to a wealth of shared resources for performance statistics and peer networking. NCATS is leading a push for common metrics.

## **D. Novel Initiatives**

We take a proactive approach to evaluating new technologies and services to address the varying needs of investigative teams. Some examples include:

1. **Evaluation of alternative IRB Models** – we previously expanded our use of a central IRB (Western IRB) initially for Phase III and IV trials. We have expanded on this initiative through a willingness to use other central IRBs, as long as they adhere to our institutional policies and procedures. We are currently working on adopting single IRB policies and procedures as mandated by the NIH for future multisite trials. Our IRB director will be serving on a NIH-sponsored committee to guide successful achievement of these goals.
2. **Electronic consenting** – Through a collaboration between the IRB, the CTRAC, and RKS, a process for capturing an electronic signature for the ICF and HIPAA documents has been developed. SOPs are under review and a pilot study is in process. This will provide for considerable improvements in the consenting process as well as storage of files.
3. **Remote consenting** – To satisfy the unique needs for clinical permissions and for clinical research in which subjects or surrogates are not physically present to sign a consent form. A novel approach (Doxy.me) was developed by our BMIC program to allow for an interaction between the investigator and subject through a Skype-like, secure format. The IRB was instrumental in perfecting the policies and procedures to make this available to investigators.

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

A research informatics team supports current operations of our HRPP program. The goals of this group are 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 fully transitioned from our system “Electronic Research Management Applications” (ERMA), which was established in 2004, although there are some legacy protocols that remain open in that system.

The research informatics team continues to work with our partners in Health Sciences South Carolina to support the statewide process for IRB submission and review through the “Click Commerce” management platform. The electronic IRB (eIRB) system was implemented at MUSC in December 2010. Training is available for new users through educational

materials (<http://research.musc.edu/ori/irb/eIRB.html>) with instructions on how to submit protocols within the system.

The Offices of Vice President for Research, Research Integrity and SUCCESS Center have staff available to assist users with system navigation. The 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 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.

#### **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 Vice President 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 Vice President for Research and all Directors of research support offices as well as IRB Staff and the SUCCESS Center.