Communication is a key component of MUSC’s Human Research Protection Program and cuts across every level of our work. The most important communication occurs between study participants and investigators around informed consent procedures and is both written (the informed consent document) and oral (answering questions and clarifying study procedures). Second most important is the two-way communication between investigators and IRB staff and chairs. Investigators are encouraged to contact IRB staff as soon as a question arises and hopefully before a problem arises. But even when there are problems, we would rather know sooner than later in order to be helpful in the solution. We also communicate important updates and policy changes on our web site. Our IRB staff and chairs will always interact and make time to talk – to principal investigators, co-investigators, research coordinators, and study staff. It is only in this way that we can have a research community that is informed and knowledgeable about our Human Research Protection Program.

It’s time for AAHRPP Re-Accreditation!

In September 2009, MUSC achieved a milestone with notification that the Council of the Association for the Accreditation of Human Research Protection Programs (AAHRPP) had awarded full accreditation status to the institution’s Human Research Protection Program (HRPP).

Accreditation is an intensive, in-depth evaluation of the policies, procedures, and practices of a human research protection program. The result is a more cohesive, efficient, and effective research program, with systems in place not only to protect research participants, but also to advance high quality science.

It’s hard to believe that it’s already time for re-accreditation! With that being said, we are currently in the middle of the first step of the process which encompasses the review and revision of policies and procedures as well as significant dialogue with the accrediting body. Once we complete the first step of the process, we will publish several updates and revisions to our policies and procedures. Data and Safety Monitoring, Medical Devices, Privacy and Confidentiality policies are just a few of the ones that are being revised. We will also publish a new policy on Transnational Research.

Please be on the look out for the HRPP updates as well as notices about the next step of the re-accreditation process, which is a site visit from AAHRPP in May 2012. During the accreditation process in 2009, the site visitors interviewed approximately 50 individuals on campus including: Principal Investigators and Research Coordinators, IRB Members and Staff, Compliance personnel, Attorneys, and Institutional Officials. Please be aware that it’s very possible that you may be chosen for an interview.

Thank you for the work that you do in maintaining a high quality Human Research Protection Program!
The IRB has begun processing Continuing Review applications for studies in eIRB. There are a few important differences in the Continuing Review application to note.

1. The Continuing Review application now requires the number of subjects enrolled since the previous review/approval. See item 5.0 below.

2. Since informed consent forms are stamped with an expiration date, a new consent form will be stamped upon approval of the Continuing Review. The new stamped informed consent with the current approval and expiration date will be found in Stamped ICF tab.

3. Continuing Review is not the same as a Status Change. Although the smart form pages are similar, the purpose of Status Changes is different. Status Change should be used when study enrollment has been suspended by a sponsor. For example, many studies will have a DSMB suspend enrollment due to adverse events. Often the study protocol and consent will need to be revised due to the increased risks. In a case such as this, the study team would submit a Status Change to suspend enrollment. They would also need to submit an amendment for the revised protocol. After the amendment is approved, the study team will need to submit another Status Change to open the study for accrual.

Status Change should not be used if the study has completed accrual earlier than expected or if data analysis has begun. This information should be reported at the time of Continuing Review.
Community Engaged Research Guidance Now Available

Community-engaged research is an approach to conducting research that requires partnership development, cooperation and negotiation, and commitment to addressing local health issues of the community of interest. At the heart of all community-engaged research is the understanding that community members will be involved in some meaningful way in the research process. The involvement of individuals from non-MUSC community sites, as members of the research team, often necessitates consideration of additional human subjects’ protections regulations in order to gain MUSC IRB approval for the research.

The involvement of individuals from non-MUSC community sites, as members of the research team, often necessitates consideration of additional federal human subjects protections regulations in order to gain MUSC IRB approval for the research. Examples of additional considerations include community members’ completion of CITI training, or the need to apply for a certificate of Federal Wide Assurance (FWA).

In response to requests from MUSC researchers, staff and community members, the MUSC IRB has created guidance materials to assist in the submission of Community Engaged Research.

These documents can be found on the IRB Community Engaged Guidance website.

In addition, education, training and information concerning Community-Engaged research can be found by visiting the South Carolina Clinical and Translational Institute’s Community Engagement Website.

IRB Tip

When an amendment is submitted in eIRB, previously stamped ancillary documents such as the HIPAA Authorization and advertisements may disappear from the Ancillary section of the Attachments tab.

The stamped documents can still be found in the History tab of the study. This issue is currently being reviewed by HSSC for a resolution.
2012 Deadline Dates for Submissions and Meetings
The 2012 Deadline Dates for Submissions and Meetings are available online at http://research.musc.edu/ori/irb/deadlines.html

IRB Forms Online Location
As a reminder, IRB Forms are available online at http://research.musc.edu/ori/irb/forms.html

Contact Information

<table>
<thead>
<tr>
<th>IRB</th>
<th>Contact</th>
<th>Title</th>
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<tbody>
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</table>

CITI Online Location
As a reminder, CITI Online is available online at http://www.musc.edu/citi

Holiday Schedule
- Thanksgiving Day—Thursday, November 24
- Day after Thanksgiving—Friday, November 25
- Christmas Eve—Friday, December 23
- Christmas Day—Monday, December 26
- Day after Christmas—Tuesday, December 27
- New Year’s Day—Monday, January 2, 2012

Hyperlinks to eIRB
- eIRB System
- eIRB User Guides and Tegrity Sessions