IRB Review
Volume 1, Issue 1  November 2010

Medical University of South Carolina

A Note from the ORI Director

I am delighted that you’re reading the first edition of the MUSC IRB Newsletter. We have developed this newsletter in order to keep the research community apprised of the many changes that are occurring in the human subjects research world. Some of these changes, such as the introduction of Click Commerce (our new eIRB system) have to do with our internal operations, while others, such as VA updates, have to do with regulatory policies at the national level. We hope you find this communication useful, and look forward to your feedback and suggestions.

Kathy Magruder, MPH, PhD
Director, Office of Research Integrity

MUSC Rollout of Click Commerce eIRB

As of December 1, 2010, all “Not Human Research”, “Exempt” and “Expedited” protocols submitted to IRB I, II or III will be accepted only through the eIRB system. In addition, all “Full Board” protocols going to IRB I and IRB II will be accepted only through the eIRB system. The eIRB system is located at: https://eirb.healthsciencessc.org.

We will continue to provide computer training sessions for as long as we have requests for additional instructions. All sessions are held in the computer labs on the 4th floor of the library.

In addition to guidance material and integrity sessions on use of the eIRB system available at http://research.musc.edu/ori/irb/eIRB.html, support is available through IRB administration (ori@musc.edu, 792-4148), the Success Center (success@musc.edu, 792-8300) and the office of the Associate Provost for Research (veatchlm@musc.edu, 792-3247)

eIRB Rollout by IRB

<table>
<thead>
<tr>
<th>Initial Protocol</th>
<th>IRB I and IRB II</th>
<th>IRB III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Board Protocols</td>
<td>eIRB as of 12/01/2010</td>
<td>ERMA until notified*</td>
</tr>
<tr>
<td>Expedited Protocols</td>
<td>eIRB as of 12/01/2010</td>
<td>eIRB as of 12/01/2010</td>
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<td>Exempt Research</td>
<td>eIRB as of 12/01/2010</td>
<td>eIRB as of 12/01/2010</td>
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<tr>
<td>Not Human Subjects Research</td>
<td>eIRB as of 12/01/2010</td>
<td>eIRB as of 12/01/2010</td>
</tr>
<tr>
<td>Amendments</td>
<td>Same system as Original Study</td>
<td>ERMA</td>
</tr>
<tr>
<td>Continuing Review</td>
<td>Same system as Original Study</td>
<td>Same system as Original Study</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>Same system as Original Study</td>
<td>Same system as Original Study</td>
</tr>
</tbody>
</table>

IRB Tip

WHILE YOUR STUDY HAS BEEN APPROVED BY THE MUSC IRB, YOU MAY NOT BEGIN WORK ON YOUR RESEARCH STUDY AT THE VAMC UNTIL YOU HAVE RECEIVED VAMC R&D COMMITTEE APPROVAL.
Dr. K. Kringle, Adjunct Professor of Child Psychology  
Far Northern University  

Dear Dr. Kringle:  

At the regularly scheduled December 24 meeting the IRB reviewed your protocol, “A Global Observational Study of Behavior in Children.” While we believe it has many good features, it could not be approved as submitted. If you choose to revise your study, please address the following concerns:  

1. You propose to study “children of all ages”. Please provide an exact lower and upper age limit, as well as the precise number of subjects. Provide a statistically valid power calculation to justify this large of a study.  
2. Your only inclusion criterion is “belief in Santa Claus”. Please provide a copy of the screening questionnaire that determines such a belief. Provide a Waiver of Authorization under HIPAA in order to record these beliefs prior to enrollment in your study. The Board recommends that you obtain a Certificate of Confidentiality as beliefs are sensitive and personal information.  
3. You propose to “know when they are sleeping and know when they are awake”. How will this be done? Will children undergo video monitoring in their beds? Will they have sleep EEGs? You list 100 elves as research assistants. Are any of them a sleep physiologist?  
4. Your primary outcome measure is to “know when they’ve been bad or good”. What standard is being used to determine ‘goodness’? Do children have to be good all year or just most of the time? What if they have been really, really good except for one time when they hit their little brother?  
5. You propose to conduct your research by entering the subjects’ homes through the chimney. Have you considered the damage to the roof, carpeting, etc. that this will cause? Moreover, children are likely to be startled by your appearance late at night. Please revise your protocol to conduct your home visits between 9am and 5pm Monday through Friday with at least one parent being present.  
6. You state that compensation for participation will be “sugarplums, candy, and toys” for the good little boys and girls. This may not be appropriate for the children with obesity, dental caries, and hyperactivity. Also, your proposal to leave a lump of coal in the stockings of bad children will be unfairly stigmatizing to them individually and as a group. In general, the Board suggests a small token of appreciation for all participants. Perhaps a $5 Toys-R-Us gift card would be better.  
7. The database of good and bad children will be kept “on a scroll at the North Pole”. Please describe the security provisions you have in place to protect the research data. Is the scroll kept in a locked cabinet in a locked room? Who has access to the scroll? Are there backup copies of the scroll and how often are they compared to the original?  
8. You mention the participation of “eight tiny reindeer” in your protocol. Please provide the Board with documentation of Institutional Animal Care and Use Committee approval.  
9. Please provide Human Subjects Protection Training dates for Mrs. Claus and the elves.  
10. As this study involves prospective data collection and is more than minimal risk without prospect of direct benefit to the subjects, informed consent signed by both parents will be required. Please have the consent form translated into every language spoken by children.  

Please submit 25 copies of your revised protocol to the IRB. The IRB will be on Holiday Season schedule for the next two weeks. If approved, you will be able to conduct your study sometime in January.  

Sincerely,  

E. Scrooge, MD-Chair, Institutional Review Board  

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Policy Updates

NEW POLICY:

Quality Improvement Projects Policy and Procedures – HRPP 3.8

This policy assists in determining whether Quality Improvement (QI) activities involving human participants or individually-identifiable data must be submitted to the IRB by defining when a QI project involves research and is subject to IRB review.

QI activities are done to improve quality of programs, improve services, or improve the provision of medical care, customer service, etc. QI projects are usually done for internal purposes only. However, some QI projects may fall under the federal definition of human subject’s research and therefore, may require IRB review.

REVISED POLICY:

Unanticipated Problems and Adverse Events Policy and Procedures - HRPP 4.7

This policy was revised to provide a clear understanding as to when to report unanticipated problems and adverse events to the IRB.

MUSC investigators are required to promptly report to the IRB if there are unanticipated problems during the course of the research that involve risks to subjects or to others. The policy defines the procedures for addressing unanticipated problems involving risks to research participants or others (UPIRSOS).

NOTE: The MUSC IRB will not review reports of adverse events, whether at MUSC or external sites, unless those reports constitute unanticipated problems involving risks to subjects or others.

An unanticipated problem involving risks to subjects or others (UPIRSOS) refers to any incident, experience, or outcome that:

- is unexpected (in terms of nature, severity, or frequency) given: (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

- is related or possibly related to a subject’s participation in the research; and

- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

In addition to the revised policy, the MUSC IRB drafted a letter for study sponsors needing further clarification about the policy. It can be found on the MUSC IRB website.

Multi-Site Research Studies Policy and Procedures - HRPP Section: 9.1

The policy was revised to help provide a better understanding of the process involved when planning to conduct research at a non-MUSC site.

This policy is for research activities conducted at sites that are not owned or operated by the Medical University of South Carolina and do not fall under the MUSC IRB’s authority. These research activities are subject to special procedures for the coordination of research review.

It is important to note that research procedures should not be initiated at an off-campus site location prior to IRB review of the appropriate documentation for that site. Researchers should first work with the IRB regarding a determination as to whether the non-MUSC institution is “engaged” in human subject research activity.
Policy Updates-Continued

HRPP Guide 6.1 – Informed Consent to Participate in Research Policy and Procedures

Item 1. J.

The policy’s previous wording was:

**Agreement to Disclose Pregnancy Testing Results**

If the research study includes children and pregnancy testing, the parent of the minor and the child must sign and date the Agreement to Disclose Pregnancy Testing Results

This has been changed to:

**Disclosure of Pregnancy Testing Results of Females Aged 17 Years and Younger**

If the research study includes children and pregnancy testing, the consent will include the MUSC required paragraphs (see MUSC Standard Consent Guide).

**MUSC Standard Consent Guide**

The language below was added to the Standard Consent Guide below the Sponsor Commitment section:

[http://research.musc.edu/ori/irb/Guidecon.html](http://research.musc.edu/ori/irb/Guidecon.html)

Disclosure of Pregnancy Testing Results:
During your participation in this study, you will be given a pregnancy test. If you are under 16 years of age, the results will be shared with your parents and/or legal guardian.

If you are 16 years or older, you have the right to direct that such test results not be shared with your parents or legal guardian. Please initial in the space below to indicate your choice. Your choice will not affect your ability to participate in this research project:

_____  Yes, you may share my pregnancy test results with my parents or legal guardian.

_____  No, you may not share my pregnancy test results with my parents or legal guardian.

The separate Pregnancy Consents have been removed from the IRB’s Website.

VA Updates

The latest version of VHA Handbook 1200.05:

**REQUIREMENTS FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH** is now available.

Below is a brief summary of the Principal Investigator responsibilities as outlined in the new handbook.

**Responsibilities of Principal Investigators**

- Upholding professional and ethical standards and practices
- Adhering to applicable VA and Federal requirements
- Disclosing conflict of interest
- Ensuring adequacy of resources
- Overseeing the research team
- Obtaining all relevant approvals in writing **before** starting the study (see VHA Handbook 1200.01)
- Implementing the protocol as approved
- **Documenting** how the protocol is being implemented
- Informed Consent
  - Must use the most recent IRB-approved version of Informed Consent Form
  - Ensure consistency among Informed Consent Form, Protocol and HIPAA authorization
- Ensure potential subjects receive “Volunteering in Research” brochure
- Initial contact of subject must be in person or by letter
  - Initial contact can never be by phone
General Question of the Month

Question:
How do I delete a person from my study who has left MUSC and no longer has a NetID on the ERMA System?

Answer:
1) Log into your study at: erma.musc.edu. Enter the amendment section and begin a new amendment.
2) Select Personnel Amendment and Click Next.
3) Check the “Not MUSC personnel” checkbox and click Save to move to the next screen.
4) Complete the required fields and click Next.
5) Select “TO AMENDMENTS LIST” at the bottom left to return to the list of amendments and click submit.
## EIRB Question of the Month

**Question:** What is the difference between ERMA and the new eIRB system?  

**Answer:**

<table>
<thead>
<tr>
<th></th>
<th>ERMA</th>
<th>eIRB</th>
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<tbody>
<tr>
<td><strong>System:</strong></td>
<td>online system with paper based files</td>
<td>Completely automated system</td>
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<td><strong>Type:</strong></td>
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<td>SmartForm Application</td>
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<td>ations, Reports and</td>
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<td>Reportable Events</td>
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<tr>
<td>Routing for Signatures</td>
<td>Labor-Intensive; Handwritten</td>
<td>Electronic through eIRB</td>
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<tr>
<td>Continuing Reviews</td>
<td>Anyone can submit</td>
<td>PI must submit</td>
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<tr>
<td>Online Access to IRB</td>
<td>N/A</td>
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<td>Approved Stamped Doc</td>
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<td>Online Submissions</td>
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<tr>
<td>Electronic Reporting</td>
<td>N/A</td>
<td>Electronic reporting of Protocol Deviations</td>
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<tr>
<td>of Protocol Deviations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Reports/Events</td>
<td>Submit via email and/or fax</td>
<td>Uniform mechanism to send DSMB, monitoring, auditing reports via the</td>
</tr>
<tr>
<td>Information</td>
<td></td>
<td>electronic system</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>√</td>
<td>System informs you that AE is not reportable if it's not serious,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>possibly related or related AND unexpected for both internal and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>external events</td>
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</tbody>
</table>
# 2011 Deadline Dates for Submissions and Meetings

As a reminder, the 2011 Deadline Dates for Submissions and Meetings are now available online at [http://research.musc.edu/ori/irb/deadlines.html](http://research.musc.edu/ori/irb/deadlines.html).

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## Contact Information

<table>
<thead>
<tr>
<th>IRB</th>
<th>Contact</th>
<th>Title</th>
<th>Responsibilities</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Linda Bunch</td>
<td>Administrator</td>
<td>New Full Board Submissions, Full Board Amendments</td>
<td>2-2525</td>
<td><a href="mailto:cooperld@musc.edu">cooperld@musc.edu</a></td>
</tr>
<tr>
<td>1</td>
<td>Katherine Duncan</td>
<td>Coordinator</td>
<td>Continuing Reviews, Expedited Amendments, Event Reporting</td>
<td>2-4843</td>
<td><a href="mailto:duncank@musc.edu">duncank@musc.edu</a></td>
</tr>
<tr>
<td>1</td>
<td>Christina Hurman</td>
<td>Coordinator</td>
<td>Expedited Personnel Amendments</td>
<td>2-4148</td>
<td><a href="mailto:hurman@musc.edu">hurman@musc.edu</a></td>
</tr>
<tr>
<td>2</td>
<td>Lisa Johnson</td>
<td>Administrator</td>
<td>New Full Board, Exempt Submissions, Event Reporting</td>
<td>2-4144</td>
<td><a href="mailto:johnsli@musc.edu">johnsli@musc.edu</a></td>
</tr>
<tr>
<td>2</td>
<td>Kaye Roberts</td>
<td>Coordinator</td>
<td>Continuing Reviews, Amendments</td>
<td>2-6710</td>
<td><a href="mailto:roberkk@musc.edu">roberkk@musc.edu</a></td>
</tr>
<tr>
<td>3</td>
<td>Jackie Shedrow</td>
<td>Administrator</td>
<td>New Full Board Submissions, Full Board Amendments</td>
<td>2-3071</td>
<td><a href="mailto:shedrow@musc.edu">shedrow@musc.edu</a></td>
</tr>
<tr>
<td>3</td>
<td>Yashmin Karten</td>
<td>Administrator</td>
<td>New Full Board Submissions, Protocol Deviations, Full Board Amendments</td>
<td>2-6521</td>
<td><a href="mailto:karteny@musc.edu">karteny@musc.edu</a></td>
</tr>
<tr>
<td>3</td>
<td>Cheryl Green</td>
<td>Coordinator</td>
<td>Expedited Amendments</td>
<td>2-3093</td>
<td><a href="mailto:greench@musc.edu">greench@musc.edu</a></td>
</tr>
<tr>
<td>3</td>
<td>Kenny Thomas</td>
<td>Coordinator</td>
<td>Continuing Reviews, Adverse Events</td>
<td>2-7457</td>
<td><a href="mailto:thomaskn@musc.edu">thomaskn@musc.edu</a></td>
</tr>
<tr>
<td>1, 2, 3</td>
<td>Summer Young</td>
<td>Administrator</td>
<td>All Expedited New Studies, Exempt (1, 3)</td>
<td>2-6534</td>
<td><a href="mailto:youngsn@musc.edu">youngsn@musc.edu</a></td>
</tr>
</tbody>
</table>

This is NOT a comprehensive list of responsibilities. Please see [http://research.musc.edu/ori/contacts/irb.html](http://research.musc.edu/ori/contacts/irb.html) for a more comprehensive list.

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## IRB Forms Online Location

As a reminder, IRB Forms are available online at [http://research.musc.edu/ori/irb/forms.html](http://research.musc.edu/ori/irb/forms.html).

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## CITI Online Location

As a reminder, CITI Online is available online at [http://www.musc.edu/citi](http://www.musc.edu/citi).

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## Holiday Schedule for the Remainder of the Year

- Thanksgiving Day — Thursday, November 25th
- Day after Thanksgiving — Friday, November 26th
- Christmas Eve — Friday, December 24th
- Christmas Day — Monday, December 27th (Observed)
- Day after Christmas — Tuesday, December 28th (Observed)
- New Year’s Day — Monday, January 3rd (Observed)

Please send comments, questions, or suggestions for future issues to Christina Hurman at hurman@musc.edu.