A Note from the ORI Director

Is informed consent for research broken? This has been the topic of several recent conferences, including our own 17th Annual Thomas A. Pitts Lectureship in Medical Ethics held in October 2010, as well as the Advancing Ethical Research Conference sponsored by Public Responsibility in Medicine and Research. In both venues, speakers agreed that most written informed consent documents are too long and too complicated; making it unlikely that subjects will pay attention to the most important aspects of the research. On the other hand, there are many requirements that must be included in every consent form, even if they are of little interest to subjects. What should we do as responsible researchers? First, we need to pay attention to how the consent form is written, making sure to avoid repetition and write in clear language that can be understood by lay people. On occasion, we have asked investigators to include charts in their consent documents to make certain aspects of the procedures more clear. When the issues are particularly complex and there is worry that a subject may not comprehend, we have sometimes asked subjects to take a test of comprehension at the end of the process. Second, we need to remember that informed consent to participate in research is a process. This means that subjects (who are often patients with difficult illnesses) must be given time to go over the consent, ask questions, and consider alternatives. The person who is obtaining consent should be knowledgeable about the study, unhurried, and willing to engage in dialogue about the procedures. In the end, the truly informed subject will be more engaged in the study procedures and a true partner in research.

MUSC Rollout of Click Commerce eIRB Update

As MUSC now has all of IRB I and II initial protocols being submitted, along with IRB III exempt & expedited, reviewed and approved in the eIRB system, we are poised to take the next step.

Now, researchers submitting corporate sponsored “full Board” initial protocols to IRB III have the option of using ERMA or the new eIRB system.

Beginning March 8, 2011, all “full Board” initial protocols going to IRB III will be accepted only through the eIRB system.

In addition to guidance material and tegrity 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>
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<th>Initial Protocol</th>
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<td>eIRB as of 12/01/2010</td>
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<tr>
<td>Amendments</td>
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<td>Same system as Original Study</td>
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<tr>
<td>Continuing Review</td>
<td>Same system as Original Study</td>
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<tr>
<td>Adverse Events</td>
<td>Same system as Original Study</td>
<td>Same system as Original Study</td>
</tr>
</tbody>
</table>

eIRB Tip

A subject must sign the Informed Consent that includes the most recent IRB Stamp.
NEW POLICY:

Protocol Deviation - Policy and Procedures – **HRPP 4.14**

*This policy defines a protocol deviation as any variance from the protocol involving a subject or subjects that is not approved by the IRB prior to its initiation or implementation, and occurs when a member of the study team departs from the IRB-approved protocol in any way without the investigator first obtaining IRB approval.*

In addition to defining a protocol deviation, this policy provides examples of deviations that may need to be reported to the IRB, as well as procedures for reporting protocol deviations to the IRB.

The above policy as well as the entire HRPP guide can be found at:

http://research.musc.edu/ori/irb/policies.html.

NOTE: The protocol deviation form used to report protocol deviations has been revised and is available for download from the IRB website at:

http://research.musc.edu/ori/irb/submissions.html.

If the study is open in the eIRB system, the reporting process for a Protocol Deviation is completed within the electronic system using the Reportable Events module within the smartforms and does not require a separate deviation form. For more information on how to report a protocol deviation in the eIRB system, please see the guidance manual on the IRB website at:


In addition to the eIRB guidance manual, a tegrity training session was created for submitting reportable events in the eIRB system and can also be accessed via the IRB website at:

http://research.musc.edu/ori/irb/eIRB.html

Please contact the IRB at 792-4148 if you have any questions or need additional information.
Policy Updates

UPDATED POLICY:
The revised HRPP section is HRPP 7.3 “Payments for Participation Policy and Procedures”.

The following summarizes this policy:

MUSC has adopted the following procedures to ensure research participant payments are reported in accordance with state and federal income reporting requirements, while maintaining an appropriate level of confidentiality. Payment types may include, but are not limited to: checks, petty cash, gift certificates/cards, personal property, and other items of value.

The MUSC Finance & Administration Policy 6-13.0 “Remuneration for Research Trial Participants” outlines three Remuneration Scenarios (see below) as well as specifics as they relate to the optional methods of payments and the reporting requirements to Accounts Payable

1. Standard (preferred) method of remuneration via University check payment.
2. Alternative method of remuneration where participant personal information is attainable for IRS reporting.
3. Alternative method of remuneration where participant personal identifying information is not collected for IRS reporting due to the very sensitive nature of the study. **The IRB must approve the non-collection of IRS information.**

Contact Information

Office Phone Numbers:

Office of Research Integrity 843-792-4148
University Accounts Payable: 843-792-3219

Questions regarding the processes for making payments to research participants may be directed to the University Accounts Payable Department.

Questions regarding implementing the requirements while maintaining confidentiality requirements for the IRB should be directed to the Office of Research Integrity.
**International Research: Applying Ethical Principles and Research Guidelines in Global Settings**

**Hosted by the SUCCESS Center**

**Wednesday, February 16, 2011, at 1:00 PM ET in Room 109 of the Library**

**Topics to include:**

- Ensure that those in international settings who will be working with your institutional review board (IRB) are aware of the relevant federal regulations pursuant to their Federalwide Assurance (FWA)
- Educate IRB members, administrators, principal investigators, and research staff about the ways in which the cultural context of each international research project should be considered
- Evaluate risks and benefits in variable risk environments
- Navigate differing power relationships, e.g. gender, social class, etc., that might impact consent authority
- Obtain informed consent in settings with oral rather than written traditions
- Develop strategies for community engagement so as to deepen our commitment to the communities in which we are working
- Help ensure equitable distribution of the fruits of the research

**Audience**

All IRB chairs, administrators, staff, and members, institutional officials, researchers, research staff, federal officials, sponsors, and others engaged with international research are invited to attend what will be a highly valuable webinar.

**Contact**

Please contact the SUCCESS Center with questions at: 792-8300

**Faculty**

When PRIM&R wants to receive authoritative information on international research matters, we turn to David Borasky and Nancy Kass, two highly esteemed speakers and among the most experienced professionals working in the field today. After their presentations, they will answer questions submitted by participants.

David A. Borasky, Jr., MPH, CIP  
IRB Manager  
Office of Research Protection  
RTI International

Nancy Kass, ScD  
Professor of Bioethics and Public Health  
Johns Hopkins University

Bloomberg School of Health
### General Questions of the Quarter

**Question:** What is informed consent and when is it needed?

**Answer:** In almost all cases, consent must be obtained from the research participants or their legally authorized representatives before participation in research begins.

The informed consent process is a basic ethical obligation for researchers. It consists of providing adequate information to the subject about the study, giving the subject the opportunity to consider options, responding to questions the subject may have and ensuring that the subject or the legal representative understands the information. In addition, the process includes obtaining the subject's voluntary agreement to participate in the research, indicated by the subject's signature on the written consent document. After the subject's signature is obtained, the informational process should continue as the situation or the subject may require both during and after the study.

The IRB may approve a waiver of consent in limited circumstances. Consent may be waived if the IRB determines:
1. That no more than minimal risk to research participants would be involved.
2. That the rights or welfare of participants would not be adversely affected.
3. That the research could not be practically conducted without a waiver.
4. Additionally, regulations require that if appropriate, there be a plan to provide research results to subjects after conclusion of the study.

**Question:** Which waiver of consent should I use?

**Answer:** The waiver of consent is generally used for retrospective chart reviews and the waiver of signed consent is generally used for survey research. Please contact your IRB Administrator for more information about the waivers.

**Question:** Can I use the sponsor-provided informed consent forms?

**Answer:** No, you must use the MUSC consent form.

**Question:** Do I have to use the MUSC informed consent format?

**Answer:** Yes. Guidelines for Standard Informed Consent

**Question:** Do we have to use the MUSC standard paragraphs in the informed consent document?

**Answer:** Yes, the MUSC standard paragraphs must be used. The MUSC standard paragraphs can be found on the IRB website Guidelines for Standard Informed Consent

**Question:** Can my sponsor change the wording of the MUSC standard paragraphs?

**Answer:** No, the wording cannot be changed.

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Please feel free to ask the IRB questions by emailing any of the staff. If you would like your question to be included in the next submission, please contact Christina Hurman at hurman@musc.edu.
**eIRB Questions of the Quarter**

**Question:** Why am I not able to log in?

**Answer:** Please make sure when entering your username you are entering your MUSC NetID name. Then enter your password.

If you continue to have log in issues, you may need to be registered in the eIRB system. This may be the case for someone who has just been assigned a netID and has not yet been added into the eIRB system. If this is the case, the 1st time a new user logs into the, a registration screen will be displayed. Fully complete the requested information. *Note: Non-faculty member study PI's will require a mentor to be able to be listed in eIRB with PI rights. To ensure this, check the box that indicates you are a student, as this is the mechanism to grant you this PI access right.* After the registration form is complete and the user clicks ok, an email is sent to the MUSC eIRB administrator. The site administrator will complete the registration, assign the user roles appropriate to the user’s research activities and activate the account. The user will receive an email notification of account activation. This process can take up to 24 hours; however, if registration is required sooner, contact the eIRB systems administrator.

If you continue to have log in issues, you may need to contact OCIO at 792-9700 to ensure your Net ID is working properly.

**Question:** I submitted an application but haven't heard from the IRB. It seems to be in a "pre-submission" status. Why is this study not being evaluated?

**Answer:** If the study is in pre-submission, then it has not yet been submitted for IRB review. Only the PI can submit a study. The submit button is found under "My Activities" of the PI.

**Question:** How are Informed Consents stamped?

**Answer:** All informed consents approved in the eIRB system will include a “watermark” in the footer. This watermark will include the protocol number, the date of approval and the expiration date. Once the informed consent is approved, it is “stamped” (information in the watermark is completed), the stamped informed consent is made “read only” and placed in a Stamped Informed Consent tab. Therefore, at all times, the current version of the informed consent will be the document in this tab. Prior versions are retained in the eIRB system for reference.

The forms page of the IRB website ([http://research.musc.edu/ori/irb/forms.html](http://research.musc.edu/ori/irb/forms.html)) has been revised, incorporating an Informed Consent Template – eIRB version (for de novo informed consent development) as well as the eIRB Watermark for Informed Consent Documents (for placement in developed informed consent documents). **NOTE:** The Watermark process is a Word-based process and will only function on .doc files.

**Question:** I cannot find the name of one of my study team members.

**Answer:** Personnel must be listed in MUSC’s system with a current netID and must have been assigned particular roles within the eIRB. Contact the eIRB administrator to discuss role assignment (i.e., why the personnel’s name is not found in a particular pick list) and to coordinate netID assignment, if needed.

Please feel free to ask the IRB questions by emailing any of the staff. If you would like your question to be included in the next submission, please contact Christina Hurman at hurman@musc.edu.
Audit Findings Involving Informed Consents

It is of the utmost importance that the Research Team adhere to the Informed Consent Process set forth by the Federal and State government regulations and MUSC policies and procedures.

Below are Common Audit Findings Involving Informed Consents:

- Missing informed consent documents (ICD)/HIPAA forms
- Obsolete ICD/HIPAA Authorization forms used
- Subjects consented by personnel not approved by the IRB
- Dating of the ICD/HIPAA Authorization forms appear to be in the same handwriting
- ICD/HIPAA Authorization missing or illegible IRB approval stamp
- Informed Consents document used from a different study
- White-out used to cover signature errors
- Subjects consented via telephone when this option is not approved by the IRB
- Subject or person obtaining consent does not date the ICD/HIPAA
- Subject does not initial the HIPAA authorization form

Actions to Reduce Findings Involving Informed Consents:

- Only those study team members that have IRB approval and have completed IRB required training are allowed to consent subjects.
- Study Members should only use the IRB approved latest version of the Informed Consent Document. All previous versions should be marked as “Obsolete” and filed in the Principal Investigator (PI’s) regulatory binder.
- The current Informed Consent version should be marked with the IRB stamp indicating approval and copies should be made directly from this document.
- Changes to the Informed Consent document must be approved by the IRB prior to its use in the study.
- The PI must ensure the informed consent form meets all applicable regulations depending upon the potential subjects included in the study, i.e. VA patients, minors, etc.
2011 Deadline Dates for Submissions and Meetings

As a reminder, the 2011 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

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<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>
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<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>
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<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>
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<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>
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<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>
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This is NOT a comprehensive list of responsibilities.

CITI Online Location

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

Holiday Schedule for the first half of 2011

- George Washington’s Birthday/President’s Day - Monday, February 21st
- Confederate Memorial Day - Tuesday, May 10th
- National Memorial Day - Monday, May 30th
- Independence Day - Monday, July 4th
- Labor Day-Monday, September 5th

Hyperlinks to eIRB

- eIRB System
- eIRB User Guides and Tegrity Sessions
- eIRB Training Calendar

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