IRB Updates: Informed Consent Template Changes, Consent Guidance and more!

Informed Consent and HIPAA
There is now a new template document that includes both the informed consent template and HIPAA wording! There is a still a stand-alone Informed Consent template and a stand-alone HIPAA document. The templates are located on the Forms page of the IRB website at: http://academicdepartments.musc.edu/research/ori/irb/forms.html

Certificate of Confidentiality – Consent language
The wording for the Certificate of Confidentiality section of the informed consent template has been revised. In addition to the revision, the new wording is now located on the Suggested Consent Language Library page of the IRB website at: http://academicdepartments.musc.edu/research/ori/irb/Suggested_Consent_Language
Note: There are three options for wording to be chosen. Please choose one as applicable.
Collection of Specimens

No change has been made to the to the consent language. The location of the wording is now located on the Suggested Consent Language Library page of the IRB website at:
http://academicdepartments.musc.edu/research/ori/irb/Suggested_Consent_Language

Suggested Consent Language

Use the following suggested Consent Language on the appropriate Informed Consent Template. Each section contains language specific to the procedure and risks and discomforts associated with the procedure.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw</td>
<td>General Anesthesia</td>
</tr>
<tr>
<td>Blood Product Transfusion</td>
<td>Genetic Research</td>
</tr>
<tr>
<td>Bone Marrow Aspiration</td>
<td>Bone Marrow or Stem Cell Transplantation</td>
</tr>
<tr>
<td>Chest X-ray</td>
<td>Incidental Findings</td>
</tr>
<tr>
<td>Contrast Material</td>
<td>Infectious Disease Testing</td>
</tr>
<tr>
<td>Certificate of Confidentiality</td>
<td></td>
</tr>
</tbody>
</table>

Collection of Specimens

Samples Linked to Participant

Samples Unlinked to Participant

Informed Consent - Standard Paragraphs:

Two new options have been added to the list of informed consent standard paragraphs. These new options are to be used when both children and adults will be enrolled in a study. The links to these paragraphs are located in the consent templates.

Informed Consent – Volunteers Statement

The Volunteers Statement of the informed consent has been updated to include a new phone number. See update below:

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study-related injury I may contact [NAME]. I may contact the Medical University of S.C. Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.
Informed Consent and HIPAA—Signature Lines
A small addition of information has been added to the informed signatures lines. See below for the new information:

Electronic Consent – Guidance/FAQs
This new guidance document is located on the forms page of the IRB website. Look for it in the guidance column of the Informed Consent section. This is a supplement to the Informed Consent policy (HRPP 6.1) that includes a section regarding electronic consent.