Investigator Signature Line Clarification

The Office of Research Integrity appreciates receiving feedback from the research community as these questions or suggestions often provide opportunities to streamline or make a simple change to clarify a requirement. One such recommendation resulted in an edit to the Medical Consent/Assent document templates relative to the investigator signature line.

Federal regulations require an IRB approved consent form to be signed and dated by the research participant (or participant’s legally authorized representative). Additional signature requirements may apply based on alternate consent methods, international guidelines, sponsor procedures, etc. The University of Kentucky (UK) IRB signature requirements depend in part on whether the research falls under the purview of the Medical or Nonmedical IRB.

If you conduct research under the approval of the UK Medical IRB, the investigator is expected to sign to appropriately document that informed consent/assent has been obtained. However, this may be either the Principal Investigator (PI) or a Sub/Co-Investigator where the responsibility has been delegated by the PI.

Unless the Nonmedical IRB mandates as a protocol specific requirement, the investigator’s signature is generally not required for research reviewed by the Nonmedical IRB. Both IRBs require the signature of the person obtaining informed consent from the participant.

The investigator’s signature on the informed consent document verifies that the person who explained the study and obtained informed consent is qualified and that the IRB has approved him/her to do so (UK IRB/ ORI Informed Consent SOP).

This line is signed and dated by the person who was involved in relaying the details of the research and obtained informed consent from the research participant.

This individual should be listed as study personnel on the IRB approved protocol with permission to obtain informed consent (“authorized to obtain informed consent” on the study personnel list).

Added to the Medical Consent/Assent templates to clarify that a sub or co investigator may sign where this responsibility has been delegated by the Principal Investigator.
Table Summarizing Consent Signature Requirements of the Medical and Nonmedical

<table>
<thead>
<tr>
<th>Informed Consent</th>
<th>Informed Consent/HIPAA combined</th>
<th>Assent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lines to be completed (unless otherwise approved by the IRB)</td>
<td>Lines to be completed (unless otherwise approved by the IRB)</td>
<td>Lines to be completed (unless otherwise approved by the IRB)</td>
</tr>
<tr>
<td>1. Research participant</td>
<td>1. Research participant</td>
<td>1. Research participant</td>
</tr>
<tr>
<td>2. Name of (authorized) person obtaining informed consent</td>
<td>2. Name of (authorized) person obtaining informed consent</td>
<td>2. Name of (authorized) person obtaining informed consent</td>
</tr>
<tr>
<td>3. Principal Investigator (PI)/Sub-Co Investigator</td>
<td>3. PI/Sub-Co Investigator</td>
<td>3. PI/Sub-Co Investigator</td>
</tr>
</tbody>
</table>

Prepared by Judi Kuhl, B.S., CIP, ORI Quality Improvement Program

2014 Update to the International Compilation of Human Research Standards
Now Available—
http://www.hhs.gov/ohrp/international/index.html

The International Compilation of Human Research Standards enumerates over 1,000 laws, regulations, and guidelines that govern human subjects research in 107 countries, as well as the standards from a number of international and regional organizations.

This Compilation was developed for use by researchers, IRBs, sponsors, and others who are involved in human subjects research around the world.

Content experts, listed on page 128, provided listing updates (or confirmations of accuracy of prior listings), which are reflected in the hundreds of changes to the Compilation.

Major changes in human subject standards were reported for Brazil, France, Kyrgyzstan, Switzerland, Taiwan, and Turkey. Three new countries are featured in the 2014 edition: Cameroon, Mozambique, and Zambia.
Holiday Announcement

The Office of Sponsored Projects Administration (257-9420), the Proposal Development Office (257-2861), the Office of Research Integrity–IRB & IACUC– (257-9428), and the Survey Research Center (257-4684) will be closed Wednesday, December 25 through Wednesday, January 1 and will reopen on Thursday, January 2, 2014. If you anticipate a need for services provided by any of these offices during this time, please call the appropriate office(s) as soon as possible so that assistance may be provided before the break.

Note for Human Research Investigators:
The last Medical IRB meeting in 2013 is December 18th and the last Nonmedical IRB meeting is December 13th. Previously advertised submission deadlines for these meetings have passed. If you have received IRB continuation review reminders for a protocol that is nearing the approval end date, please contact ORI Continuation Review Staff immediately. Karen Larson at 859-257-9819 (Medical IRB #3 & #6), Gail Cadwallader at 859-257-0581 (Medical IRB #1 & #2), or Andrew Hedrick at 859-257-1639 (Nonmedical IRB #4).

Note for Animal Research Investigators:
The last IACUC meeting in 2013 will be held on December the 11th (second Wednesday of the month rather than the third). If you have received an IACUC protocol rewrite, or annual review reminder, please be sure to submit your protocol by the recommended date to ensure IACUC review and prevent lapse of approval.

Thanks and from all of us, we wish you a safe and happy holiday season!

This message was also sent as a separate list serve announcement on 11/12/13.

Use ORI's customer service form to submit suggestions online. www.research.uky.edu/ori/concerns_suggestions.htm#feedback

Save the Date—Tuesday, January 14th
Center for Clinical and Translational Science (CCTS)
Clinical Research Update
HUMAN SUBJECT PROTECTION UPDATE
Ada Sue Selwitz, M.A. Director, Office of Research Integrity
Co-Director, Regulatory Support and Research Ethics, CCTS

Full Announcement coming soon from the CCTS

Questions or comments? Email us at belinda.smith@uky.edu. To remove your name from our mailing list click here.