Find out what's new in Human Subject Protection.

Don't miss the UK Center for Clinical and Translational Science (CCTS) January 17th Clinical Research Update!

R.S.V. P. to CCTS@uky.edu to attend

REMINDER—Revised Informed Consent & HIPAA Templates

As detailed in the December 2012 Newsletter, updated versions of the Medical and Nonmedical Informed Consent and HIPAA Forms are available for new IRB submissions on the ORI Forms Webpage. A listing of the revisions and versions of the templates with highlighted edits were provided for reference on the 2012 ORI ‘What’s New’ webpage—http://www.research.uky.edu/ori/WhatsNew2012.htm.

ORI FAQ’s

Question: My protocol needs full IRB review. How do I get it on an IRB agenda?

Answer: When you submit your IRB application to the Office of Research Integrity (ORI), your protocol materials will be assigned to an IRB meeting date. When the agenda for that meeting date is processed by ORI staff (approximately 10 days prior to the meeting date), your materials will be listed on the agenda. Medical IRB & Nonmedical IRB meeting dates are available on the Meeting Dates webpage [http://www.research.uky.edu/ori/humanIRBMeeetingDates.htm].

www.research.uky.edu/ori/humanFAQs.htm
Keys to an Effective Informed Consent/Assent Process  

Judi Kuhl, B.S., C.I.P.

The consent form or consent process should be provided in language understandable and culturally sensitive to the subject, consistently using familiar words.

Whenever possible, simple sentences should be used instead of complex ones, and medical or technical jargon should be avoided. For your convenience, under the Informed Consent topic on ORI’s Educational Materials, Regulations, and Policy Guidance web page, ORI has a glossary of select lay terms for reference: [PDF]

Avoid abbreviations and acronyms, and words containing more than three syllables where possible.

Give the potential subject ample opportunity to consider participation and to ask questions (if documentation of informed consent is involved, this may entail encouraging the potential subject to take the informed consent document home for further review and discussion with family and/or friends).

Conduct the informed consent/assent process in a private and quiet place, and allow a sufficient amount of time to complete the process.

Consider a “teach-back” tool to improve communication and evaluate comprehension. This is accomplished by asking the potential subject to verbally “teach back” information they’ve received about the proposed research (who, what, when, why, how). E.g., not asking “do you understand”, but instead, “I want to be sure we have the same understanding about the research. Can you tell me, in your own words, who to contact with questions?”; or, “…can you tell me, in your own words, what risks are associated with the research procedures?”

Source: Informed Consent Process Educational Series, Issue 2, September 13, 2012