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REVISED AND NEW UCLA CONSENT FORM TEMPLATES

Date: 2011-07-05

All UCLA Consent, Assent and Screening Templates on One Web Page

The templates for consent, assent and screening as well as the standards and guidance for preparing consent forms has been consolidated onto one web page. Rather than organizing the templates by social/behavioral and biomedical, the templates are now organized as follows:

- Minimal Risk Research Informed Consent Templates (for expedited and exempt studies)
- Greater than Minimal Risks Research Informed Consent Templates (for studies requiring full committee review)
- Consent Templates for Minimal Risk and More Than Minimal Research
- Standards, Sample Language and Comprehension Tools

If you need assistance determining whether your study is minimal risk or greater than minimal risk, see OHRPP Guidance Conducting Risk-Benefit Assessments Determining Level of Review or contact the OHRPP office.

Revised and Updated Consent, Assent and Screening Templates

Although there are minimal changes made to most of the templates, the templates for the greater than minimal risks research consents have been significantly revised. These templates have been revised primarily to increase potential research participant understanding of the research studies, to make all UCLA consent templates more consistent, and to use current best practices in obtaining consent. The UCLA template for biomedical research had not been updated for more than 10 years.

The primary changes include

- using a question-and-answer format,
- using more straightforward language so that the reading level is appropriate for a broader group of participants, and
- the removal of some former requirements that were uniquely UCLA.

Additionally, and very importantly, there is **now section-by-section linked guidance** to the greater than minimal risks research template.

Two additional greater than minimal risk research templates that have been added are templates for NCI-UCLA Biomedical Research (which may also be used for other oncology research) and a template for the use of an Humanitarian Use Device.

Start Using Now!

Please start using these versions of the templates **now** for new studies. If you have already prepared or started a consent form or document using the old format, the IRB will accept these for the time being, but by October 1, 2011 use of the new templates will be required. However, because a great deal of IRB member and researcher input and staff effort and research into best practices went in to the development of these templates, **you will be doing a service to our research participants by using the new templates as soon as possible.**