USC HSIRB Informed Consent Template and Instructions
Summary of Changes for June 2014 Revision

General Instructions for Using the Template (page 1)
• Improved wording of instructions.
• Moved instructions about formatting, style, and language of consent forms to a separate section.

Guide for Informed Consent Form Authors and Editors (pages 2-3)
• Added new instructions for the expected format, style, and language to be used when writing new consent forms or revising existing consent forms.
  • New or revised consent forms that do not comply with these IRB instructions may be returned without review.

General Instructions for California Experimental Subject’s Bill of Rights (page 4)
• Simplified wording of instructions.

Introductory Section (page 6)
• Added information about use of the adult consent for as a youth assent and parental permission form.

Why Is this Study Being Done? (page 6)
• Deleted the requirement to provide the number of participants enrolled at USC.

What Is Involved in the Study? (pages 7-8)
• Reorganized instructions.
• Added instruction to explain that positive reportable disease test results will be reported to local health agencies.
• Revised suggested language for genetic research.

What about Pregnancy? (page 9)
• Added instruction to describe precautions that should be taken by female participants, male participants, and sexual partners of participants.

What Are the Possible Risks and Discomforts? (page 10)
• Added risk language for blood draws.
• Added option to use OHRP language when describing the Genetic Information Nondiscrimination Act (GINA).

Will Your Information Be Kept Private? (page 12)
• The ClinicalTrials.gov identifier is not required; if it is added to the FDA-mandated paragraph, it should be added as a separate sentence at the end.

What Other Options Are There? (page 14)
• Added instruction to state when participants can receive the drug, device, or procedure without being in the study.
What Are the Costs? (pages 15-17)
- Revised the options and template language for costs to participants.
- Added instruction that cost language must be consistent in the consent form and iStar #25.1.

What Happens if You Get Injured or Need Emergency Care? (pages 17-19)
- Revised the options and template language for research-related injury.
- Added instruction that injury language must be consistent in the consent form and iStar #25.3.

Do the Investigators or the Institution Have a Conflict of Interest? (pages 19-20)
- Updated information about USC’s conflict of interest policy.

Agreement Section (pages 21-24)
- Added instruction about obtaining the signature of a witness when a participant cannot see, read, write, or physically sign the consent form.
- Revised the boxed instruction about when a witness signature is needed.