USC HSIRB Informed Consent Template
Guide for Informed Consent Form Authors and Editors

Informed consent form authors and editors must follow these instructions when creating new consent forms or revising approved consent forms. These instructions are intended to make it easier for participants to read and understand the research information. Following these instructions will speed up IRB review and approval of your consent forms. If you submit new or revised consent forms that do not comply with these instructions, your submission may be returned without review.

Formatting Instructions

- Use a font size of 12 or larger.
- Leave a one-inch left margin and right margin to accommodate the IRB stamp.
- Adjust the margins to be left justified only ("ragged" right margin, not full justification).
- If you start with a sponsor's consent template, strip out all paragraph formatting. To do this in Word, select the "Home" tab, open the paragraph ribbon, click on the "Line and Page Breaks" tab, and uncheck all the boxes under "Pagination."
- Use bullets for long lists of procedures or risks.
- Use subheadings to break up large amounts of text.

Language / Style Instructions *

- Avoid medical and scientific jargon; instead, use common, everyday language that can be understood by a participant with an 8th grade education.
- If a technical term is used, define or explain it in lay language the first time.
- Spell out abbreviations or acronyms the first time they are used.
- Use short sentences and short paragraphs.
- Avoid details that do not help participants make a decision about being in the study.
- Avoid unnecessary duplication of information.
- Write in the second person ("you"), not the first person ("I").
- Use active voice rather than passive voice whenever possible; for example, use "We will draw a blood sample", not "A sample of blood will be drawn."

Word Usage

Do Not Use:	Use:
adverse event or adverse effect	side effect
approximately	about
data	information or study information
dosing	
e.g., etc, or i.e.	
patients (when referring to research participants)	participants
prior to	before
Sponsor	sponsor (do not capitalize)
symbols such as < or > or &	
subjects	participants
treat or treatment when the study involves unapproved drugs, devices, or procedures	

*** Applicable Regulations and Guidance:**

The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. (45 CFR 46.116, 21 CFR 50.20)

The procedures used in seeking and obtaining informed consent should be designed to communicate with the subject population in terms that they can understand. The information must be conveyed in language understandable to those being asked to participate. (OHRP Informed Consent FAQs)

The IRB should ensure that technical and scientific terms are adequately explained or that common terms are substituted. The IRB should ensure that the informed consent document properly translates complex scientific concepts into simple concepts that the typical subject can read and understand. (FDA Information Sheet - A Guide to Informed Consent)

Sample or draft consent documents may be developed by a sponsor or cooperative study group. However, the IRB of record is the final authority on the content of the consent document that is presented to the prospective study subject. (FDA Information Sheet - A Guide to Informed Consent)