OHRPP Update

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Using the UCLA Biomedical Consent Form Template
Consent, Assent and Screening Templates

Rather than dividing the templates into biomedical and behavioral templates, they are divided into the templates used for minimal risk studies, greater than minimal risk studies or for both. In addition, please see guidance and references at the bottom of this page. If you are unsure which template to use, please contact the OHRPP office.

Minimal Risk Research Informed consent Templates (expedited or exempt)
- Consent Template for Subjects Recruited from Student Subject Pools
- Consent Template (includes signature) - for minimal risk studies
- Parent Permission Template (parents provide permission for child to participate) - for minimal risk studies
- Parent Consent Template (parents complete research procedures themselves) - for minimal risk studies
- Oral Consent Script Outline
- Study Information Sheet (no signature)

Greater than Minimal Risk Research Informed Consent Templates (full committee review)
- Consent Template (w/section-by-section hyperlinks to guidance) - for greater than minimal risks studies (biomedical focus) New!
- Consent Template (w/one hyperlink to guidance) - for greater than minimal risks studies (biomedical focus) New!
- NCI-UCLA Biomedical Consent Template - for greater than minimal risks studies (can be used for all oncology)
- Humanitarian Use Device (HUD) Consent Template New!

Templates for Minimal Risk and More Than Minimal Risk Research
- Addendum Consent Template for Non-Treatment Studies (for new procedures, risks)
- Addendum Consent Template for Treatment Studies (for new procedures, risks)
- Adolescent Assent Template for Non-Treatment Studies (Age 13-17)
- Child Assent Template (Age 6-12)
- Screening Script for non-Treatment Studies
- Screening Script for Treatment Studies

Standards, Sample Language & Comprehension Tools
- Behavioral Consent Form Standards and Sample Language
- Medical Consent Form Standards and Sample Language New!
- PRISM Readability Tool Kit New!
- Self-Certification of Surrogate Decision Makers for Potential Research Subject’s Participation in UC Research (Only to be used when approved by IRB)
- Subject Comprehension Assessment Tool

Other References
- Research Participant’s Bill of Rights - available in 34 languages
- Conducting Risk-Benefit Assessments New!

Feedback
We appreciate your suggestions for improving templates and/or adding sample language to the standards documents. Please email sfriend@research.ucla.edu to provide your feedback.
Improved Readability, Better Comprehension

- **Question and answer format**
  - Assists in reading comprehension
  - Function like FAQs

- **Use of active voice**
  - Headings in 1\textsuperscript{st} person
  - Responses in 2\textsuperscript{nd} person

- **Plain language, conversational style**
  - 6-8\textsuperscript{th} grade reading level (\textit{USA Today} newspaper)
  - When read aloud, it sounds like a conversation
New Consent Standards Document

- General consent preparation instructions
- **Section-by-section** instructions and guidance (e.g., what to include in the risks section)
- Sample consent language
Required vs. Optional Sections

- **Required sections** are the basic elements of informed consent (per regulation) and must be in every consent document*.

- **Optional sections** are the additional elements of informed consent and should be included if they apply to the study.

*unless an alteration is approved by IRB; minimal risk research only.
Very little of the template and standards language is required to be used; **However**, the suggested language is:

- Crafted with readability & comprehension in mind
- Endorsed by IRB members
  - IRBs might request language from these documents when alternate language is not in lay language.
  - Example: costs language for insurance billing
Required Language is Required

Do not alter it!

- UC(LA) treatment and compensation for injury
- Collection and use of specimens
- April 2012: Clinicaltrials.gov statement
Updated and New Guidance
- Updated Formats
- Improved Readability
- Table of Contents for Each Guidance
- Linked References
- Examples Provided
- One-Page Tip Sheets or Quick Guides when Possible
New Guidance

- Determining When Use of Data and Specimens Requires IRB Review
- Conducting Risk-Benefit Assessments and Determining Level of IRB Review
- ClinicalTrials.gov Registry
- Use of Drugs and Biologics in Clinical Research and Treatment
- Media Interviews
Updated Guidance

- Obtaining and Documenting Informed Consent
- Research Involving Multiple Performance Sites or Collaborations
- Post-Approval Reporting Requirements—Summary Sheet
- Reporting Suspected Abuse of Children, Elderly and Others