

- GUIDANCE -

Informed Consent Document

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1. Getting Started:

Review the “Informed Consent Template w/ Guidance” (which is located on our [forms](#) page) for an in-depth look at all of the potential items which, depending on the type of research (i.e., medical, behavioral, with children, etc.), could be included in your consent document. The “Template w/ Guidance” contains detailed instructions and guidance under each section.

TO BEGIN CREATING A NEW CONSENT DOCUMENT, use the “Informed Consent Template **w/o** Guidance” (which is also located on our [forms](#) page). The “Informed Consent Template w/o Guidance” contains the basic framework and local requirements. You fill in the rest.

2. General Recommendations:

- Text font should be 12 point or higher.
- Use the second person (“you/your” instead of “I/my”).
- For research involving children:
 - Include the following statement at the beginning of the document “You/Your throughout this consent form refers to your child.”
- Include page footers with the page numbers (x of y), and the version date of the document. The CHRMS or CHRBS number is not available before the first submission, but it should be added to the footer before the next IRB approval of the document (i.e., at Continuing Review, etc.).
- If applicable, the risk section must address the frequency and severity of each risk by using percentages, or the terms common or uncommon then provide the likelihood, e.g. 1 in 10 or 1 in 100.
- Avoid statements that would suggest:
 - the study is FDA approved (FDA does not approve studies; it only approves medical treatments and devices for marketing).
 - subjects are waiving their rights in any way.
 - the PI or study sponsor is relieved from liability for negligence.
- Do not make claims about safety/efficacy of the study agent or device that have not been demonstrated (i.e. approved by the FDA), or are not applicable to the study population.
- Do not include a sponsor until you have obtained actual funding. Then revise to take out the sponsor when that funding ends.

3. Writing an Understandable Consent:

The consent document can be made readable without compromising the content by applying the following recommendations:

- Use lay terms, simple, straightforward sentences and remember that vocabulary should not exceed the 8th grade level. Refer the [UC Davis glossary](#) for examples of common lay terms.
- Avoid use of scientific jargon or technical language, and explain terms that may not be easily understood.
- Spell out acronyms, at least the first time the term is used within the text.
- Always spell check your document.
- Emphasize the important information.
- Use recognizable terms and measurement amounts, such as converting mL to teaspoons (5mL = 1 teaspoon) or tablespoons (15mL = 1 Tablespoon) for blood draw amounts.
- Use graphs and/or tables (i.e. study calendars showing study procedures and participant responsibilities at different study visits or randomization schemas).

4. Optional Items:

- The IRB does not require a witness line, however if you wish to use one, be sure that it is completed at the time the subject signs the consent document.
- Use of supplemental materials is encouraged; however these require IRB review and approval. The following supplemental materials have been developed by the IRB for general use:
 - **BROCHURE:** [Should I Participate In A Research Study?](#)
 - **BROCHURE:** [The Informed Consent Process: What You Need To Know...](#)