INSTITUTIONAL REVIEW BOARD
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Informed Consent Tips

An informed consent document is typically used to provide subjects with the information they need to make a decision to volunteer for a research study. This information is most often presented to subjects in the form of a written document, and reviewed verbally by a member of the study team. Regulations and policies require that certain information be provided as part of the consent process.

Informed Consent Templates

- For your convenience, CHOA IRB recommends using the CHOA or CHOA/Emory Informed Consent Templates which have been developed to include the required documentation *elements* (per federal regulations 45 CFR 46, part 46.116 (link is external), *language*, and *formats*. Use of the applicable template may facilitate IRB review. Download the template then modify to reflect your study activities. Delete sections that are not applicable to your study.
  Consent Templates

General Information & Tips

READING LEVEL- Informed consent documents should be written at a level appropriate to the subject population, generally at an 8th grade reading level.

- Tailor the document to the subject population
- Use Grammar check to determine reading level
- Use straightforward language that is understandable.
- Use a logical order for the topic within each section. For example, in the risk section, begin with research related risks that are expected, likely, and serious. Conclude with rarely expected risks and convey the likelihood.
- Insert hard page breaks if the page breaks at a place that makes it hard for the reader to follow such as right after a subhead.
- Discuss only one or two ideas per paragraph.
- Keep paragraphs short.
- Avoid compound sentences.

- Use shorter, simpler words whenever they can convey appropriate meaning.
- Define or explain medical terms, procedures, and technical or complex words.
    - Definitions and Lay Glossary of Medical Terms

OTHER WRITING TIPS

- Present study details in the second person (you, or your child). Avoid use of the first person (I).
- Sponsored Informed Consents must be revised to CHOA IRB Consent format.
- Proofread for inconsistencies, grammatical and typographical errors.
- Be clear what interventions are research/experimental vs. routine care.
- Do not include risks that are not related to research (i.e. would be present if they participated in the study or not).
- Use shorter sentences and/or bullets for easy readability.
- Be sure to thoroughly explain the study, especially what will happen to the subject. Do not sacrifice information in order to make it easier to read.
- Number pages (1 of 5, 2 of 5, 3 of 5, etc.).
- Include Version date.