

GUIDANCE: GENERAL CONSENT WRITING TIPS

The tips below can be used to ensure the consent document uses appropriate language for the targeted enrollment population and meets regulatory requirements

CONSENT
<input type="checkbox"/> The UIC consent template language should be used when crafting a consent.
<input type="checkbox"/> Consent should be written using language that would be understood by the population being recruited for the study. For the general population, consents should be written at the 6-8 th grade reading level. <ul style="list-style-type: none"> ➤ Shorten and simplify words and sentences ➤ Define technical terms – several glossaries are available to provide lay language, especially for medical terms. ➤ May want to use tool such as Flesch-Kinkaid readability scale
<input type="checkbox"/> The consent should be written in the second person (you) with the exception of the section headers and signature section
<input type="checkbox"/> Accurate and complete information should be presented regarding study aims, procedures, and risks. <ul style="list-style-type: none"> ➤ When describing research procedures, include details such as the amount of blood drawn, fasting requirements, and information on how long the study visits are expected to last. ➤ It is helpful to include information that would be relevant to the study participant though not necessarily relevant to the science. Examples: quality of life issues related to wearing long-term tracking devices such as an actiwatch and situations when it can / should be removed; testing intoxicants which might require that the participant have someone drive them home; research procedures that might require washing hair or body afterwards. ➤ Omissions of relevant information are allowed in very limited circumstances, and constitute “deception”. ➤ Omissions of information, outlined in the federal regulations but deemed unnecessary or irrelevant to the understanding of the study, are allowable in some situations. These constitute an “alteration of consent”.
<input type="checkbox"/> If the information presented in the “Important Information” short summary section at the beginning of the consent is complete regarding study procedures and risks (the research is not complicated or has few risks), then the corresponding sections later in the consent can be removed. <ul style="list-style-type: none"> ➤ If you can reasonably include all of the required information into the short summary section, they you are encouraged to do so to avoid duplication and shorten the overall consent document.
<input type="checkbox"/> The description of study benefits should not be overstated, and should not include either compensation as a benefit, or promise free medical treatment if the treatment is part of the research.

<p><input type="checkbox"/> If any components of the research are optional, these should be clearly designated in the consent, and the consent should include a way to indicate yes/no or agreement for each optional component</p>
<p><input type="checkbox"/> If the research involves treatment of a medical or mental health condition, the consent should clearly delineate between the components of treatment that are research related, versus those that are part of standard care outside of the research context. In addition:</p> <ul style="list-style-type: none"> ➤ Research risks should focus on risks associated with the research components. ➤ The description of study costs should be careful to indicate which costs are billable to the subject or their insurance because they are consistent with standard of care treatments, versus those that will covered by the research because it is strictly for research.
<p><input type="checkbox"/> For research that includes use or disclosure of protected health information, the HIPAA drop-in text should be incorporated into the consent</p> <ul style="list-style-type: none"> ➤ A separate, stand-alone HIPAA authorization should only be used if a separate HIPAA document would be required, such as when protected health information (PHI) is used or disclosed only for optional components of the research.
<p><input type="checkbox"/> Special attention should be paid when creating the consent to ensure all required additional language is included. The OPRS website has consent template language that can be used or adapted for the specific research. Situations when additional language will be required include:</p> <ul style="list-style-type: none"> ➤ Federally funded research ➤ Clinical trials ➤ Research that includes genetic testing, biobanking or data repositories ➤ Research compensation is given ➤ Special considerations to privacy or data confidentiality (focus groups, collection of data on STDs, mandatory reporting requirements for abuse / neglect, research in Chicago Public Schools) ➤ HIPAA – research use or disclosure of protected health information (PHI) ➤ Enrolling UIC students and/or employees ➤ Consent obtained by a legally authorized representative
<p><input type="checkbox"/> Witness signature lines, date, and printed name are required on consent when:</p> <ul style="list-style-type: none"> ➤ the research participant is non-English speaking and a short form consent will be used ➤ the research participant understands English but is either illiterate (cannot read or write), physically unable to talk or write, blind, or with motor difficulties that prevent obtaining signature ➤ the IRB makes an independent determination that the consent process will require a witness
<p><input type="checkbox"/> Proofread the consent to correct errors in spelling, grammar, and format. Make final edits. Ensure that the consent document is presentable for participants.</p> <ul style="list-style-type: none"> ➤ Verify that template instructions have been removed. ➤ Make sure that names and contact information are added as instructed on the template, ensuring they are correct. ➤ Add a version number, date, short title, and page numbers to the footer. ➤ Ensure font type and font size are consistent. Font should be at least 12 point, larger if needed for the study population (older, or with vision impairments)

<ul style="list-style-type: none"> ➤ It might be helpful to have someone independent of the research read over the consent document to proofread. ➤ Having a layperson read the consent would be helpful to point out any sections that may be difficult to understand to the general population.
<input type="checkbox"/> What if a model consent is provided by the study sponsor? <ul style="list-style-type: none"> ➤ The model consent should be merged with the UIC consent template. ➤ Start with the UIC consent template, and plug in the model consent sections describing the research aims, procedures, and risks. ➤ The UIC template language in the sections describing privacy and confidentiality (who will have access to the data), injury (if the sponsor will be providing compensation for injury), HIPAA (data disclosure), and the introductory section (to identify the sponsor), will likely need to be updated to provide sponsor-specific information.
<p><u>Resources:</u></p> <ul style="list-style-type: none"> • General consent policy: http://research.uic.edu/node/2510 • Johns Hopkins University – How To Prepare a Readable Consent Document: Informed Consent Guidance - How to Prepare a Readable Consent Form (hopkinsmedicine.org) • Checklist for Plain Language: https://plainlanguage.gov/resources/checklists/checklist/ • Readable (tests readability, spelling, grammar): https://readable.com/ • Flesch-Kinkaid Readability Scale: http://www.readabilityformulas.com/flesch-grade-level-readability-formula.php

GUIDANCE: Tips for Writing Assent, Parental Permission, and Proxy (LAR) Consent

The tips below can be used to ensure the assent/parental permission/ proxy consent document uses appropriate language when enrolling children and individuals who lack the capacity to consent, and meets regulatory requirements for these populations

<h3>Assent / Parental Permission / Proxy (LAR) Consent</h3>
<input type="checkbox"/> Assent documents provide information about the study in a simpler format
<input type="checkbox"/> Assent documents are used for individuals who cannot provide consent for themselves.
<input type="checkbox"/> Writing assent documents is more art than science, in that there is a great deal of variability, there are no regulatory requirements specific to the content of the assent documents, and it may be difficult to explain complicated research in a short and simple document. The OPRS website has a model assent document as well as guidance regarding the assent document and process.
<input type="checkbox"/> For adults, an assent is used for individuals with limited or impaired cognitive capacity, and are used in conjunction a consent document for their legally authorized representative (LAR). <ul style="list-style-type: none"> ➤ Individuals who can act as LAR are defined by Illinois State Law

<ul style="list-style-type: none"> ➤ The IRB will need to be notified in advance, and must approve any plans to enroll cognitively impaired participants. The IRB must also be notified of the plan to recruit this population, identify the LAR, and obtain consent and assent. ➤ The assent document should be written at a reading level appropriate to the expected population. ➤ The assent process should include a method to determine cognitive impairment and capacity to consent in individuals ➤ Note that the IRB may require, on a case by case basis, additional safeguards in the consent / assent process ➤ If the participants regains capacity to consent at a later time point, consent should be obtained.
<p><input type="checkbox"/> For children, assent are generally required, and the type and content of the assent depends on the age and cognitive capacity of the child. The research should include a plan to assess the capacity to consent in children. In general, assents should be provided as follows:</p> <ul style="list-style-type: none"> ➤ Age 0-6: assent is not required. These individuals are considered too young to provide assent, a waiver of assent will be applied ➤ Age 7-12: verbal assent should be obtained from typical children. The assent document should use simple, age-appropriate descriptions of the research, modeled on the UIC assent template. ➤ Age 13-15: written assent should be obtained from typical children. The assent can be more complex than the verbal assent, thought should still be simple and age-appropriate, and modeled on the UIC assent template. ➤ Age 16-17: written assent should be obtained from typical children. The assent can be an age-appropriate version of the UIC assent template, or the adult consent document can be modified to serve as the assent. ➤ All ages: If the minors to be enrolled in the study, regardless of age, will not have the cognitive capacity to understand and assent to the research, then a waiver of assent may be requested. ➤ If a child reaches the age of majority (18 in State of Illinois) while participating in the research, then consent from this individual should be obtained upon becoming a legal adult.
<p><input type="checkbox"/> Assent can be written or verbal, as appropriate to the population.</p> <ul style="list-style-type: none"> ➤ The assent should indicate the participant’s name, and for children include their age and grade in school. ➤ Written assent should include signature lines for the participant ➤ Verbal assent should include a place where the person obtaining assent indicates that the participant verbally agreed to participate.
<p><input type="checkbox"/> Situations where a waiver of assent / parental permission may be granted</p> <ul style="list-style-type: none"> ➤ Child: too young, does not have the capacity to assent, or if the research is such that it holds out the prospect of direct benefit to the child and available only in the context of the research. ➤ Parental permission: A waiver may be granted if the IRB determines that the research is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect subjects (example: neglected or abused children). In this case, an appropriate mechanism for protecting participants is substituted as long as it is not inconsistent with federal, state, or local law.

<ul style="list-style-type: none"> ➤ Applicable to all groups: research otherwise meets criteria for a waiver under 116(f) and (g)
<ul style="list-style-type: none"> <input type="checkbox"/> Writing a parental permission or consent for legally authorized representative: <ul style="list-style-type: none"> ➤ Enrolling minors: When writing the content of a parental permission, refer to the tips on writing a consent document. <ul style="list-style-type: none"> ○ Parental Permission: modify the consent template throughout to replace references to “you” with “your child” where appropriate. ○ Combined parental permission / consent: Add a statement in the header indicating that the document is both a “consent” and “parental permission”; include a statement on the first page indicating that if a parent is consenting for their child, the references to “you” in the consent refer to the subject (use language on UIC consent template). ○ Combined parental permission / assent: A consent document can be combined with a parental permission and/or an assent for participants age 16-17 (as long as it is otherwise age-appropriate). These combined documents should include: <ul style="list-style-type: none"> ▪ A statement in the header indicating that a combined document is used, and include “parental permission” or “assent age 16-17” (as appropriate). ▪ If a parental permission, include a few sentences on the first page indicating that if a parent is consenting for their child, the references to “you” in the consent refer to the subject. (Follow UIC consent template instructions) ▪ Update the signature lines to include all required signature information (ie, signature of parent/guardian, name / age of child, signature of minor). ○ Federal regulations govern whether both parents are required to sign the consent document, or whether one parent signature is sufficient. The signature lines should be modified accordingly. ➤ Enrolling adults lacking the capacity to consent: Use the standard consent (refer to consent writing tips) when writing the proxy consent, but update the signatures to include “Legally Authorized Representative”.

Guidance: Consent documents for Exempt research

The tips below can be used to ensure the consent document for research granted a Claim of Exemption uses appropriate language for the targeted enrollment population and meets the recommendations outlined on the OPRS website.

<h3>Claim of Exemption (Exempt) Consent Document Guidance</h3>
<ul style="list-style-type: none"> <input type="checkbox"/> The OPRS website has guidance on informed consent for research that falls under a Claim of Exemption. The information can be found here, under their FAQs: https://research.uic.edu/general-faqs/

The FAQ states:

Although exempt research is not subject to the federal regulations at 45 CFR 46, UIC policy requires all research involving human subjects, including exempt research, to be performed responsibly and in accordance with the ethical guidelines of the Belmont Report. If interactions, interventions or other contact will occur with participants, the IRB / OPRS expects investigators to provide the participants with information about the research protocol and to obtain their voluntary informed consent to participate in the research. Obtaining informed consent is not expected with the use of existing materials or other activities where no contact with participants will occur, such as retrospective medical chart reviews or the analysis of existing de-identified data.

An appropriate consent document may include an information sheet, oral informed consent script, survey cover letter or a letter to the subjects. The following information should be provided, when possible, to potential research subjects participating in exempt studies:

1. That the activity involves research
2. Name, affiliation, and contact information for investigator
3. The purpose of the research
4. A description of the procedures
5. Measures to protect the privacy of subjects and the confidentiality of the research information
6. Description of any reasonable foreseeable risks, as well as anticipated benefits
7. Statement that participation is voluntary
8. Statement that the research is available to answer any questions
9. If the research involves an online survey, include the following information:
“Confidentiality will be maintained to the degree permitted by the technology used.
Your participation in this online survey involves risks similar to a person’s everyday use of the Internet.”

Because exempt research is minimal risk and if the primary risks involve privacy and confidentiality, written documentation of informed consent (i.e., participant’s signature) is generally not required by the IRB / OPRS.

Consent should be written using language that would be understood by the population being recruited for the study. For the general population, consents should be written at the 6-8th grade reading level.

- Shorten and simplify words and sentences
- Define technical terms – several glossaries are available to provide lay language, especially for medical terms.
- May want to use tool such as Flesch-Kinkaid readability scale

Proofread the consent to correct errors in spelling, grammar, and format. Make final edits. Ensure that the consent document is presentable for participants.

- Make sure that names and contact information are correct.
- Add a version number, date, short title, and page numbers to the footer.
- Font size should be at least 12 point, larger if needed for the study population (older, or with vision impairments)

- It might be helpful to have someone independent of the research read over the consent document to proofread.
- Having a layperson read the consent would be helpful to point out any sections that may be difficult to understand to the general population.

Resources:

- Johns Hopkins University – How To Prepare a Readable Consent Document: [Informed Consent Guidance - How to Prepare a Readable Consent Form \(hopkinsmedicine.org\)](https://www.hopkinsmedicine.org/health/conditions-and-diseases/informed-consent-guidance-how-to-prepare-a-readable-consent-form)
- Checklist for Plain Language: <https://plainlanguage.gov/resources/checklists/checklist/>
- Readable (tests readability, spelling, grammar): <https://readable.com/>
- Flesch-Kinkaid Readability Scale: <http://www.readabilityformulas.com/flesch-grade-level-readability-formula.php>