Guidance for Writing an Informed Consent Document

Writing the consent form is an important part of the research process. The goal of the consent form is to present the details of the research study to the participant in a manner that provides enough information for them to make an educated decision about participating in research.

A successful consent form combines all the required information with a writing style that is easy for the targeted participant to understand. Here are some things to consider:

Readability

When writing a consent form, keep the target audience in mind. The reading level for the general public is approximately 7th grade. If your target audience is educationally disadvantaged, the level should be lower. The same is true when you are assenting minors—make the reading level match the participant. It can be challenging to write a document at this level.

Here are some tips

- Use Word to check the reading level: Word has proofing options that can “show readability statistics” every time you spell check a document. Keep readjusting your consent form until it meets the desired reading level.
- Use common language—not jargon. Whenever possible, use words that are non-technical, non-academic, and non-medical.
- Do not assume the reader knows the acronym or abbreviation for a word. Be sure to spell it out the first time, putting the acronym in parenthesis after the phrase.
- Keep words to 3 syllables or less
- Keep sentences short with just one subject per sentence.
- Do not use run on sentences. Divide longer sentences, or those sentences with more than one subject, into two or more sentences.
- Keep paragraphs short, with only one subject per paragraph.
- Refrain from using the word “participant.” Instead, write in second person using “you” or “your”
- Do not use contractions
- Be consistent throughout by repeating the same terms. For example, if “school administrator” and “principal” refers to the same person in the study, use only one of those terms throughout the consent form.
- Research terms such as “double blind,” “randomized,” and “placebo/controlled” are not common terms for people who are not regularly involved in research. These should be explained in simple terms
- There are several links at the end of this guidance that provide lay terms for research
**Structure & Format**

While there are specific items that must be in a consent form, you are free to arrange these items in a way that provides for easy readability and understanding.

- Write in a logical sequence. Template paragraphs may need to be reorganized into a sequence that matches your study.
- If the consent form is 4 or more pages, include a concise summary at the beginning of the consent form that outlines the key information that a reasonable person would want to have when deciding to participate in research.
- Bulleted or numbered lists are easy to read.
- Using a question/answer approach can also provide better understanding.
- Large blocks of text are difficult to read. Break paragraphs up so there is some white space on the page.
- Highlight important points using underline or bold text.
- Use a font that is easy to read. Consider your target audience. For example, if you are dealing with elderly people who may have poor eyesight, use a larger font.
- Leave at least a one-inch margin on all sides. This is especially true for the bottom margin as there needs to be enough room for the electronic IRB approval stamp.
- Include a footer with the page number and a version date.

**Medical Terms**

Many research participants are not familiar with medical terms. It can be difficult to write in a way that the participant can understand. Here are a few pointers.

- Refer to a Plain Language Medical Dictionary. See the end of this guidance for several examples.
- Use commonly known measurements when collecting fluids. For example, use teaspoon and tablespoon rather than ml. or cc.
- Avoid using symbols that could be unclear. For example, write “greater than” rather than “>”.

**Required Elements of Consent:**

Regardless of how you lay out your consent form, the following items are required. Feel free to change the order to suit your study ensuring that it makes sense to the reader:

- Disclosure that the study involves research (The word “research” must be present in the document.)
- Explain the purpose of the research.
- An explanation of the expected duration of the participant’s participation.
- A description of the procedures to be followed.
- Identification of any procedures that is experimental.
- Description of any reasonably foreseeable risks or discomforts to the participants.
- Disclosure to which confidentiality of records identifying the participant will be maintained.
• Description of any **benefits** to the participants or to others which may reasonably be expected from the research

• Disclosure of appropriate **alternative procedures or courses of treatment**, if any, that might be advantageous to the participant (If there are no alternatives, you do not need to include this section)

• For ETSU studies deemed more than minimal risk: Include ETSU **compensation paragraph**, the second sentence must state, “ETSU makes no commitment to pay for any other medical treatment” instead of “ETSU will not pay for any other medical treatment”

• Disclosure that participation is **voluntary**,

• Disclosure that **refusal to participate will involve no penalty or loss of benefits** to which the participant is otherwise entitled,

• Disclosure that the participant **may discontinue participation at any time without penalty or loss of benefits** to which the participant is otherwise entitled.

• **Contact information** for answers to questions about the research,

• **Contact information** for answers to pertinent questions about the participants’ rights

• **Contact information** in the event of a research-related injury to the participant

• In **contact information** section, the following **mandatory** sentence is included, “**If you have any questions or concerns about the research and want to talk to someone independent of the research team or you can't reach the study staff, you may call an IRB Coordinator at 423/439-6055 or 423/439/6002.**”

• For studies subject to the New Rule: If your study includes **identifiable data**, you must include one of the following statements
  • All information that can identify you will be removed from the data. This data will then be stored for possible use in future research studies. We will not ask for additional consent for those studies. OR
  • Your information or biospecimens will not be used for any future studies. [If not using biospecimens, remove that word.]

• **Concise Summary**: For studies subject to the New Rule, consent forms that are 4 or more pages must start with a concise and focused presentation of key information. This information is used to outline the key information that a reasonable person would want to have when deciding to participate in research.

**Additional Elements that might be Required**

• Disclosure that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable UNLESS the risk profile of all research-related interventions is well-known and the research involves no investigational drugs or devices.

• Disclosure that the particular treatment or procedure may involve risks to the embryo or fetus, if the participant is or may become pregnant, which are currently unforeseeable UNLESS the research excludes women of child bearing potential and pregnant women or the risk profile of all research-related interventions or interactions on embryos and fetuses is foreseeable and risks are described in the ICD or there is no reasonable expectation that this research causes risks to fetuses or embryos.
• Disclosure of anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent UNLESS there are no anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent

• Disclosure of additional costs to the participant that may result from participation in the research UNLESS there are no costs to the participant that may result from participation in the research

• Disclosure of the consequences of a participant’s decision to withdraw from the research and disclosure of procedures for orderly termination of participation by the participant UNLESS there are no adverse consequences (physical, social, economic, legal, or psychological) of a participant’s decision to withdraw from the research

• Disclosure that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant UNLESS significant new finding during the course of the research which may relate to the participant’s willingness to continue participation are unlikely

• Disclosure of approximate number of participants (locally or in total) involved in the study UNLESS the approximate number of participants involved in the study (locally and in total) is not important to a decision to take part in the research.

• For studies subject to the New Rule, the consent process must disclose a statement that biospecimens, even if identifiers are removed, may be used for commercial profit and whether the participant will or will not share in this commercial profit UNLESS the study does not involve the collection of biospecimens

• For studies subject to the New Rule, the consent process must disclose a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions UNLESS there will be no clinically relevant research results. This provision is intended to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results.

• For studies subject to the New Rule, the consent process must disclose a statement about whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) UNLESS the study does not involve the collection of biospecimens OR the study will not include any whole genome sequencing

• If it is determined that the study topic or design involves the possibility of a researcher becoming aware of elder or child abuse, we recommend adding the following suggested language to the Informed Consent Document:
• If the research takes place in Tennessee, use Tennessee language: “If the study staff finds evidence of child or elder abuse or neglect, they may be required by Tennessee law to report it to local law authorities.”

• If not in Tennessee, use more generic language: “If the study staff finds evidence of child or elder abuse or neglect, they may be required to report this to local law authorities.”

• Is your study VA? If yes, see VA template for additional VA specific required elements.

**After writing your consent form:**

• Read it out loud to yourself.
• Let someone else read, preferably someone in your target audience demographic, to see if they understand it. (However, this should not be someone you are actually planning to consent.)
• Run readability statistics

**Links to help with readability and lay language:**

• Readability Toolkit—this is a great overall tool for writing consent forms with or without medical terms:
• Glossary for Informed consent (includes medical terms):
  http://www.firstclinical.com/icfglossary/
• Lay Language list (includes medical terms):
• Kids’ Medical Dictionary: https://kidhealth.org/en/kids/word/#cata
• Plain Language Medical Dictionary: https://www.lib.umich.edu/taubman-health-sciences-library/plain-language-medical-dictionary