

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 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.
- 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** statement is included: This research is being overseen by an Institutional Review Board (IRB). An IRB is a group of people who perform independent review of research studies. You may also contact the ETSU Institutional Review Board at 423.439.6054 or IRB@etsu.edu for any questions you may have about your rights as a research participant.
- 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 outline the key information that a reasonable person would want to have when deciding to participate in research.

Additional Elements that might be Required, as appropriate for your research

- 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 Informed Consent Template for additional VA specific required elements and language.

Is your study covered by a Certificate of Confidentiality?

- The consent process should inform participants of the protections and limitations of the CoC. This language is usually included in the Confidentiality section of the consent form; see the example CoC language on the IRB website under Forms and Templates.
- NOTE: All studies funded in whole or in part by the NIH are issued a CoC as part of the terms of the award. Other studies may request a CoC from an HHS agency as an additional measure of protection for participants.
- If part of the study cohort was recruited prior to issuance of the Certificate (i.e., prior to being awarded an NIH grant), but are no longer actively participating in the study, NIH does not expect participants consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were previously consented to be re-contacted to be informed of the Certificate, although the IRBs may determine whether it is appropriate to inform participants.

Is your study a clinical trial? See the additional requirements below:

- A researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant distinguishes between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information.
- The researcher must obtain the participant's consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The IRB must approve the consent document.
- If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the researcher must not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent. However, a researcher may review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status.
- If the study meets the New Rule or FDA definition of a clinical trial, the consent form must include the following statement **verbatim**: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

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.)

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:
https://irb.research.chop.edu/sites/default/files/documents/prism_readability_toolkit.pdf

- Glossary for Informed consent (includes medical terms):
<http://www.firstclinical.com/icfglossary/>
- Lay Language list (includes medical terms):
http://humansubjects.stanford.edu/new/docs/glossary_definitions/lay_language.pdf
- Kids' Medical Dictionary: <https://kidshealth.org/en/kids/word/#cata>
- Plain Language Medical Dictionary: <https://www.lib.umich.edu/taubman-health-sciences-library/plain-language-medical-dictionary>