Consent Forms

Capacity to consent

- Assessment of capacity to consent to participate in research

Consent Form Readability

Recent changes to the Federal Regulations governing human subject research (the “Common Rule”) have included a focus on improving the readability of consent forms and include regulations requiring understandable language, and organization and presentation of information that facilitates understanding.

In response to these requirements, beginning October 31, 2019, consent forms must satisfy minimum readability standards. **We are working on a way to receive proof of PRISM training. Therefore, until further notice, we are not requiring physical proof, but written assurance.**

Though we expect to extend the standard to other sections, initially only the readability of the **Invitation and Summary section** will be assessed.

This section must have Flesch Kincaid reading level ?8 and Flesch Reading Ease ?60. Readability may be scored within the RSS application by clicking on the “Readability” button.

CFs not meeting these minimum readability measures will be returned to the investigator for modification.

To assist investigators and their staff in developing necessary skills to write effective consent forms, the PI and the person responsible for writing the consent form, **must complete online training through PRISM** (Program for Readability in Science and Medicine). The hour-long training covers health literacy and readability, plain language strategies and examples, and interactive editing examples and exercises.

For more information on process, readability standards, and readability tips, see below.

Readability Assessment Process:

- Readability can be assessed within the RSS application by clicking on the “Readability” button. This will open a new page with assessments of Flesch-Kincaid reading level and Flesch Reading Ease for the invitation and summary section.
- In computing reading levels, technical terms (especially drug names and names of medical procedures) may unavoidably adversely affect the score. You may choose to use the name once, and then say "the test drug" or "the operation" subsequently. However, in all cases, an effort should be made to use a simpler word or phrase.
- The IRB recognizes that sections of some consent forms may be of such a technical nature that it may not be possible to keep to an 8th grade reading level. In these situations, the invitation and summary at least must meet the standard described above, and the investigator must describe what additional tactics will be used to assure and assess comprehension.

Readability Standards:

- The Flesch–Kincaid readability tests are readability tests designed to indicate how difficult a passage in English is to understand. There are two tests, the Flesch Reading Ease, and the Flesch–Kincaid Grade Level. Although they use the same core measures (word length and sentence length), they have different weighting factors.
- The results of the two tests correlate inversely: a text with a comparatively high score on the Reading Ease test should have a lower score on the Grade-Level test.
- Many other measures of readability exist. SMOG (Simple Measure Of Gobbledygook) is a more exacting measure of readability, and accurately scores for the grade level required for complete text comprehension. (The Flesch-Kincaid formula grades for less than complete comprehension). SMOG demonstrates strong correlation with the required reading level in validation studies. The SMOG formula is based on the number of words consisting of three or more syllables. The SMOG score is commonly used to assess readability of healthcare information.

Tips for writing readable Consent Forms:

- PRISM online training is a web-based plain language tutorial for research professionals, including scientists, research staff, Institutional Review Boards (IRBs), or communications staff. The hour-long training covers health literacy and readability, plain language strategies and examples, and interactive editing examples and exercises.
- There are a variety of tools available to assist investigators in improving readability of CFs. PRISM online training addresses some tactics. The PRISM Readability Toolkit is available here.
- The Readability Toolkit is a plain language handbook illustrating how to improve the readability of research consent forms and other materials for study participants. The Toolkit includes plain language principles and strategies, quick reference guide and editing checklist, Plain language alternatives to complex terms, easy-to-read template language for consent forms and links to readability resources.

Do	***Do Not***

Use short sentences and use words familiar to the non-medical reader.	Use medical terminology without explaining it, or use words that an 8th grader would not understand.
Refer to thesauruses and medical glossaries made for children to find alternative ways to refer to medical terminology.	Use medical “jargon” or words longer than three syllables, when another word is also appropriate.
Use the second person (“you”) and note that they are asked to participate in a research study. Be personal.	Use the third person (“the subject”), and avoid writing “invite” to refer to their participation.
Use pictures and graphs wherever possible.	Provide information solely in large blocks of text, with long sentences.
Say “for example” or “so forth.”	Say e.g. or etc.
Use tablespoons or teaspoons to refer to the measurement of bodily fluids, and spell them out.	Use ml or cc to refer to volumes of bodily fluids, or abbreviate teaspoons/tablespoons.
Say “greater than” or “less than”.	Use “>” or “<” or other symbols that an 8th grader might have trouble understanding at first glance.
Describe study terminology such as “randomized”, “placebo”, or “double blind”; such as “like the flip of a coin”.	Use medical or study terminology without explaining it in lay terms.
Use the words “study drug” or “study regimen”.	Use the terms “therapy” or “treatment” to describe drugs, devices, or procedures.
Refer to investigational drugs or devices as “experimental” or “investigational”, and that it means the FDA has not yet approved it.	Refer to investigational drugs or devices as “new.”

Readability Examples and Templates:

- Invitation and Summary Template
- Invitation and Summary Sample 1 (Phase I Oncology Drug)
- Invitation and Summary Sample 2 (QOL Oncology)
- Invitation and Summary Sample 3 (Phase III Drug)
- Invitation and Summary Sample 4 (Knee Replacement)

Consent Teach-Back Tool

UNMC is recommending that study teams utilize the "teach-back" method during the informed consent process for their clinical studies. This method will enhance the informed consent process, ensuring participants are well-prepared before consenting and enrolling in clinical studies.

Our aim is to empower clinical research investigators and coordinators with the tools and knowledge to ensure that research study participants are fully informed and understand all aspects of the informed consent form.

Teach-Back Tool

Ethical Responsibility in Research

- Disclosure: It's our duty to provide all necessary information to potential research participants.
- Decision-making: We must ensure that participants can make informed decisions based on the information provided.

The Importance of Health Literacy

"Health literacy plays a crucial role in maintaining a healthy lifestyle and making informed decisions about our health care. Yet, a report from the HHS Surgeon General in 2019 highlighted that *only 12% of Americans possess proficient health literacy skills*. This underscores the importance of clear communication in the informed consent process."

Reference: HHS Surgeon General Reports and Publications, 2019

Consent Teach Back: A Strategy for Clarity

- A strategy to improve the researcher's ability to explain the ICD content in a way that is clear and understandable.
- An opportunity to facilitate understanding of why a participant may or may not want to participate.
- A tool to assure that the participant is provided with sufficient opportunity to discuss the information given to them and to consider whether or not to participate

The 5 T's of Teach Back

1. Triage: Concentrate on one topic at a time.
2. Tools: Utilize models, written tools, posters, graphics, etc., to aid in explaining the desired information.
3. Take Responsibility: Phrase it as, "I want to make sure I did a good job explaining…"
4. Tell Me: Encourage the participant to express their understanding in their own words. Be specific about what you expect them to relay back.
5. Try Again: If the participant's understanding isn't clear, revisit the topic.

Reference: Anderson, Leister and DeRego, Health Literacy Research and Practice, 2020

Evaluating Understanding with Teach-Back

- Participant's Understanding of the Study:
  - Purpose
  - Procedures
  - Risks
- Appreciating the Consequences of Participation:
  - Recognizing it's a research study
  - Potential benefits (or lack thereof)
  - Impact on current or future treatments
  - Confidentiality and data access
- Participant's Reasoning/Decision Process:
  - Awareness of other options

    - Understanding that participation is VOLUNTARY
- Participant’s Ability to Make a Choice.

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