DUKE UNIVERSITY HEALTH SYSTEM
Human Research Protection Program

USE OF THE SHORT FORM CONSENT DOCUMENT

11/20/2023

The federal regulations at 45 CFR 46.117 and 21 CFR 50.27 permit the use of a short form consent document stating that the required elements of informed consent have been presented to the participant or the participant's legally authorized representative orally, with a witness present. Within DUHS use of a short form consent document is largely limited to two situations:

- When English is not understandable to a potential research participant who is considering whether to participate in a research study, and the investigator does not have an IRB-approved consent document (long form) translated into a language understandable to the potential participant, or
- In the very unusual situation when the window of opportunity for a participant to benefit from research participation is brief, and the IRB finds that by use of the short form consent document the participant or the participant's legally authorized representative will have sufficient opportunity to comprehend the nature of the study and the risks and benefits associated with the study to make an informed decision about study participation.

When proposing to use a short form consent document, the investigator must prepare:

- A written summary of what is to be said to the participant or the participant's legally authorized representative following the standard consent template. This summary may be written in English and may either be a script or it can be the IRB-approved English long form consent document.
- A short form consent document prepared in a language understandable to the participant stating that the elements of informed consent required by regulations have been presented orally to the participant or the participant's legally authorized representative.

The IRB must approve both the written summary and the short form consent document.

For the oral presentation to the potential participant or their legally authorized representative:

- There must be an adult witness to the presentation. For potential participants for whom English is not understandable, the witness must be fluent in both English and the language understandable by the potential participant or the participant's legally authorized representative. The witness may not be affiliated with the study team.
- The presentation must be done using a translator. The translator and the witness cannot be the same person.
- The participant or the participant's legally authorized representative must sign and date the short form consent document.
- The witness must sign and date both the short form consent document and the summary.
- The person obtaining consent (the translator) must sign and date the summary.
- The study coordinator (CRC) should document the consenting process, including what was used for the script, who the adult witness was/relation to theparticipant, who was the translator, and who was the CRC present for the consent process and Q&A.

If the CRC does speak the non-English language of the participant, then the CRC can serve as the translator for consenting. A bilingual adult witness who is not affiliated with the study team must still be present. In this case, the short form would be signed by the participant, the adult witness, and the CRC who served as translator. Documentation of the consent process is required, as above.

The person obtaining consent must give to the participant or the participant's legally authorized representative:

- A copy of the summary.
- A copy of the signed and dated short form consent document.

Previous Version Date(s): 11/13/2007, 3/2/2016, 4/18/2021