



## **USE OF THE SHORT FORM CONSENT DOCUMENT**

11/13/2007

The federal regulations at 45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2) permit the use of a short form consent document stating that the required elements of informed consent have been presented to the subject or the subject'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 subject who is considering whether to participate in a research study, and the investigator does not have an IRB-approved consent document translated into a language understandable to the potential subject, or
- in the very unusual situation when the window of opportunity for a subject to benefit from research participation is brief, and the IRB finds that by use of the short form consent document the subject or the subject'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 subject or the subject's legally authorized representative following the standard consent template. This summary may be written in English.
- A short form consent document prepared in a language understandable to the subject stating that the elements of informed consent required by regulations have been presented orally to the subject or the subject'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 subject or his/her legally authorized representative:

- There must be a witness to the presentation. For potential subjects for whom English is not understandable, the witness must be fluent in both English and the language understandable by the potential subject or the subject's legally authorized representative.
- The subject or the subject'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 must sign and date the summary.

- The person obtaining consent must give to the subject or the subject's legally authorized representative:
  - A copy of the summary.
  - A copy of the signed and dated short form consent document.