Office of Human Research Ethics Training Tips

Use of the Short Form Consent Document

The federal regulations at 45 CFR 46.117(b)(2) and 21 CFR50.27(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.

28.6 Short form consent procedures

There may be circumstances when a subject is unable to read the full consent document (e.g., when the subject is illiterate or does not speak the language in which the consent document is written). In most circumstances, the IRB expects that a translation of the full form will be provided. However, there may be times when there is no opportunity to prepare a long form in advance; in such cases, a short form may be used.

The short form is not to be used when a study team has simply failed to make provisions for translated versions of the consent document in commonly spoken languages in the recruitment area/population. However, it is OK for a study to submit a short consent form to the IRB for approval as a back-up for unanticipated subjects needing a language that is not a commonly spoken one in the recruitment area/population.

- A short form is a written consent document stating that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative.
- When this method is used, there shall be a witness to the oral presentation.
- Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Under many circumstances the full consent form may serve as this written summary.
- The short form should be signed and dated by the subject, witness/interpreter and by the member of the research team obtaining consent.
- In addition, the witness and the member of the research team obtaining consent shall sign and date a copy of the summary.
- A copy of the signed summary shall be given to the subject or the representative, in addition to a copy of the signed short form.

Don't Forget:

- May also need an alteration of HIPAA authorization unless all elements of a valid authorization are included in the "short form".
- IRB waivers or alterations of written documentation of consent/authorization must be documented in the Minutes.

Consent Monitoring

The IRB has the authority under 45 CFR 46.109(e) and 21 CFR 56.109(f) to observe or have a third party observe the consent process and the research. In order to ensure that the consent process is appropriate and the approved process is being followed, the IRB may determine that special monitoring of the process must occur.

IRB Options:

Recommend monitoring of the consent process for high risk studies, studies that include the following:

- Vulnerable populations
- Study using very risky and innovative procedure(s)
- Study led by new investigator; or
- Any study the IRB is concerned about the conduct of the study
- Applies to both new and continuing studies.