Use of Short Forms for Informed Consent

Policy

The Department of Health and Human Services (DHHS) regulations (***45 CFR 46.116*** and ***45 CFR 46.117***) and FDA regulations (***21 CFR 50.25*** and ***21 CFR 50.27***) require that informed consent information be presented in language understandable to the subject, and in most situations, that informed consent be documented in writing. Investigators should carefully consider the ethical/legal ramifications of enrolling a subject when there is a language barrier. If subjects do not clearly understand the consent document or freely ask and receive answers to their questions, then their consent will not be truly informed and may not be legally effective. When subjects/families do not speak English use of a translated consent is always preferred. If researchers can reasonably expect that more than an incidental number of subjects speaking the same non-English language will be enrolled (for example, if the investigator is targeting a non-English speaking group), translation of the entire English version is required.

The Committee on Clinical Investigation realizes that with increasing numbers of non-English speaking subjects and family members, investigators cannot always anticipate the interest of a particular non-English speaking individual and provide him/her with a translation of the informed consent document in a timely manner. However to exclude individuals on the basis of not speaking English is not ethically justifiable.

Under these circumstances and in accordance with the regulations, a translation of the "short form" (which attests that the elements of consent have been presented orally) can be used to document informed consent in writing .Children's Hospital will allow the use of the "short form" for non–English speaking individuals only in the following situations

1) The research has been determined by the IRB to represent minimal risk. For these protocols investigators will be able to access the short forms in the appropriate language and utilize it without the need to notify the IRB.
2) For greater than minimal risk research when the research has potential for benefit that is not available outside the context of the research and there is insufficient time to obtain a translated version of the consent, the IRB will consider whether the short form is appropriate for use on a case by case basis, however investigators must get permission from the IRB. (This situation should be an occasional exception, not the rule)

When a "short form" is used to document informed consent, the consent process must include an oral presentation of the entire English informed consent in language understandable to the potential subject. The subject then signs a "short form" which is available in his/her native language. The short form is an attestation that the elements of consent have been presented orally.

Procedure

The informed consent process for enrolling subjects using the "short form" consent document is outlined below. **ALL** of the following requirements (1, 2, 3 and 4) must be completed

1) The principal investigator or assistant, through the Interpreter must orally present the approved English version of the consent form to the subject in a language understandable to him/her, and the subject must be given a written translation of the "short form" consent document to read;
2) The entire consent process must be witnessed by an individual who is fluent in both English and the language understandable to the subject. The interpreter may serve as the witness. (In this context the term witness is used only to attest to the fact that the information was presented in a language understandable to the subject/family and the subject/family had the opportunity to ask questions);
3) The approved English version of the consent form must be signed by the investigator or study staff authorized by the IRB to obtain consent and the witness to the consent process, and the translated "short form" must be signed by the subject and the witness to the consent process (see 2 above); **AND**
4) The subject/family must be given copies of both the approved English version of the consent form and the translated version of the "short form" consent document. The original signed English version with the original signed "short form" attached should be placed in the subject's research record and a copy of both placed in his/her medical record, if appropriate.

The Committee on Clinical Investigation requires that the interpreter comes from the pool of experienced interpreters obtained through Interpreter Services. Only in very exceptional circumstances will the IRB allow other individuals to serve in this capacity. Approval to use someone outside of Interpreter Services needs to granted on a case by case basis and only after consultation with Interpreter Services. It is important that Interpreter Services be provided with as much advance notice as possible so they can accommodate the request. For questions about obtaining the assistance of Interpreter services please page #0335 for Spanish, and #0120 for other languages through the page operator at 617-355-6363.

Because informed consent is an ongoing process, issues related to the subject's ability to understand and ask questions should continue to be considered throughout the study, and not just at the time of initial consent. For example, it is recommended to arrange for a medical interpreter to be available at subsequent study visits to ensure that subjects have an opportunity to ask questions and receive relevant study information

Document Attributes

Title	**Use of Short Forms for Informed Consent**		
Author	**Susan Kornetsky**	**Dates Reviewed/ Revised**	3/09/2010
Reviewed/ Revised by	Susan Kornetsky		
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