Albert Einstein College of Medicine

Short-Form Procedure for Non-English-Speaking Subjects

I. Purpose

This Procedure describes the short-form consent process for research conducted under the auspices of the Institutional Review Board ("IRB") at Albert Einstein College of Medicine ("Einstein"). The short-form consent process may be used when a non-English-speaking research subject is unexpectedly encountered and, as a result, the investigator must rely on oral translation.

II. Scope

This Procedure applies to all human research conducted under the auspices of the Einstein IRB.

III. Procedure

1. To obtain a short-form consent template, call or email the Office of Human Research Affairs ("OHRA").
2. The foreign language copy of the short form must be reviewed and approved by the Einstein IRB before it may be used.
3. The short-form consent should be used along with a summary document (in English) of the information provided orally to the subject. The summary document may be the English language version of the consent form.
4. If the person obtaining consent is not fluent in both English and the language of the subject, an interpreter (fluent in both English and the language of the subject) is required.
    a. This should be a professional member of the institutional staff (e.g., physician, nurse, social worker, psychologist, study coordinator, etc.). The identity of the interpreter must be documented, as described below.
    b. If a subject refuses the use of an institutional interpreter, they may designate a family member or friend to interpret. The researcher must document in the record the subject's refusal to use an institutional interpreter and the name and relationship of the person designated by the subject to interpret. Whenever a non-professional interpreter is designated by a subject, the researchers must consider issues of competence, appropriateness, conflicts of interest, and confidentiality.
5. A witness to the oral presentation, who is fluent in both English and the language of the subject, is required. To provide greater protection, this should not be a friend or family member.

6. The subject must be given copies of the short-form document and the summary document.
7. The following signatures are required:
   (i) the short-form document must be signed by the subject (or the subject's legally authorized representative);
   (ii) the summary document must be signed by the person obtaining consent and the interpreter, if they are not the same person; and
   (iii) the short-form document and the summary document must be signed by the witness.

Note, the short-form consent procedure may only be used when non-English speaking subjects are unexpectedly encountered. The short-form consent procedure may only be used up to five times for a particular language, after which a fully translated consent form is required to continue enrollment in that language. However, OHRA has discretion to modify this requirement, depending on the nature of the study and its anticipated total enrollment. For studies that anticipate enrolling a significant number of non-English speaking subjects who speak the same language, such as Spanish, the Einstein IRB may require fully translated consent documents at its discretion.

For studies under review by an external IRB, Einstein may defer to the short-form policy of the reviewing IRB, depending on the nature of the study and its anticipated total local enrollment. The decision to defer to the reviewing IRB's short-form policy will be made by the reliance team or OHRA leadership on a case-by-case basis.

IV. Effective Date

Effective as of: March 23, 2020

Revised as of: January 4, 2023

V. Document Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this document. Einstein's Executive Dean is the Responsible Executive for this document. The OHRA Director is the Responsible Officer for the management of this document.