

# 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 Einstein Institutional Review Board (“IRB”). 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, s/he 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 Einstein IRB requires the submission of fully translated consent documents for studies that plan to enroll 5 or more subjects who speak the same non-English language.

#### **IV. Effective Date**

Effective as of: March 23, 2020

#### **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.