# University of Kentucky Guidance for the Short Form Consent Process for Non-English-Speaking Individuals

Equitable selection is a regulatory criterion for IRB approval. While non-English speaking participants should not be routinely excluded from research offering potential benefit, their enrollment requires time, effort, and financial cost typically borne by the researcher.

Participants who have limited or no English proficiency may be enrolled in your research provided you have the resources to communicate effectively with the participants during the recruitment process, while obtaining consent, and for the duration of the study.

Use of the short form process is appropriate when you don't anticipate encountering non-English speaking individuals. If you expect to enroll more than an incidental number of participants speaking the same non-English language, it is best in most cases to use a translated full form.

## Short Form Consent Process

A short form consent process may be used when a potential participant does not speak English and there is not enough time or resources available to translate the English version of the approved consent document into a language the potential participant understands. The short form is provided in the language the participant understands as a summary of what will be discussed verbally with an interpreter. It also documents that the elements of informed consent, as required by the Department of Health and Human Services (HHS) and the Federal Food and Drug Administration (FDA), have been presented orally to the participant and/or the participant's legally authorized representative (LAR).

Short forms and stand-alone HIPAA Authorizations, translated in several languages, are available on the UK Office of Research Integrity (ORI) website. In the IRB application check non-English speaking on the subject demographic section and describe your proposed consent process in the Research Description. Include the applicable translated short form(s) with your IRB submission. Attach as a "consent document type" forms to receive the IRB approval stamp. If you need a form in a language that is not currently available as a template, you must have the English short form and HIPAA Authorization translated into the applicable language and then approved by the IRB prior to use.

## Short Form Consent Parties

Enrolling a non-English speaking participant with a short form generally involves the following:

1. The participant (and/or the participant's LAR, if applicable)
2. The study personnel obtaining consent
3. An interpreter (might not be needed if the person obtaining consent is fluent in the respective language)
4. A witness to the oral presentation

*An interpreter*

After the interpreter presents the short form to the potential participant, the study personnel obtaining informed consent presents the IRB-approved English version of the consent form while the interpreter orally translates the information to the participant or participant's LAR.

The investigator may propose, and IRB consider who would be qualified to serve as interpreter, given the context of the research and applicable facility requirements. In some cases, study personnel fluent in both English and the non-English language would be available to conduct the oral process. Family members may be adequate for non-technical or minimal risk research. However, they may not be best suited if potentially biased, or if not familiar with complex research or medical terminology. Also, physical facilities in which the research will take place may have specific policies on who may serve as interpreter (e.g., UK Healthcare). Ensure you are aware of and compliant with all applicable facility-based requirements.

*A study personnel obtaining consent*

Study personnel authorized to obtain informed consent verbally present the English informed consent with the assistance of the interpreter. The process should incorporate standard efforts such as dialog to determine participant's key concerns and teach back to ensure understanding. If the participant does not clearly understand the information presented, consent will not be truly informed.

*A witness*

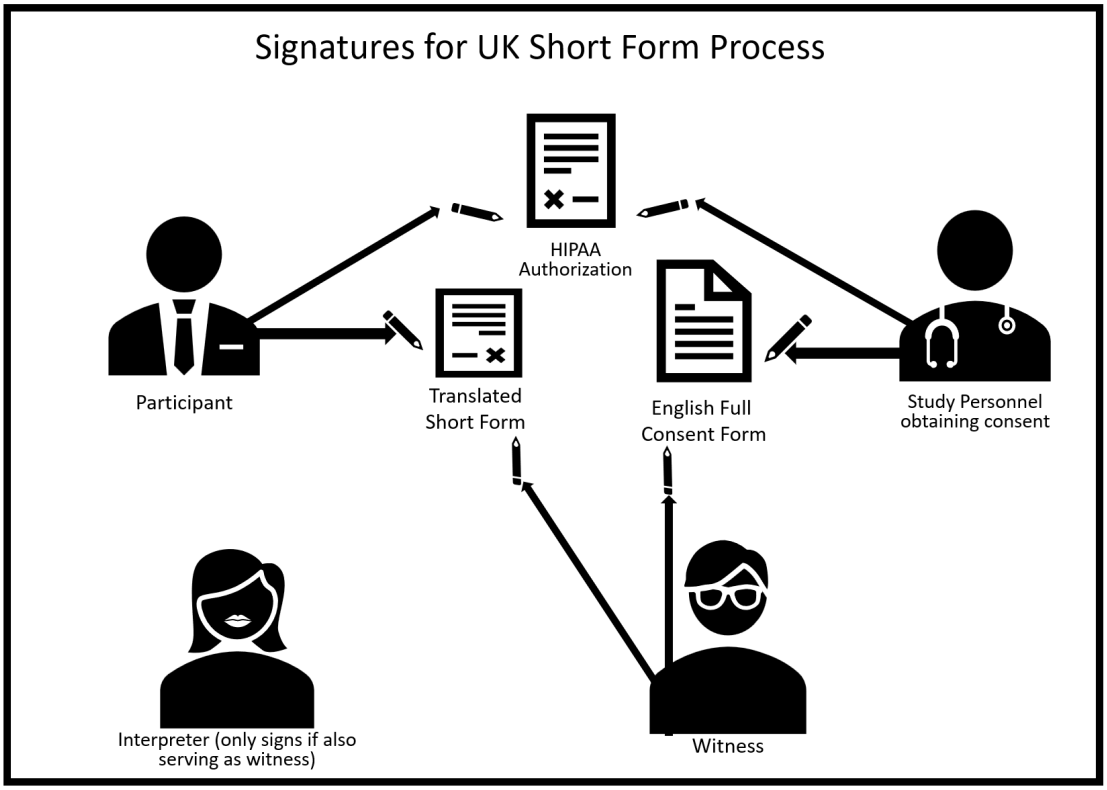
The role of the witness in this situation is to verify that the oral consent process took place in the participant's (or LAR's) language. The witness must be impartial and independent of the study team such as a family member of the participant or a hospital staff member who is not part of the study team. The witness should have enough proficiency in the language to be able to attest to the adequacy of the verbal process and voluntariness of the participant. Also, if the interpreter is present for the process in person or by video conference, the interpreter may also serve as the witness. If the interpreter takes part by phone, use a separate witness.

| The witness: | The interpreter: |
|---|---|
| • Observes the full process and attests to the participant's voluntary consent<br>• Need not be fluent in the respective language<br>• Must be impartial and independent of the study team<br>• If possible, not a family member, unless IRB approves based on the context of the study | • May serve as witness<br>• May be study personnel if fluent in both languages, but must include a separate witness, not affiliated with the study team<br>• Should be able to understand study concepts and be compliant with applicable facility policies |

## SIGNATURES

If the participant agrees to be in the study:

1. The English version of the full IRB-approved consent form is signed and dated by both the person obtaining informed consent and the witness.
2. The short form is signed and dated by the participant (and his/her/their legal authorized representative (LAR), if applicable), the witness. The interpreter does not have to sign unless they are also acting as the witness. However, the investigator should document who served as the interpreter for reference.
3. The translated stand-alone HIPAA Authorization (if applicable) is signed and dated by the participant. The person obtaining consent then prints his/her/their name and dates the stand-alone HIPAA Authorization.
4. The study personnel obtaining informed consent provides the participant with a copy of the fully executed short form consent and the full IRB-approved consent document (and HIPAA Authorization, if applicable).




## SHORT FORM USE LIMITATION

A short form may be used up to five times in the same language. Generally, if a sixth participant is to be enrolled, the entire IRB-approved English consent form must be translated. The fully translated consent form must then be submitted as a Modification Request and approved for use by the UK IRB before being used to consent a participant. After the translated consent form is approved, any previous participants still active in the study may need to be re-consented with the approved translated consent form as deemed appropriate by the IRB.

## Additional Actions Post-Enrollment

For FDA clinical investigations with complex or long-term interventions, the investigator should obtain a translated version of the standard IRB-approved consent for the subject's ongoing reference. All studies should provide interpreter services throughout as needed.