**Short Form Consent**

**For Non-English Speakers: Process and Requirements**

This instructional document is formatted for the study team to use as an internal checklist and/or process guide.

This form is for studies that meet the following criteria:

IRB approval to enroll non-English speakers and to use the short form process, as reflected in the IRB submission and IRB approval letter

Study sponsor allows the use of a short form (if applicable)

**Requirements:**

You have IRB approval to enroll non-English speakers and to use the short form process

If you need to use the short form process for an ongoing study but did not get prior IRB approval for short form use, submit a modification to request it.

Study sponsor allows the use of a short form (if applicable)

You will either use the Emory IRB-provided short forms or, if the desired language is not available, submit new versions to the IRB for approval as needed. You must follow the IRB’s requirements for quality translations.

If your study targets a particular non-English speaking population, you must translate the consent form into that language.

If you expect to, or find you have needed to, enroll more than two people of a specific non-English speaking population in a study, you may be required to translate consent documents into that particular language instead of using the short form. Please consult with the IRB.

**Process Checklist:**

The **study team member obtaining consent** ensures the contact information of the study team is noted on the translated short form document in the blanks provided with the name on the first line and the phone number on the second line.

A **qualified interpreter** reads the English consent form and verbally conveys the information to the participant or the participant’s legally authorized representative (LAR).

If the qualified interpreter is part of the study team, the qualified interpreter is deemed qualified by Emory Healthcare or another applicable healthcare entity.

The qualified interpreter is 18 or over (REQUIRED)

If the qualified interpreter is a member of the participant’s family, one of the following applies:

This is an emergency situation.

The participant specifically requested their family member be the qualified interpreter.

This is unique circumstance such as a socio-behavioral or public health study where the consent form (or script) and study instruments are fully translated into the participant’s language.

The participant is 18 or older

A **witness** witnesses the short form process.

Witness is fluent in both English and the participant’s language (REQUIRED)

Witness is not part of the study team (REQUIRED)

Witness and qualified interpreter are the same person (Optional)

The **participant**:

The participant is under six years old.

The participant is six years old or older and the approved assent document is verbally translated in the participant’s language.

The participant is 18 or older

**Signatures:**

Informed consent document in English:

Study team member obtaining consent signs

Witness signs

Translated short form document:

Participant or their LAR or their parent signs. Note: Participants under 18 do not sign any documents.

Witness signs

**Note: Time stamp isn’t required for IRB purposes but can be added to signature as needed by the study team.**

Optional consent items:

Witness, Translator, or Investigator writes a comment on last page of short form to indicate participant made specific choices.

Witness, Translator, or Investigator indicates participant’s choices on English consent form and includes the witness’s initials beside each choice.

**Documentation and records:**

The participant or their LAR or parent were provided with copies of the short form (signed by the participant and the witness) and the English consent or assent signed by the witness and the person obtaining consent.

Study team files the original signed and dated English consent form in the participant’s research record.

LAR or parent gave consent and this is documented in the participant’s research record

**Resources:**

* Informed Consent of Non-English-Speaking Subjects Chapter in [Emory IRB Policies and Procedures](https://irb.emory.edu/_includes/documents/sections/policiesandprocedures.pdf)
* [OHRP on Short Form Process](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-infomed-consent-non-english-speakers/index.html)
* [FDA on Short Form Process](https://www.fda.gov/media/88915/download)

**FOR REFERENCE ONLY – ENGLISH SPEAKING SUBJECTS MUST SIGN FULL IRB-APPROVED ENGLISH CONSENT FORM**

**Chuo Kikuu cha Emory**

**Idhini ya Kushiriki katika Utafiti**

Unaombwa kushiriki katika utafiti wa utafiti.

Kabla ya kukubali, mpelelezi lazima akuambie kuhusu (i) madhumuni, taratibu, na muda wa utafiti; (ii) taratibu zozote ambazo ni za majaribio; (iii) hatari zozote zinazoonekana, usumbufu na manufaa ya utafiti; (iv) taratibu au matibabu mbadala yanayoweza kuwa na manufaa; na (v) jinsi usiri utakavyodumishwa.

Inapohitajika, mpelelezi lazima pia akuambie kuhusu (i) fidia yoyote inayopatikana au matibabu ikiwa jeraha litatokea; (ii) uwezekano wa hatari zisizotarajiwa; (iii) hali ambapo mpelelezi anaweza kusitisha ushiriki wako; (iv) gharama zozote za ziada kwako; (v) nini kitatokea ukiamua kuacha kushiriki; (vi) wakati utaambiwa kuhusu matokeo mapya ambayo yanaweza kuathiri nia yako ya kushiriki; na (vii) ni watu wangapi watakuwa kwenye utafiti.

Ikiwa unakubali kushiriki, lazima upewe nakala iliyotiwa saini ya waraka huu na muhtasari wa maandishi wa utafiti.

Unaweza kuwasiliana na \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ saa \_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ wakati wowote una maswali kuhusu utafiti.

Unaweza kuwasiliana na Chuo Kikuu cha Emory IRB kwa 404-712-0720 ikiwa una maswali kuhusu haki zako kama somo la utafiti au nini cha kufanya ikiwa umejeruhiwa.

Kushiriki kwako katika utafiti huu ni kwa hiari, na hutaadhibiwa au kupoteza faida ikiwa utakataa kushiriki au kuamua kuacha.

Kutia saini waraka huu kunamaanisha kuwa utafiti wa utafiti, ikijumuisha taarifa hapo juu, umeelezewa kwa mdomo, na kwamba unakubali kwa hiari kushiriki.

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Sahihi ya Tarehe ya Mshiriki

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Sahihi ya Tarehe ya Shahidi