



**Children's**<sup>®</sup>  
*Healthcare of Atlanta*

# **Informed Consent for Non or Limited English Speaking Participants, and Short Forms**

Children's Healthcare of Atlanta IRB



# Informed Consent

- A person's voluntary agreement, based upon ***adequate knowledge and understanding of relevant information***, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of the legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence. (CFR 116:21, CRF 50.20, and 50.25)



# Short Form Definitions

- Per CFR, Part 50, Sec. 50.27- “ A short form written consent document stating the elements of informed consent required by 50.25 have been presented orally to the subject or the subject’s legally authorized representative....Also, the IRB shall approve a *written summary* of what is to be said to the subject or the representative.”
- Per Emory’s policy and (newly revised!) Children’s policy- this “written summary” can be the IRB approved English Informed Consent.



# Short Forms- When, Why?

*When can the short form be used?*

- The participant or LAR does not speak/understand English; AND
- The participant of LAR speaks only a language(s) that was not anticipated in the study population or location; AND
- An approved translated consent form in participant's language has not been approved by the IRB; AND
- There is not adequate time for preparation and IRB review and approval of a translated consent form



# Short forms- When and why?

*Why should a short form be used?*

- To ensure that LES (Limited English Speaking) subjects are included in studies performed at Children's. (Fair and Equitable Selection of Subjects! 😊)



# How do I consent using a Short Form?

- An oral translation of the approved English language consent form should be presented in a language understood by the prospective participant.
- There must be a translator. Children's IRB custom is to encourage the use of professional or certified translators as we do for written translations. Exceptions may be made, however, on a case-by-case basis depending on availability of professionals.
- There must be a witness to the oral presentation. The witness must be fluent in both English and the language of the presentation. The translator may also serve as the witness.



# How do I consent using a Short Form?

Using a Translator, the English Informed Consent is explained to the potential subject/parent (in person or via telephone).

## 2 scenarios

1. Translated Short Form available-The language in question has a short form available in that language online- Spanish, Korean, Vietnamese, Chinese, Russian, French, Somalian, Portuguese
2. Translated Short Form not available- The language in question does NOT have a short form available.

# With Translated Short Form

- Consent using the Translated Short Form and English Informed Consent

Short Form (Translated) signed by-

- Subject/Parent
- Witness (usually interpreter)- can be done via fax

IC (English) signed by-

- Person Obtaining Consent (must be study staff)
  - Witness (often the Interpreter)

Copies of both to Subject/Parent



# Without Translated Short Form

Rules regarding who signs what-

- A LES person can not sign an English consent form or short form. You must submit the consent for translation and have it approved by the IRB prior to enrollment in a study.
- IF a participant needs to be enrolled within a limited time frame, and there is direct benefit to their enrollment, and there is not time to obtain a translated form, call the IRB for guidance.



## After Consent is Complete:

Important note, per the regulations-

When you use the English consent and a translated short form to consent a participant, you must then get the consent translated into that particular language, approved by the IRB, and mail to the participant for their records.



# Translation Services

- Currently the Children's IRB does not require a "Certified" Translation. Emory IRB does. If Certification is required, Children's can use their contracted company for this.
- Children's Translation Services can translate your IC to Spanish for free. For other languages, they are contracted with "Language Services", and will coordinate your translation for a fee.
- Contact- Jose Sanchez X: 52189



## Translation Services (cont.)

- Through Children's contracted provider (Language Services)-
  - Spanish- \$ . 21/ word (if "certified" translation is required)
  - Others (varies)- up to \$ .30/ word
  - *Short Form is 544 words (Approx. \$163 at \$.30/word)*
- Link2Spanish- \$ . 23/ word
- Harvard Student Services- \$40/ page

# To Translate IC or Not to Translate?

- 2008, US Census Bureau- Georgia's "Persons of Hispanic/Latino Origin" was 8%
- Since we have the ability to get documents translated (free!), we should have them translated and available for this growing Spanish speaking population.
- Once IC is approved, submit a Modification request to add translated documents.