SHORT FORM CHECKLIST: Interpreter Present

Important Notes

This checklist is required when you are using an in-person interpreter.

This process can only be used for **minimal risk** studies. The BCH IRB must have already approved the use of the Short Form consent process. Please check the protocol's IRB approval letter if you are uncertain about the risk category and whether the Short Form may be used. Use of the Short Form for greater than minimal risk studies must be approved as exceptions.

Principal Investigator: _____ IRB Protocol Number: _____

Subject Name: _____ Date (MM/DD/YEAR): _____

Person Obtaining Consent: _____ Study Role: _____

Step 1: ☐ Verify Short Form consent method approved by IRB (see IRB final approval letter or call IRB)

☐ Call Interpreter Services at 617-355-7198 to request and schedule an interpreter.

Step 2: Before conducting the consent process with the interpreter at the scheduled date/time, do the following:

☐ Download a copy of valid English consent form ("long form") from Informed Consent Library (ICL)

☐ Verify dates are current on the consent form footer:

Activation Date: _____ Expiration Date: _____

☐ Download a copy of Short Form in subject/parent/guardian's primary language:

Link to BCH's Short Form: http://www.childrenshospital.org/research/institutional-review-board/information-for-researchers/informed-consent

☐ Gather in private room with subject/parent/guardian.

Step 3: Conduct consent process with interpreter assistance.

Step 4: After consent discussion obtain the following signatures:

☐ Subject/parent/guardian signs, dates and specifies the relationship to child on Short Form.

☐ The person obtaining consent (PI/Coordinator), signs the English consent form ("long form") used as the summary of the verbal discussion.

☐ The interpreter signs

- ☐ The witness signature line on the Short Form.
- ☐ The witness signature line on the English consent form ("long form").

☐ If the IRB required ASSENT, you need to check one of the following:

- ☐ Minor subject signs and dates the Short Form.
- ☐ Reason assent was not obtained: _____
- ☐ N/A: assent not required for this study.

Step 5: Provide the subject/parent/guardian a copy of the signed and dated Short Form document and a copy of the signed and dated English consent form ("long form").

Step 6: ☐ Document the consent process and all pertinent notes and concerns:

All pertinent notes, concerns and questions should be documented, even after the consent form has been signed. The informed consent process lasts throughout the entire study! Keep a record of all updates, changes and discussions with the subject/parent/guardian.

_____

_____

Step 7: ☐ File signed consent. Attach signed English consent, signed Short Form together and file:

☐ Original: in Principal Investigator research files.

If required by IRB (reference initial IRB final approval letter):

☐ Copy: subject's medical record. Ensure there is a barcode in header of signed consent.