SHORT FORM CHECKLIST: Remote Interpreter (OPI or VRI)

Important Notes

This checklist is required when you are using a remote interpreter, whether OPI (over the phone interpretation) or VRI (video remote interpreting) is used. This checklist also serves to document the witness signature for the remote 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. The process described on this form should not be used if an in-person medical interpreter is available. The Interpreter Services specific VRI iPads are available throughout the hospital.

If there is a dropped call and another interpreter comes online the entire consent process must be started over.

This checklist must be completed and signed by the person obtaining consent (PI or PI-designated staff); the checklist must be attached to and kept along with both the original signed English consent form ("long form"). and Short Form consent in the subject binder.

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 final IRB approval letter or call IRB).

☐ Call Interpreter Services at 617-355-7198 to request an interpreter. If an in-person interpreter is not available, then use this process.

☐ Specify why remote interpreter used (e.g. scheduled late, language is not available at BCH, BCH Interpreter Service is not available etc).

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Step 2: Before calling the remote interpreter at the scheduled date/time, do the following:

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

☐ Verify dates are current on the English consent form ("long 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: Call the remote interpreter using the VRI iPAD or by phone to start consent session, using English consent form ("long form") as a guide for discussion.

Date (MM/DD/YEAR): _____ Time started: _____

Interpreters First Name: _____ ID#: _____

Language used: _____

Step 4: State the following and ask the remote interpreter:

"Because you are not here and unable to sign documents we need to ask if you will allow us to sign on your behalf by writing your name and ID# on the consent forms in a section that says witness. We want to let you know that the term witness has a very limited definition when used for this purpose. It means 1) you were present by phone or live video during the consent process; 2) the information was presented in the language you were told was understood by the subject/parent/guardian; and 3) the subject/family was given the opportunity to ask questions while you were present. The consent form includes this definition.

"Will you agree and allow me to sign on your behalf by writing your name and ID# on the consent forms?"

☐ If yes, proceed.

☐ If no, you may want to ask what the concern is and try and resolve it. It they will not agree you should not enroll the subject until you can find another interpreter who is able to serve this role.

Step 5: After consent discussion, with interpreter still on the line, the person obtaining the consent, must ask the remote interpreter to ask the subject/family/guardian the following two questions:

1. **Did you understand the information about the research**?

☐ No, consent process must continue until Yes.

☐ Yes, continue to 2.

2. **Do you have any questions?**

☐ No, continue to Step 6.

☐ Yes, all questions must be answered before moving on to Step 6.

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Step 6: Obtain the following signatures:

☐ Subject/parent/guardian signs, dates and specifies the relationship to child on Short Form (2nd line).

☐ The person obtaining consent (PI/Coordinator), signs the English consent form ("long form").

☐ The person obtaining consent (PI/Coordinator) records the Interpreter name and ID# on both the Short Form and on the English consent form ("long form") and writes "**As authorized by [insert interpreter's name]"(note #4 as to the terms of authorization) on:**

☐ The witness signature line on the Short Form (last line).
☐ The witness signature line on the English consent form ("long form"), the last line under "Or."

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

☐ Minor subject signs and dates the Short Form (1st line)
☐ Reason assent was not obtained: _____
☐ N/A: assent not required for this study

Step 7: 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 8: ☐ 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.

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Step 9: ☐ File signed consent. Attach signed English consent form ("long form"), signed Short Form **and this checklist** 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.

Step 10: Once the process is complete, please sign and date below:

_____ _____
Signature of Person Obtaining Consent Date (MM/DD/YEAR)