1 PURPOSE

1.1 This guidance establishes the process to obtain and document informed consent from non-English speaking subjects, legally authorized representatives of adult subjects unable to consent, or the parent(s) or guardian(s) of children, using the Short Form Consent method.

1.2 The guidance begins when:

1.2.1 a member of the research team identifies an individual as a potential subject for a research study.

1.2.2 the individual, their legally authorized representative, or child's parent(s) or guardian(s) do(es) not speak English; and

1.2.3 there is no translated long form informed consent document in the subject's/representative's language.

1.3 The guidance ends when the subject, the subject's legally authorized representative, or child's parent(s) or guardian(s) provide(s) legally effective informed consent or declines to do so.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Previous versions are available in Human Research Protection Program Change Log.

3 POLICY STATEMENT

3.1 Preferred Method of Informed Consent: If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative. The investigator obtains and submits written translations of the Institutional Review Board (IRB) -approved consent and Protected Health Information (PHI) Health Insurance Portability and Accountability Act (HIPAA) Authorization form(s), after the study is approved. Refer to *GUIDANCE: Informed Consent Process for Research (HRP-090) and TEMPLATE: Informed Consent with California Bill of Rights (HRP-502).*

3.2 Short Form Consent Method: Instead of signing the English-language consent form (which the subject does not understand), the subject signs the California Experimental Subjects Bill of Rights and *TEMPLATE: Consent - Short Form (HRP-507)* that has been translated to his/her language.

3.2.1 The short form method should only be used for the occasional and unexpected enrollment of a non-English-speaking subject in a study for which there is no translated long form informed consent document in the subject's language.

3.2.2 Routine use of this method is strongly discouraged by Sharp HealthCare IRB and federal regulators.

3.2.3 The investigator shall obtain certified translations of *TEMPLATE: Consent – Short Form (HRP-507)* and California Experimental Subjects Bill of Rights documents.

3.2.3.1 Certified translations of *TEMPLATE: Consent – Short Form (HRP-507)*, with the California Experimental Subjects Bill of Rights, are available in over 30 languages via Researcher Resources in IRBANA, or by request to research@sharp.com.

3.2.3.2 If the potential subject/representative speaks a language other than what is currently translated, the investigator shall obtain and submit to the IRB for approval a certified translation of the English version of the *TEMPLATE: Consent - Short Form (HRP-507)* with California Experimental Subjects Bill of Rights, or a certified translation of the long form consent document(s), and shall utilize the preferred method of informed consent per *GUIDANCE: Informed Consent Process for Research (HRP-090)*.

3.2.4 The translated *TEMPLATE: Consent – Short Form (HRP-507)* with California Experimental Subjects Bill of Rights, Summary Document, and modified PHI (HIPAA) Authorization must be submitted to and approved by the IRB, prior to enrolling a non-English speaking subject via the short form consent method.

3.2.5 In the event English long form consent document(s) is/are revised and the sponsor and/or IRB requires re-consent of subjects, the investigator shall obtain IRB approval

of certified translated long form consent document(s), in the language(s) understandable to the enrolled subject(s).

3.3 The IRB must have specifically approved the protocol to allow the enrollment of subjects/representatives who cannot speak English.

3.4 When the short form consent method will be used with a non-English speaking legally authorized representative, the IRB must have specifically approved the protocol to allow the enrollment of adult subjects who are unable to consent. Refer to *GUIDANCE: Legally Authorized Representatives (Surrogate Consent) (HRP-013)*.

3.5 When the short form consent method will be used with a non-English speaking parent or guardian, the IRB must have specifically approved the protocol to allow the enrollment of children. Refer to *GUIDANCE: Child Assent, Parents or Guardians Permission, Waiver and Special Circumstances (HRP-014)*.

4 RESPONSIBILITIES

4.1 The principal investigator is responsible to ensure these procedures are carried out. If these procedures are carried out by a designee of the principal investigator, that designee must be approved by the IRB.

5 PROCEDURE

5.1 The investigator or designee submits the following for IRB approval:

5.1.1 *FORM: Modification Request (HRP-213)*: At the time the investigator determines that the criteria of section 1.2 of this guidance have been met, the investigator or designee:

5.1.1.1 Submits completed *FORM: Modification request (HRP-213)* with all required documents to the IRB via the “IRB: Revision Log” in IRBANA (or electronically to research@sharp.com, if previously instructed to do so).

5.1.2 *TEMPLATE: Consent - Short Form (HRP-507)*, with California Experimental Subjects Bill of Rights: Obtain the current short form consent document in the language understandable to the subject/representative via Researcher Resources in IRBANA, or by request to research@sharp.com.

Prior to IRB submission, make the following modifications:

5.1.2.1 Update the header/footer with the sponsor’s Protocol ID number, IRB number, and version date.

5.1.2.2 In the fields provided on page 2 of the Short Form Consent document, enter:

- Study Title.
- Sponsor’s Protocol ID, if applicable.
- IRB #.
- Principal Investigator Name / Address.
- Daytime Phone Number.
- 24-hour Phone Number (required for research that is greater than minimal risk); and
- Sponsor name, if applicable.

5.1.3 Summary Document: The investigator or designee verifies that the current study-specific and IRB-approved version of the English informed consent document (long form) is being used.

Prior to IRB submission, the investigator or designee makes the following modifications to the English informed consent document:

5.1.3.1 Delete the California Experimental Subjects Bill of Rights from the first page.

5.1.3.2 Change the title of the informed consent document on the first page (and in the header/footer, if applicable) to “Study Summary Document”.

5.1.3.3 Only the person obtaining informed consent and the witness sign the Summary Document. Revise the signature page to include:

- A line for the printed name of the subject.
- A line for the printed name of the person obtaining informed consent, their signature and date; and
- A line for the printed name of the witness, their signature, and date.

5.1.4 *TEMPLATE: PHI Authorization (HRP-509)*: Neither the subject nor their representative should sign the authorization, whether there is a standalone PHI Authorization or one embedded in the Summary Document (i.e., the modified English long form consent). Prior to IRB submission, make the following modifications to the English PHI Authorization:

5.1.4.1 Remove line(s) for printed name(s), signature(s), and date(s) of signature.

5.2 IRB Review:

5.2.1 IRB review of documents associated with use of the Short Form Consent method may be carried out via expedited procedures per 21 CFR 56.110(b)(2) and/or 45 CFR 46.110(b)(1)(ii) (2018 Requirements) or 45 CFR 46.110(b)(2) (Pre-2018 Requirements).

5.2.2 An IRB member or designee reviews the submitted documents and confirms the requirements of *WORKSHEET: Short Form of Consent Documentation (HRP-317)* are met.

5.2.3 An IRB member or IRB Specialist documents an alteration of the HIPAA authorization requirements (i.e., waiver of signature) via *CHECKLIST: HIPAA Waiver of Authorization (HRP-441)*, which is retained in the agenda item file.

5.2.4 An IRB Specialist issues written approval of the submitted documents via the "IRB: Revision Log" or electronically via research@sharp.com.

5.3 Obtaining informed consent using the short form consent method:

5.3.1 The investigator or designee verifies that:

5.3.1.1 the short form consent with California Experimental Subjects Bill of Rights are in the language understandable to the subject/representative; and

5.3.1.2 the Short Form Consent with California Experimental Subjects Bill of Rights, Summary Document, and PHI Authorization are the current, IRB approved versions (i.e., documented in an IRB approval letter).

5.3.2 Follow the steps outlined in:

5.3.2.1 *WORKSHEET: Short Form of Consent Documentation (HRP-317)*; and

5.3.2.2 *CHECKLIST: Informed Consent Process (HRP-490),* if required by your site.

5.3.3 Provide copies of the Short Form Consent with California Experimental Subjects Bill of Rights, Summary Document, and modified PHI Authorization to the subject/representative. Whenever possible provide all documents to the subject/representative in advance of the consent discussion.

5.3.4 Obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, family member, or friend of the subject/representative.

5.3.5 Obtain the services of a witness who is fluent in both English and the language spoken by the subject/representative to be present during the entire consent discussion to attest that the information in the short consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness and the interpreter may be the same person, provided the interpreter is physically present during the entire informed consent discussion. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.

5.3.6 Have the interpreter translate the Summary Document (not the Short Form Consent) and PHI Authorization to the subject/representative.

5.3.7 Through the interpreter, explain the details in such a way that the subject/representative understands what it would be like to take part in the research study. When necessary, provide a different or simpler explanation to make the information understandable.

5.3.8 Have the subject/representative read the California Experimental Subjects Bill of Rights and Short Form Consent, or have the interpreter read the California Experimental Subjects Bill of Rights and Short Form consent to the subject/representative.

5.4 Investigators or designee's documentation of informed consent using the short form consent method:

5.4.1 Have the following individuals print their names, and personally sign and date the translated California Experimental Subjects Bill of Rights and Short Form Consent document:

5.4.1.1 Subject/Representative

5.4.1.2 Witness

5.4.2 Print the names of the following individuals on the Summary Document:

5.4.2.1 Subject/Representative

5.4.2.2 Person obtaining consent

5.4.2.3 Witness

5.4.3 Have the following individuals personally sign and date the Summary Document:

5.4.3.1 Person obtaining consent

5.4.3.2 Witness

5.4.4 If the IRB required written documentation of assent, note on the signature block on the Short Form Consent document one of the following:

5.4.4.1 Assent of the child was obtained.

5.4.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

5.4.5 Provide a copy of the signed and dated short form consent document and a copy of the signed and dated summary to the subject/representative. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of the Short Form Consent and Summary Document.

5.5 If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/representative had to be offered the opportunity to document his or her consent in writing, offer the subject/representative the option to document his or her consent in writing.

5.5.1 If the subject/representative declines, take no further action.

5.5.2 If the subject/representative accepts, follow the process to document consent in writing with the Short Form Consent documents.

5.6 Place the original signed and dated documents in the subject's source document or study binder. Place a copy of the signed and dated documents in the subject's inpatient hospital chart, and/or clinic chart.

6 MATERIALS

6.1 GUIDANCE: Informed Consent Process for Research (HRP-090)

6.2 FORM: Modification Request (HRP-213)

6.3 WORKSHEET: Short Form of Consent Documentation (HRP-317)

6.4 CHECKLIST: HIPAA Waiver of Authorization (HRP-441)

6.5 CHECKLIST: Informed Consent Process (HRP-490)

6.6 TEMPLATE: Informed Consent with California Bill of Rights (HRP-502)

6.7 TEMPLATE: Consent – Short Form (HRP-507)

6.8 TEMPLATE: PHI Authorization (HRP-509

7 REFERENCES

7.1 FDA: 21 CFR 50.20; 21 CFR 50.25; 21 CFR 50.27

7.2 DHHS: 45 CFR 46.117

7.3 ICH-GCP(E6): Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry

This document is available on www.sharp.com/research, IRBANA, or by contacting research@sharp.com.