

GUIDANCE: Written Documentation of Consent						
NUMBER	DATE	AUTHOR	APPROVED BY	AUDIENCE	USE	PAGE
HRP-091	9/1/2018	Center For Research	Institutional Official	Investigator or Designees	Required: X Elective:	Page 1 of 2

1 PURPOSE

- 1.1 This guidance establishes the process to document the informed consent process in writing.
- 1.2 The guidance begins when a subject agrees to take part in a research study.
- 1.3 The guidance ends when the consent process is documented in writing to the extent required by this procedure.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 If applicable, previous versions available in Human Research Protection Program Change Log.

3 POLICY STATEMENT

- 3.1 In this guidance, “investigator” means a principal investigator or an individual authorized by the principal investigator and approved by the Sharp HealthCare (SHC) Institutional Review Board (IRB) to obtain consent for the specific protocol, such as a sub-investigator, research assistant, or clinical research coordinator (CRC).
- 3.2 In this guidance, “subject/representative” means:
 - 3.2.1 The subject when the subject is an adult capable of providing consent.
 - 3.2.2 Legally authorized representative when the subject is an adult unable to give consent.
 - 3.2.3 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent, a person authorized under applicable law to consent on behalf of the child to the child’s general medical care.
- 3.3 In this guidance, “California Experimental Subject’s Bill of Rights” refers to the list of rights of a subject in a medical experiment as set forth under Health & Safety Code § 24172. It is the policy of Sharp HealthCare that all research subjects or their representatives sign and date this document in addition to providing their signature on the informed consent.

4 RESPONSIBILITIES

- 4.1 The principal investigator is responsible to ensure these procedures are carried out.

5 PROCEDURE

- 5.1 If the consent process will be documented in writing with the long form of consent documentation (*TEMPLATE: Informed Consent with California Bill of Rights [HRP-502]*):
 - 5.1.1 Verify that the consent form is in language understandable to the subject/representative and the most current IRB approved consent form. The California Experimental Subject’s Bill of Rights must be the first page of the consent form.
 - 5.1.2 Print the name of the following individuals on the consent document:
 - 5.1.2.1 Subject/Representative
 - 5.1.2.2 Person obtaining consent
 - 5.1.3 Have the following individuals personally sign and date the consent document:
 - 5.1.3.1 Subject/Representative
 - 5.1.3.2 Person obtaining consent
 - 5.1.4 Have the following individuals personally sign and date the California Experimental Subject’s Bill of Rights:
 - 5.1.4.1 Subject/Representative
 - 5.1.5 If the IRB required written documentation of assent, note on the signature block one of the following:
 - 5.1.5.1 Assent of the child was obtained.
 - 5.1.5.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 - 5.1.6 Have the person obtaining consent personally sign and date the consent document. If the subject does not sign the California Experimental Subject’s Bill of Rights page, document that it was provided to and read by the subject.
 - 5.1.7 If an impartial witness was part of the consent process:
 - 5.1.7.1 Print the name of the impartial witness on the consent document.

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- 5.1.7.2 Have the impartial witness personally sign and date the consent document to attest that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent was freely given.
- 5.1.8 Provided copies of the signed and dated consent document to the subject/representative. This may be accomplished either by making a photocopy or by having the above individuals sign and date two copies of the consent document.
- 5.2 If the consent process will be documented in writing with the short form of consent documentation (*TEMPLATE: Informed Consent – Short Form [HRP-507]*):
 - 5.2.1 Verify that the short consent form is in language understandable to the subject/representative and the most current IRB approved consent form.
 - 5.2.2 Print the name of the following individuals on the short form consent document and the summary:
 - 5.2.2.1 Subject/Representative
 - 5.2.2.2 Person obtaining consent
 - 5.2.2.3 Impartial witness
 - 5.2.3 Have the following individuals personally sign and date the short form consent document and the summary:
 - 5.2.3.1 Subject/Representative
 - 5.2.3.2 Person obtaining consent
 - 5.2.3.3 Impartial witness
 - 5.2.4 If the IRB required written documentation of assent, note on the signature block on the short consent document one of the following:
 - 5.2.4.1 Assent of the child was obtained.
 - 5.2.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 - 5.2.5 Provide a copy of the signed and dated short 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 consent document and summary.
- 5.3 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.
 - 5.3.1 If the subject/representative declines, take no further action.
 - 5.3.2 If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation
- 5.4 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 *TEMPLATE: Informed Consent with California Bill of Rights (HRP-502)*
- 6.2 *TEMPLATE: Informed Consent – Short Form (HRP-507)*

7 REFERENCES

- 7.1 21 CFR §50.27
- 7.2 45 CFR §46.117

This document is available on www.sharp.com/research, [IRBANA](#), or by contacting research@sharp.com.