UC DAVIS
UNIVERSITY OF CALIFORNIA

SOP: Written Documentation of Consent				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-091	09/19/2024	L. Smith	C. Kiel	1 of 2

1 PURPOSE

1.1 This procedure establishes the process to document the informed consent process in writing.

1.2 The process begins when a subject agrees to take part in a research study.

1.3 The process ends when the consent process is documented in writing to the extent required by this procedure.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Revised Section 5.2 to comply with 21 CFR 50.27(b)(2).

2.2 Revised regulatory citation in Section 3.3.

2.3 Removed Sections 5.3 and 5.4 regarding electronic signature and documentation requirements. Sections 5.5 and 5.6 were moved up in their stead.

2.4 Simplified 3.3, revised 5.1.2 to align with regulatory criteria, and consolidated 5.1.2 and 5.1.3. into a single section at 5.1.2

3 POLICY

3.1 In this procedure “investigator” means a principal investigator or an individual authorized by the principal investigator for the specific protocol, such as a co-investigator, research assistant, or coordinator.

3.2 In this procedure “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 Electronic signatures that comply with institutional policies and applicable regulations are acceptable for documentation of research 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:

- 5.1.1 Verify that the consent form is in language understandable to the subject/representative.
- 5.1.2 Obtain the required signatures and dates:
  - 5.1.2.1 For all studies, the subject/representative
  - 5.1.2.2 For studies complying with ICH-E6, the person obtaining consent
  - 5.1.2.3 When a witness is part of the consent process, the witness
  - 5.1.2.4 If the IRB required written documentation of assent, note on the signature block one of the following:
    - 5.1.2.4.1 Assent of the child was obtained.
    - 5.1.2.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
- 5.1.3 Provide a paper or electronic copy of the signed consent form to the subject. Electronic copies may be provided on an electronic storage device or via email.
  - 5.1.3.1 If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and information should be accessible until study completion.
  - 5.1.3.2 If the electronic consent document uses hyperlinks or other Web sites or podcasts to convey information specifically related to the research, the information in these hyperlinks will be included in any printed paper copy, if one is provided.

5.2 If the consent process will be documented in writing with the short form of consent documentation:

5.2.1 Verify that the short consent form is in language understandable to the subject/representative.

5.2.2 Obtain the required signatures and dates:

5.2.2.1 Subject/Representative: Only on the short form consent document

5.2.2.2 Person obtaining consent: Only on the summary or long form consent document.

5.2.2.3 Witness: On both the short form consent document and the summary or long form consent document.

5.2.2.4 If the IRB required written documentation of assent, note on the signature block on the short consent document one of the following:

5.2.2.4.1 Assent of the child was obtained.

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

5.2.2.5 Provide a paper or electronic copy of the signed and dated short consent document and a copy of the signed and dated summary to the subject/representative. Electronic copies may be provided on an electronic storage device or via email.

5.2.2.5.1 If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and information should be accessible until study completion.

5.2.2.5.2 If the electronic consent document uses hyperlinks or other Web sites or podcasts to convey information specifically related to the research, the information in these hyperlinks will be included in any printed paper copy, if one is provided.

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 is writing, offer the subject/representative the option to document his or her consent is 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 binder or electronic folder.

5.4.1 For clinical studies, place the consent document in the participant's electronic medical record (EMR).

6 MATERIALS

6.1 If the consent process will be documented in writing with the long form of consent documentation:

6.1.1 Consent document

6.2 If the consent process will be documented in writing with the short form of consent documentation:

6.2.1 Short consent document

6.2.2 Summary (same content as the long form of consent documentation)

7 REFERENCES

7.1 21 CFR §50.27

7.2 45 CFR §46.117

7.3 ICH-E6 R2