

SOP: Written Documentation of Consent

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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.

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 are compliant with 21 CFR 11 may be approved by a Committee or designated reviewer for FDA-regulated studies. Electronic signatures which are compliant with institutional policies, and the applicable regulations that these policies are drawn from, may be approved by a Committee or designated reviewer for all other studies.
 - 3.3.1 It is UC Davis IRB policy to accept the use of a secure system for electronic or digital signature that provides an encrypted identifiable “signature”.

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 For pen and ink signatures
 - 5.1.2.1 Print the name of the following individuals on the consent document:
 - 5.1.2.1.1 Subject/Representative
 - 5.1.2.1.2 Person obtaining consent
 - 5.1.2.2 Have the following individuals personally sign and date the consent document:
 - 5.1.2.2.1 Subject/Representative
 - 5.1.2.2.2 Person obtaining consent
 - 5.1.2.3 If an impartial witness was part of the consent process:
 - 5.1.2.3.1 Print the name of the impartial witness on the consent document.
 - 5.1.2.3.2 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.
 - 5.1.2.4 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.

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- 5.1.2.5 Provide 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.
- 5.1.3 For Electronic Signatures, follow the steps above to type in the names of the Subject/Representative, the person obtaining consent and the impartial witness, when applicable.
 - 5.1.3.1 Use the electronic signature procedure to obtain the signatures of the subject/representative, person obtaining consent and impartial witness, when applicable.
 - 5.1.3.2 If the IRB required written documentation of assent, note on the signature block one of the following:
 - 5.1.3.2.1 Assent of the child was obtained.
 - 5.1.3.2.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 - 5.1.3.3 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.
 - 5.1.3.3.1 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.
 - 5.1.3.3.2 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 For pen and ink signatures:
 - 5.2.2.1 Print the name of the following individuals on the documents as follows:
 - 5.2.2.1.1 Subject/Representative: Only on the short form consent document
 - 5.2.2.1.2 Person obtaining consent: Only on the summary.
 - 5.2.2.1.3 Impartial witness: On both the short form consent document and the summary.
 - 5.2.2.2 Have the Subject/Representative personally sign and date the short form consent document.
 - 5.2.2.3 Have the person obtaining consent personally sign and date the summary.
 - 5.2.2.4 Have the impartial witness personally sign and date the short form consent document and the summary.
 - 5.2.2.5 If the IRB required written documentation of assent, note on the signature block on the short consent document one of the following:
 - 5.2.2.5.1 Assent of the child was obtained.
 - 5.2.2.5.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 - 5.2.2.6 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.

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- 5.2.3 For Electronic Signatures, follow the steps above to type in the names of the Subject/Representative, the person obtaining consent and the impartial witness.
 - 5.2.3.1 Use the electronic signature procedure to obtain the signatures of the subject/representative, person obtaining consent and impartial witness.
 - 5.2.3.2 If the IRB required written documentation of assent, note on the signature block one of the following:
 - 5.2.3.2.1 Assent of the child was obtained.
 - 5.2.3.2.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 - 5.2.3.3 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.
 - 5.2.3.3.1 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.
 - 5.2.3.3.2 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.
 - 5.3 If the signature will be documented using an electronic process, the IRB will consider:
 - 5.3.1 How the electronic signature is created
 - 5.3.2 Whether the signature can be shown or verified to be legitimate
 - 5.3.3 Whether the consent document can be produced for review by the potential participant/representative
 - 5.4 If the consent process will be documented electronically the following language must be included in the documentation:
 - 5.4.1 California law provides specific rights when you are asked to provide electronic consent:
 - 5.4.1.1 You have the right to obtain a copy of the consent document in non-electronic format
 - 5.4.1.2 You have the right to provide consent in a non-electronic format.
 - 5.4.1.3 If you change your mind about electronic consent, you have the right to request your electronic consent to be withdrawn and you can then provide consent in a non-electronic format; however a copy of your electronic consent will be maintained for regulatory purposes. If you wish to withdraw your electronic consent please tell the study team
 - 5.4.1.4 This agreement for electronic consent applies only to your consent to participate in this research study.
 - 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 is writing, offer the subject/representative the option to document his or her consent is 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 long or short form of consent documentation
 - 5.6 Place the original signed and dated documents in the subject's binder or electronic folder.
 - 5.6.1 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

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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