

	OIA-091 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 including in an electronic format. In this procedure, documenting the informed consent process refers to obtaining the applicable signatures on the informed consent document or any alternative method of documentation required by the IRB.
- 1.2 The procedure begins when a subject indicates they would like to participate in the study after being presented with the informed consent information.
- 1.3 The procedure ends when the consent process is documented in writing to the extent required by this procedure.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 REQUIREMENTS¹

- 3.1 Electronic signatures that are compliant with [21 CFR Part 11](#)² may be approved by an IRB or designated reviewer for FDA-regulated studies. Electronic signatures which are compliant with institutional policies, and the applicable regulations from which these policies are drawn, may be approved by an IRB or designated reviewer for all other studies.
 - 3.1.1 It is Office of IRB Administration (OIA) practice to accept the use of a secure system for electronic or digital signature, provided the system generates an encrypted identifiable “signature.” OIA can assist researchers in determining whether their proposed system meets the requirements of this SOP.

4 RESPONSIBILITIES

- 4.1 The principal investigator or individual delegated by the principal investigator to obtain consent is responsible to ensure these procedures are carried out.

5 PROCEDURE

- 5.1 After completing the procedures under *OIA-090 SOP: Informed Consent Process for Research*, if the consent process will be documented in writing with the long form consent form:
 - 5.1.1 Verify that the long form consent form is in language understandable to the subject/legally authorized representative (LAR).
 - 5.1.2 For pen and ink signatures:
 - 5.1.2.1 The individual obtaining consent or the subject/LAR prints the name of the following individuals on the long form consent form:
 - 5.1.2.1.1 Subject/LAR
 - 5.1.2.1.2 Person obtaining consent
 - 5.1.2.2 Ask the following individuals to personally sign and date the consent form:
 - 5.1.2.2.1 Subject/LAR
 - 5.1.2.2.2 Person obtaining consent
 - 5.1.2.3 If an impartial witness participated in the consent process:
 - 5.1.2.3.1 The individual obtaining consent or the impartial witness prints the name of the impartial witness on the consent form.
 - 5.1.2.3.2 Ask the impartial witness to personally sign and date the consent form to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject/LAR, and that consent was freely given.
 - 5.1.2.4 If the IRB requires written documentation of assent of a cognitively impaired adult, complete the documentation on the signature block that one of the following conditions was met:

¹ Investigators and study team members may review the required elements for consent documents as outlined in *OIA-314B WORKSHEET: Requirements for Informed Consent*.

² [21 CFR Part 11 Electronic Records; Electronic Signatures](#)

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- 5.1.2.4.1 Assent of the subject was obtained.
- 5.1.2.4.2 Assent of the subject was not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
- 5.1.2.5 Provide copies of the signed and dated consent form to the subject/LAR. This may be accomplished by various methods (e.g., making a photocopy, signing and dating two original consent forms, scanning the document electronically and emailing³ to the subject/LAR, etc.).
- 5.1.3 For electronic signatures:⁴
 - 5.1.3.1 Authenticate the identity of the subject/LAR and the impartial witness, when applicable, using the method described in the electronic submission system application approved by the IRB.
 - 5.1.3.2 Follow the steps in 5.1.2 above to enter the names of the subject/LAR, the person obtaining consent and the impartial witness, when applicable.
 - 5.1.3.3 Use the IRB-approved electronic signature procedure to obtain the signatures of the subject/LAR, person obtaining consent and impartial witness, when applicable.
 - 5.1.3.4 If the IRB requires written documentation of assent of a cognitively impaired adult, complete the documentation on the signature block that one of the following conditions was met:
 - 5.1.3.4.1 Assent of the subject was obtained.
 - 5.1.3.4.2 Assent of the subject was not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 - 5.1.3.5 Provide a paper or electronic copy of the signed consent form to the subject. Electronic copies may be provided via secure document link, on an electronic storage device or via email.⁵
 - 5.1.3.5.1 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.
 - 5.1.3.5.2 If the electronic consent form uses hyperlinks or other Web sites or podcasts to convey information specifically related to a participant's willingness to participate, the information in these hyperlinks will be included in any printed paper copy, if one is provided to a subject/LAR who does not have Internet access.
- 5.2 After completing the procedures under *OIA-090 SOP: Informed Consent Process for Research*, if the consent process will be documented in writing with the short form consent form:
 - 5.2.1 Verify that the short form consent form is in language understandable to the subject/LAR.
 - 5.2.2 For pen and ink signatures:
 - 5.2.2.1 The individual obtaining consent, the impartial witness, or the subject/LAR prints the name of the following individuals on the documents as follows:
 - 5.2.2.1.1 Subject/LAR: Only on the short form consent form
 - 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 form and the summary⁶
 - 5.2.2.2 Ask the subject/LAR to personally sign and date the short form consent form.
 - 5.2.2.3 Ask the person obtaining consent to personally sign and date the summary.

³Email correspondence with research subjects must follow applicable UCSD [email encryption procedures](#)

⁴[FDA Guidance Use of Electronic Informed Consent In Clinical Investigations - Questions and Answers](#)

⁵Email correspondence with research subjects must follow applicable UCSD [email encryption procedures](#).

⁶ If the currently approved long form consent form will be used as the summary and does not contain the witness signature block, the current witness signature block from the IRB's template consent form may be added without requiring an amendment to be submitted.

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- 5.2.2.4 Ask the impartial witness to personally sign and date the short form consent form and the summary to attest that the information in the consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the subject/LAR, and that consent was freely given.
- 5.2.2.5 If the IRB requires written documentation of assent of a cognitively impaired adult, complete the documentation on the signature block that one of the following conditions was met:
 - 5.2.2.5.1 Assent of the subject was obtained.
 - 5.2.2.5.2 Assent of the subject was not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
- 5.2.2.6 Provide a copy of the signed and dated short form consent form and a copy of the signed and dated summary to the subject/LAR. This may be accomplished by various methods (e.g. making a photocopy, signing and dating two original consent forms and summaries, scanning the documents electronically and emailing⁷ to the subject/LAR, etc.).
- 5.2.3 For electronic signatures:
 - 5.2.3.1 Authenticate the identity of the subject/LAR and the impartial witness, when applicable.
 - 5.2.3.2 Follow the steps in 5.2.2.1 above to enter the names of the subject/LAR, the person obtaining consent and the impartial witness.
 - 5.2.3.3 Use the IRB-approved electronic signature procedure to obtain the signatures of the subject/LAR, person obtaining consent and impartial witness, when applicable.
 - 5.2.3.4 If the IRB requires written documentation of assent of a cognitively impaired adult, complete the documentation on the signature block that one of the following conditions was met:
 - 5.2.3.4.1 Assent of the subject was obtained.
 - 5.2.3.4.2 Assent of the subject was not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 - 5.2.3.5 Provide a paper or electronic copy of the signed consent form to the subject/LAR. Electronic copies may be provided via secure document link, on an electronic storage device or via email.⁸
 - 5.2.3.5.1 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.
 - 5.2.3.5.2 If the electronic consent form 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 to a subject/LAR who does not have Internet access.
- 5.3 After completing the procedures under *OIA-090 SOP: Informed Consent Process for Research*, if the requirement for written documentation of the consent process has been waived by the IRB:
 - 5.3.1 If an impartial witness observed the consent process, the research record should include documentation of the witness's attestation that the information on the form was accurately explained to the participant/LAR, that the participant/LAR appeared to have understood, and freely gave consent to take part in the research.
 - 5.3.2 If the IRB determined that a waiver of documented consent was appropriate because the consent form would be the only link between the subject/LAR and the research, and the

⁷Email correspondence with research subjects must follow applicable UCSD [email encryption procedures](#)

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UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-091 SOP: Written Documentation of Consent				
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principle risk is a breach of confidentiality, the subject/LAR must be offered the opportunity to document their consent in writing.⁹ Offer the subject/LAR the option to document their consent in writing.

5.3.2.1 If the subject/LAR declines, take no further action with regard to this procedure.

5.3.2.2 If the subject/LAR accepts, follow the procedure to document consent in writing with the consent documentation, as approved for the study.¹⁰

5.4 Place the original signed and dated documents, if any, in the subject's binder or electronic folder.

5.4.1 For clinical studies, upload a copy of the signed consent form, and experimental participant's bill of rights (when a separate document) into the subject's electronic medical record (EMR).

6 MATERIALS

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

6.1.1 Long form consent form

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

6.2.1 Short form consent form

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

6.2.3 Experimental Participant's Bill of Rights

6.3 *OIA-001 SOP: Definitions*

6.4 *OIA-090 SOP: Informed Consent Process for Research*

7 REFERENCES

7.1 [21 CFR Part 11](#)

7.2 [21 CFR 50.27](#)

7.3 [45 CFR 46.117](#)

7.4 [UCSDHP 340.1 Informed Consent for Human Research Subjects](#) (UCSD Pulse Intranet page)

7.5 [Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers](#)

7.6 [Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers](#)

⁹ [45 CFR 46.117\(c\)\(1\)\(i\)](#)

¹⁰ If the currently approved consent documentation will be used and does not contain the signature block, the current signature block from the IRB's template consent form may be added without requiring an amendment to be submitted.