	OIA-093 SOP: Written Documentation of Assent				
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1 PURPOSE

- 1.1 This procedure establishes the process to document the assent process in writing when the IRB has required documentation of assent.
- 1.2 The procedure begins when a subject or their parent/guardian/LAR indicates they would like to take part in a research study, whichever comes first.
- 1.3 The procedure ends when the assent process is documented in writing to the extent required by the IRB-approved procedure.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 REQUIREMENTS

- 3.1 Electronic signatures that are compliant with [21 CFR Part 11](#)¹ 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.
- 3.2 If a child is participating in a study with parent/guardian consent and subsequently reaches the legal age of consent while still participating, unless the IRB waives the requirement for obtaining informed consent, the now-adult subject's legally effective informed consent must be sought prior to continuing any on-going study procedures, including data collection.^{2,3}

4 RESPONSIBILITIES

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


5 PROCEDURE

- 5.1 After completing the procedures under *OIA-092 SOP: Assent Process for Research*, if the assent process will be documented in writing with the assent form:
 - 5.1.1 Verify that the assent form is in language understandable to the subject.
 - 5.1.2 For pen and ink signatures using the assent form:
 - 5.1.2.1 Ask the following individuals to personally sign or write their name, as appropriate, and date the assent form:
 - 5.1.2.1.1 Subject. Writing their first name or making their mark is sufficient.
 - 5.1.2.1.2 Person obtaining assent
 - 5.1.2.2 If an impartial witness participated in the assent process:
 - 5.1.2.2.1 The individual obtaining assent or the impartial witness prints the name of the impartial witness on the assent form.
 - 5.1.2.2.2 Ask the impartial witness to personally sign and date the assent form to attest that the information in the assent form and any other information provided was accurately explained to, and apparently understood by, the subject, and that assent was freely given.
 - 5.1.2.3 Provide copies of the signed and dated assent form to the subject/legally authorized representative. This may be accomplished by various methods (e.g. making a photocopy, signing and dating two original assent forms, scanning the

¹ [21 CFR Part 11 Electronic Records: Electronic Signatures](#)

² [OHRP Guidance - Research with Children FAQs](#)

³ If the continued study procedures involve only data collection, the PI should apply for a waiver of consent from the IRB for the collection of data on the now adult subjects.

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document electronically and emailing⁴ to the subject/legally authorized representative, etc.).

- 5.1.3 For electronic signatures:⁵
 - 5.1.3.1 Authenticate the identity of the subject if aged 18 years or older and the impartial witness, when applicable, using the method described in the electronic submission system application approved by the IRB.
 - 5.1.3.2 Use the IRB-approved electronic signature procedure to obtain the signatures of the subject, person obtaining assent and impartial witness, when applicable.
 - 5.1.3.3 Provide a paper or electronic copy of the signed assent form to the subject/legally authorized representative/family, depending on the capability of the subject. Electronic copies may be provided via secure document link, on an electronic storage device or via email.⁶
 - 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 assent 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 who does not have Internet access.
- 5.2 After completing the procedures under *OIA-092 SOP: Assent Process for Research*, if the IRB-approved requirement for written documentation of the assent process is by a method other than the subject writing their name or signing the assent form:
 - 5.2.1 If the IRB requires written documentation of assent of a cognitively impaired adult, complete the documentation on the signature block of the consent form that one of the following conditions was met:
 - 5.2.1.1 Assent of the subject was obtained.
 - 5.2.1.2 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 If an impartial witness observed the assent process, the research record should include documentation of the witness' attestation that the information on the form was accurately explained to the participant, that the participant appeared to have understood, and freely gave assent to take part in the research.
 - 5.2.3 If the subject declines, take no further action with regard to this procedure.
 - 5.2.4 If the subject assents, follow the procedure to document assent in writing using the method approved by the IRB for the study.
- 5.3 Place the original signed and dated documents in the subject's binder or electronic folder.
 - 5.3.1 For clinical studies, upload a copy of the assent form into the participant's electronic medical record (EMR).⁷

6 MATERIALS

- 6.1 If the assent process will be documented in writing with the assent form:
 - 6.1.1 Adolescent or child assent form
- 6.2 If assent will be documented via check box on the consent form:
 - 6.2.1 Long form consent form
- 6.3 *OIA-001 SOP: Definitions*

⁴Email correspondence with research subjects must follow applicable UCSD [email encryption procedures](#)

⁵[FDA Guidance Use of Electronic Informed Consent Questions and Answers](#)

⁶Email correspondence with research subjects must follow applicable UCSD [email encryption procedures](#).

⁷[UCSDHP 340.1 Informed Consent for Human Research Subjects](#) (UCSD Pulse Intranet page)

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6.4 *OIA-092 SOP: Assent Process for Research*

7 REFERENCES

7.1 [21 CFR Part 11](#)

7.2 [21 CFR 50.27](#)

7.3 [21 CFR 50.55](#)

7.4 [45 CFR 46.117](#)

7.5 [OHRP Guidance – Research with Children FAQs](#)

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

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

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