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1 PURPOSE

- 1.1 This procedure establishes the process to obtain assent from subjects who are children¹ or adults unable to consent but able to express assent or dissent when the IRB requires an assent process. This procedure does not address the process to document assent. For that procedure, refer to *OIA-093 SOP: Written Documentation of Assent*.
- 1.2 The procedure begins when a potential candidate for a research study is identified who is a child or an adult unable to consent but able to express assent or dissent.
- 1.3 The procedure ends when the subject agrees to participate in the study or declines to do so. If parent/guardian/legally authorized representative (LAR) consent is required for participation and the parent/guardian/LAR declines participation, the procedure ends.


2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 REQUIREMENTS

- 3.1 While this specific procedure ends once initial assent is obtained in accordance with this SOP and *OIA-093 SOP: Written Documentation of Assent* according to the determinations of the IRB, assent is an on-going process and starts at the initial contact with the potential participant and continues throughout the duration of the subject's participation in the study. If at any time during the initial assent discussion or the subject's participation in the study the subject withdraws their assent to participate, all study procedures in which the subject no longer wishes to participate must stop.
- 3.2 Only the principal investigator or those delegated by the principal investigator, appropriately trained on the study, and included as IRB-approved key personnel may obtain assent from subjects.
- 3.3 Conduct all discussions in a setting that provides reasonable measures to protect subject privacy.
 - 3.3.1 Group assent processes, such as those that may be done in a classroom setting, require explicit IRB approval.
 - 3.3.2 Unless the IRB has waived parental consent or otherwise approved a different assent process, the parent/guardian may be present for the assent process.
- 3.4 If the subject understands more than one language, whenever possible, conduct the assent process in the preferred language of the subject.
- 3.5 If the subject cannot speak/read English, and there is not someone on the study team who is trained to conduct the assent process and who speaks the subject's/LAR's language, arrange for the services of an interpreter fluent in both English and the language understood by the subject, as determined by the person obtaining assent.
- 3.6 If an interpreter is required, the interpreter may be a professional interpreter provided by the institution, a family member, or friend of the subject. The interpreter may not be the same person who provided/will provide consent for the subject's participation in the study.
- 3.7 If the subject cannot read:
 - 3.7.1 If the subject cannot read due to visual impairment, assess whether the visual impairment can be overcome via technological means (e.g., screen reader, magnifying glasses, braille reader, etc.). If the visual impairment cannot be overcome, arrange for an impartial witness to be present during the entire assent discussion 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.
 - 3.7.2 If the subject cannot read due to illiteracy, developmental delay, learning disability, or any other reason, arrange for an impartial witness to be present during the entire assent discussion to attest that the information in the assent form and any other information

¹ If research on a specific treatment involves solely treatments or procedures for which minors can give consent outside the research context (under applicable state and local laws, for example, research on sexually transmitted diseases or pregnancy), such individuals would not meet the definition of children as defined at [45 CFR 46.402\(a\)](#). Thus, [subpart D](#) would not apply to the research and parental consent (or waiver thereof) is not a consideration for these minors. Under these circumstances, minors may provide their own informed consent. This is consistent with the Office of IRB Administration's (OIA) definition of children in *OIA-001 SOP: Definitions*.

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provided was accurately explained to, and apparently understood by, the subject and that assent was freely given.

- 3.8 If an impartial witness is required, the impartial witness may not be a person involved in the design, conduct, or reporting of the research or the person(s) who provided/will provide consent for the subject's participation.
- 3.9 If both an impartial witness and an interpreter are required for the assent process, the witness and the interpreter may be the same person, provided they meet requirements of 3.6 and 3.8 above.
- 3.10 If the subject is an adult unable to consent but able to express assent or dissent, the IRB must have specifically approved the protocol to allow the use of surrogate consent.
- 3.11 If the subject is a child:
 - 3.11.1 The IRB must have specifically approved the protocol to allow the enrollment of children.
 - 3.11.2 The IRB must have specifically required that assent be obtained from some or all of the children who are subjects.²
 - 3.11.3 The child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.
 - 3.11.4 If a child is capable of assent and the IRB requires that assent be sought, it must be obtained before the child can participate in the research activity. If the child dissents from participating in research, even if his or her parents or guardian have granted consent, the child's decision prevails.
 - 3.11.5 If the IRB requires that assent be sought from some or all children, such assent should generally be sought after obtaining parent/guardian consent. If assent will be sought from some or all children prior to obtaining parent/guardian consent, this requires specific IRB approval.
 - 3.11.6 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.^{3,4}

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 If the assent process will be documented in writing on the assent form:
 - 5.1.1 Obtain the current IRB-approved assent form and, if the subject is an adolescent, a copy of the experimental participant's bill of rights⁵ (medical experiments⁶ only), which may be incorporated into the adolescent assent form.
 - 5.1.2 Confirm the form is the most current IRB-approved version of the study specific assent form and that the assent form is in language understandable to the subject. For non-English speakers, the assent form should be an IRB-approved translated version in their preferred language.
 - 5.1.3 Provide copies of the assent form to the subject. Whenever possible and appropriate, provide the assent form to the subject in advance of the assent discussion.

² The IRB may waive assent for some or all of the children based on a variety of factors (e.g. population being studied, availability of intervention outside of the research environment, etc.). If assent is waived for all children, this SOP does not apply.

³ [OHRP Guidance - Research with Children FAQs](#)

⁴ If the continued study procedures involve only data collection, the principal investigator should apply for a waiver of consent from the IRB for the collection of data on the now adult subjects.

⁵ If using a stand-alone bill of rights document, one copy can be shared between the parent and adolescent; however, if requested, each individual providing consent/assent must be provided with their own copy of the bill of rights.

⁶ [California Health and Safety Code Section 24174](#)

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- 5.1.4 Using the assent form as a guide, go over the details of the study (using an interpreter as necessary) with the subject, explaining the details in such a way that the subject understands what it would be like to take part in the research study and commensurate with the subject's capability. When necessary, provide a different or simpler explanation to make the information understandable.
- 5.2 If the IRB has required documentation of assent by a method other than having the subject sign an assent form (most commonly, documented by the study team in the study record, medical record, or check box on the consent form as appropriate):
 - 5.2.1 Obtain the current IRB-approved assent script or information sheet.⁷
 - 5.2.2 Confirm the form is the most current IRB-approved version of the study specific assent script or information sheet.
 - 5.2.3 Confirm that the script or information sheet language is understandable to the subject.
 - 5.2.3.1 For non-English speakers who will be specifically targeted by the study or are expected to present for recruitment regularly (e.g., Spanish), the script or information sheet should be an IRB-approved translated version.
 - 5.2.3.2 For non-English speakers who are not specifically targeted by the study and are not expected to present for recruitment regularly, use an interpreter to conduct the assent discussion and, when LAR or guardian consent is waived, use an impartial witness.
 - 5.2.4 Provide copies of the assent script or information sheet to the subject. When possible and appropriate provide a copy of the script or information sheet to the subject in advance of the assent discussion.
 - 5.2.5 If the subject cannot read, arrange for an impartial witness to be present during the entire assent discussion to attest, e.g., in a note to file or other documentation, that the information in the script or information sheet and any other information provided was accurately explained to, and apparently understood by, the subject, and that assent was freely given.
 - 5.2.6 Read the script or information sheet (or have an interpreter translate the script) with the subject. Explain the details in such a way that the subject understands what it would be like to take part in the research study and commensurate with the subject's capability. When necessary, provide a different or simpler explanation to make the information understandable.
- 5.3 Invite and answer the subject's questions.
- 5.4 Give the subject time to read the assent document further and discuss taking part in the research study with family members, friends and other care providers as appropriate.
- 5.5 Invite and encourage the subject to take the written information home to consider the information and discuss the decision with family members and others before making a decision.
- 5.6 In conducting the assent process with the subject, the person obtaining assent should be able to affirm that:
 - 5.6.1 The subject understands the information provided to the extent that their age or capacity permits.
 - 5.6.2 The subject does not feel pressured by time or other factors to make a decision.
 - 5.6.3 The subject understands that there is a voluntary choice to make.
 - 5.6.4 The subject is capable of making and communicating their decision. This communication might be done verbally or behaviorally.
 - 5.6.5 The subject had ample time to review the assent form and ask questions.
- 5.7 Once a subject indicates that they do not want to take part in the research study, which might be communicated verbally or behaviorally, this procedure stops.

⁷ The assent script or information sheet may be developed, for example, by using the template assent form but without the signature block. In the case of an adult unable to consent, the assent script will be the IRB-approved consent form.

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5.8 Obtain written documentation of the assent process according to *OIA-093 SOP: Written Documentation of Assent*, unless waived by the IRB.

6 MATERIALS

6.1 Assent form documentation:

6.1.1 Child assent form

6.1.2 Adolescent assent form

6.2 The IRB requirement for written documentation of the assent process is other than on the assent form:

6.2.1 Assent script (may be same as assent form used for documentation of assent except that signature block is optional)

6.2.2 Consent form with incapable adult assent checkboxes

6.3 *OIA-001 SOP: Definitions*

6.4 *OIA-013 SOP: Legally Authorized Representatives, Children, and Guardians*

6.5 *OIA-093 SOP: Written Documentation of Assent*

7 REFERENCES

7.1 [California Health and Safety Code 24174](#)

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

7.3 [21 CFR 50.3\(n\)](#)

7.4 [21 CFR 50.55](#)

7.5 [21 CFR 46.402\(b\)](#)

7.6 [45 CFR 46.408](#)

7.7 [FDA Information Sheet: A Guide to Informed Consent](#)

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