

UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-090 SOP: Informed Consent Process for Research				
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1 PURPOSE

- 1.1 This procedure establishes the process to obtain informed consent from subjects, the legally authorized representatives (LAR) of adults unable to consent, or the parents or guardians of children. This procedure does not address the process to document informed consent. For that procedure, refer to *OIA-091 SOP: Written Documentation of Consent*.
- 1.2 The procedure begins when a potential candidate for a research study is identified.
- 1.3 The procedure ends when a subject or the subject's LAR agrees to participate in the study or declines to do so.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 REQUIREMENTS


- 3.1 While this specific procedure ends once initial consent is obtained in accordance with this SOP and *OIA-091 SOP: Written Documentation of Consent* according to the determinations of the IRB, informed consent 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 consent discussion or during the subject's participation in the study, the subject/LAR withdraws their consent to participate, all study procedures in which the subject/LAR no longer wishes to participate must stop.
- 3.2 Only the principal investigator or those delegated by the principal investigator, appropriately trained for the study, and included as IRB-approved key personnel may obtain consent from subjects or their LAR.
- 3.3 Conduct all discussions in a setting that provides reasonable measures to protect patient privacy.
 - 3.3.1 Group consent processes, such as those that may be done in a focus group, require explicit IRB approval.
 - 3.3.2 The consent process need not be conducted in-person regardless of whether the person consenting is the subject or a(n) LAR/guardian. The consent process may be done via teleconference or other remote means in accordance with prevailing privacy policies and the IRB-approved study consenting process.
- 3.4 If the subject/LAR understands more than one language, conduct the consent process in the preferred language of the subject/LAR.
 - 3.4.1 If the short form process will be used, follow the procedures noted below in Section 5.2.
- 3.5 If the subject/LAR cannot speak/read English and there is not someone on the study team who is trained to conduct the consent procedures and speaks the subject's/LAR's language, arrange for the services of an interpreter and, when required by regulation, statute, policy, or the IRB (e.g. when using the short form consent form), an impartial witness fluent in both English and the language understood by the subject/LAR, as determined by the person obtaining consent.
- 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/LAR. The interpreter may not be the same person who provided/will provide consent for the subject's participation in the study.
- 3.7 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.
 - 3.7.1 When required, the impartial witness attests that the information required by the IRB to be presented as a part of the informed consent process has been accurately explained to the subject/LAR, that the subject/LAR apparently understood the information, and that the subject/LAR freely gave consent to participate in the study.
- 3.8 If both an impartial witness and an interpreter are required for the consent process, the witness and the interpreter may be the same person, provided they meet requirements in 3.6 and 3.7 above.
- 3.9 If the subject/LAR cannot read:

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- 3.9.1 If the subject/LAR 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 consent discussion 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.
- 3.9.2 If the subject/LAR cannot read due to illiteracy, arrange for an impartial witness to be present during the entire consent discussion 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.
- 3.10 If the subject is an adult unable to consent:
 - 3.10.1 The IRB must have specifically approved the protocol to allow the use of surrogate consent.
 - 3.10.2 Consent is obtained from an LAR, who must be in the class of persons as described by *OIA-013 SOP: Legally Authorized Representatives, Children, and Guardians*.
 - 3.10.3 While interactions and/or interventions with the subject are ongoing, if the subject regains capacity to consent to research procedures, they must either consent to continue in the study or decline further participation in the study.
- 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 Consent is obtained from both parents unless:
 - 3.11.2.1 One parent is deceased, unknown, incompetent, not reasonably available;
 - 3.11.2.1.1 “Not reasonably available” does not apply to situations when a parent is at work, traveling, caring for other children or living in another state or country and is not intended to mean that a parent is temporarily unavailable, unless there are specific circumstances where time is of the essence.¹
 - 3.11.2.1.2 A parent who is “not reasonably available” is one whose whereabouts are unknown or there is no way to reach them by phone, mail, email, fax, or any type of videoconferencing to arrange for consent or who has not responded to multiple contact attempts.
 - 3.11.2.2 Only one parent has legal responsibility for the care and custody of the child; or
 - 3.11.2.3 The IRB has specifically approved the protocol to allow the consent of one parent regardless of the status of a second parent.
 - 3.11.3 In the absence of a parent, consent may be obtained from an individual authorized to consent to general medical care on behalf of a child under applicable law.
 - 3.11.4 The IRB must have specifically approved the protocol to require assent from none, some, or all of the children as described in *OIA-092 SOP: Assent Process for Research*.
- 3.12 Re-consenting study participants may be necessary if new information that is relevant to the subject’s continued participation in the study becomes available during the study.
 - 3.12.1 New information must be submitted to the IRB in accordance with *OIA-103 IRB Handbook* section “What are my obligations after IRB approval?” and/or Appendix A.
 - 3.12.2 The principal investigator must indicate in their submission whether, when, and how re-consent will occur.

¹ The assessment of whether a child’s enrollment necessitates proceeding with one parent signature because “time is of the essence” is to be made by the principal investigator or co-investigator with qualifications to make such an assessment. This determination must be documented in the research record.

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3.12.3 The IRB or designated reviewer may approve a re-consent process, as necessary, in accordance with prevailing regulations and guidance, taking into consideration the information to be communicated, the status of any enrolled subjects, and the status of the study.

3.13 If the short form consent form is used to enroll a non-English speaking subject/LAR into a study that is greater than minimal risk and/or a study that has multiple study visits/interactions, the long form consent form must be translated into the language spoken by the subject/LAR and the subject/LAR reconsented with the translated long form consent form.

3.13.1 The IRB recommends that reconsent occur within 30 days of initial consent.

4 RESPONSIBILITIES

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

5 PROCEDURE

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

5.1.1 Obtain the current IRB approved long form consent form and a copy of the experimental participant's bill of rights (required for medical experiments², optional for non-medical experiments), which may be incorporated into the long form consent form.

5.1.2 Confirm the form is the most current IRB-approved version of the study specific long form consent form and that the consent form is in language understandable to the subject/LAR. For non-English speakers, the long form consent form should be an IRB-approved translated version in their preferred language.

5.1.3 Provide copies of the long form consent form to the subject/LAR. Whenever possible provide the consent form to the subject/LAR in advance of the consent discussion.

5.1.4 Using the long form consent form as a guide, go over the details of the study (using an interpreter as necessary) with the subject/LAR, explaining the details in such a way that the subject/LAR understands what it would be like to take part in the research study. When necessary, provide a different or simpler explanation to make the information understandable.

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

5.2.1 Obtain the current IRB-approved short form consent form³ and the summary (which may be the IRB-approved English long form consent form), and a copy of the experimental participant's bill of rights (medical experiments⁴ only), which may be incorporated into the short form consent form.

5.2.2 Confirm the form is the most current IRB-approved version of the study specific long form consent form if this is the document used as the summary.

5.2.3 Provide copies of the consent forms to the subject/LAR. Whenever possible provide the short form consent form and summary to the subject/LAR in advance of the consent discussion.

5.2.4 Arrange for an impartial witness,^{5,6} who is fluent in English (and, when consenting a non-English speaking subject/LAR, the language spoken by the subject/LAR) to be present during the entire consent discussion to attest that the information in the short form 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.

5.2.5 When using this procedure for a non-English speaking subject/LAR, ask the interpreter to translate the summary (the English long form consent form) to the subject/LAR.

² [California Health and Safety Code Section 24174](#)

³ Short form consent forms available on the IRB's [Forms and Instructions page](#).

⁴ [California Health and Safety Code Section 24174](#)

⁵ [21 CFR 50.27 \(b\)\(2\)](#)

⁶ [45 CFR 46.117\(b\)\(2\)](#)

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- 5.2.6 Explain the details in such a way that the subject/LAR understands what it would be like to take part in the research study. When necessary, provide a different or simpler explanation to make the information understandable. When using this procedure for a non-English speaking subject/LAR, this conversation will be conducted through the interpreter.
- 5.2.7 Ask the subject/LAR to read the short form consent form, or if the subject cannot read the form themselves, read, or if applicable ask the interpreter to read, the short form consent form to the subject/LAR.
- 5.3 If the requirement for written documentation of the consent process has been waived by the IRB:
 - 5.3.1 Obtain the current IRB-approved script or information sheet.
 - 5.3.2 Confirm the form is the most current IRB-approved version of the study specific script or information sheet.
 - 5.3.3 Confirm that the script or information sheet language is understandable to the subject/LAR.
 - 5.3.3.1 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.
 - 5.3.3.2 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 consent discussion and, when an information sheet is required, use an impartial witness and provide the subject/LAR with the short form consent form in the language they understand.
 - 5.3.4 When an information sheet is used, provide a copy of the information sheet to the subject/LAR. When possible, provide a copy of the information sheet to the subject/LAR in advance of the consent discussion.
 - 5.3.5 Read the script or information sheet, using an interpreter as necessary, with the subject/LAR. Explain the details in such a way that the subject/LAR understands what it would be like to take part in the research study.
- 5.4 Invite and answer the subject's/LAR's questions.
- 5.5 Give the subject/LAR time to read any written information further. Invite and encourage the subject/LAR to take any written information home to discuss taking part in the research study with family members, friends and other care providers as appropriate before making a decision.
- 5.6 In conducting the informed consent process with the subject/LAR, the person obtaining consent should be able to affirm that:
 - 5.6.1 The subject/LAR understands the information provided.
 - 5.6.2 The subject/LAR does not feel pressured by time or other factors to make a decision.
 - 5.6.3 The subject/LAR understands that there is a voluntary choice to make.
 - 5.6.4 The subject/LAR is capable of making and communicating an informed choice.
 - 5.6.5 The subject/LAR had ample time to review the consent form and ask questions.
- 5.7 If the study is an FDA-regulated clinical investigation and the person obtaining consent above is not a physician or physician extender,⁷ the person obtaining consent should consider, and the IRB may require, that a physician or physician extender complete the following steps:
 - 5.7.1 Invite and answer the subject's/LAR's questions.
 - 5.7.2 Confirm that the following are true, in the person obtaining consent's judgment, or repeat the above steps:
 - 5.7.2.1 The subject/LAR understands the information provided.
 - 5.7.2.2 The subject/LAR does not feel pressured by time or other factors to make a decision.

⁷ A physician assistant (PA) or nurse practitioner (NP).

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- 5.7.2.3 The subject/LAR understands that there is a voluntary choice to make.
- 5.7.2.4 The subject/LAR is capable of making and communicating an informed choice.
- 5.7.2.5 The subject/LAR had ample time to review the consent form and ask questions.

5.7.3 This step in this procedure, when completed, is to be documented in the research record.

5.8 Once a subject/LAR indicates that they do not want to take part in the research study, this procedure stops.

5.9 If the subject/LAR agrees to take part in the research study:

5.9.1 If the subject is a child:

5.9.1.1 Whenever possible explain the research to the extent compatible with the child's understanding.

5.9.1.2 Request the assent (affirmative agreement) of the child unless:

5.9.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.

5.9.1.2.2 The IRB determined that assent was not a requirement.

5.9.1.3 Once a child indicates that they do not want to take part in the research study, this procedure stops.

5.9.2 If the subject is an adult unable to consent:

5.9.2.1 Whenever possible explain the research to the extent compatible with the adult's understanding.

5.9.2.2 Request the assent (affirmative agreement) of the adult unless:

5.9.2.2.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.

5.9.2.2.2 The IRB determined that assent was not required.

5.9.2.3 Once an adult unable to consent indicates that they do not want to take part in the research study, which might be done verbally or behaviorally, this procedure stops.

5.9.3 Obtain written documentation of the consent process according to *OIA-091 SOP: Written Documentation of Consent*, unless waived by the IRB.

6 MATERIALS⁸

6.1 Long form consent form documentation:

6.1.1 Long form consent form

6.1.2 Experimental participant's bill of rights (when the study is a medical experiment,⁹ may be incorporated into the long form consent form)

6.2 Short form consent form documentation:

6.2.1 Short form consent form

6.2.2 Summary (the English long form consent form used for long form of consent documentation)

6.2.3 Experimental participant's bill of rights (when the study is a medical experiment,¹⁰ may be incorporated into the short form consent form)

6.3 Requirement for written documentation of the consent process has been waived by the IRB:

6.3.1 Consent script (may be same as long form consent form used for long form of consent documentation except that signature block is optional)

6.4 *OIA-001 SOP: Definitions*

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

⁸ Note: HIPAA Authorization, when required, is often completed at the same time as the consent process. Please refer to the [Office of Compliance and Privacy's](#) (UCSD Pulse Intranet page) policies for more information on obtaining HIPAA authorization.

⁹ [California Health and Safety Code 24174](#)

¹⁰ [California Health and Safety Code 24174](#)

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6.6 *OIA-091 SOP: Written Documentation of Consent*

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

7 REFERENCES

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

7.2 [21 CFR 50.20](#)

7.3 [21 CFR 50.25](#)

7.4 [21 CFR 50.27\(b\)\(2\)](#)

7.5 [45 CFR 46.116](#)

7.6 [45 CFR 46.117\(b\)\(2\)](#)

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](#)