**Human Subject Protection Program**
**Investigator Guidance**
**June 3, 2020**

# OBTAINING AND DOCUMENTING INFORMED CONSENT AND ASSENT



## Introduction

This guidance document provides information about obtaining and documenting informed consent for research participants who are children, adults unable to consent for themselves, and adults able to consent for themselves.

- **Children:** Consent (permission) and child assent (in most cases) is required to participate in research. Refer to the CHLA investigator guidance, Research Involving Children, for more details.

- **Adults Unable to Consent for Themselves:** Consent from a legally authorized representative and assent from the participant (when capable) is required to participate in research. Refer to the CHLA investigator guidance, Consent from Adults that Require a Legally Authorized Representative, for more details.

- **Adults Able to Consent for Themselves:** Consent is required to participate in research.

## Informed Consent Fundamentals

- Investigators are required to obtain the legally effective informed consent of each participant and/or their parent(s)/guardian(s)/representative(s), unless the IRB approves a consent procedure which does not include, or which alters, some or all of the elements of informed consent.

- Obtaining informed consent involves an exchange of information and on-going communication that takes place between the investigator, the potential research participant and/or the parent(s)/guardian(s)/representative(s).

    1. The consent process starts with the initial presentation of a research study (e.g., responding to an advertisement).
    2. The consent process requires documenting that consent was obtained and continues through the research activity until the participant and/or parent(s)/guardian(s)/representative(s) decides to end their participation, or the study closes.

- An effective informed consent process involves these elements:

    1. Conducting the process in a manner and location that ensures participant privacy.
    2. Giving adequate information about the study in language understandable to the participant and/or parent(s)/guardian(s)/representative(s).
    3. Providing adequate opportunity for the participant and/or parent(s)/guardian(s)/representative(s) to consider all options.
    4. Responding to questions from the participant and/or parent(s)/guardian(s)/representative(s).
    5. Ensuring that the participant and/or parent(s)/guardian(s)/representative have comprehended the information provided.
    6. Obtaining the participant and/or parent(s)/guardian(s)/representative(s) voluntary agreement to participate.
    7. Continuing to provide information to the participant and/or parent(s)/guardian(s)/representative(s), as the research requires.

- Obtaining and documenting consent, permission and assent from research participants must include the following procedures:

1. Providing the research participant and/or parent(s)/guardian(s)/representative(s) copies of the consent and assent forms ahead of the consent conference.
2. Holding a consent conference to review the consent and assent forms with a question and answer session about the research.
3. Documenting agreement to participate:
    - Obtaining consent signature(s) from the adult participant or parent(s)/guardian(s)/representative(s).
    - Obtaining assent from children or adults unable to consent but able to assent (may or may not involve a signature).
    - Assuring that the investigator obtaining consent and assent signs the consent form.

- Informed consent must be obtained prior to initiating any research activities, including screening procedures.

## Preparing Informed Consent Documents

- Investigators should use one of the CHLA IRB templates to prepare written consent and assent forms or study information sheets and refer to the CHLA Consent Form Standards and Sample Language guidelines for specific information.

## Using IRB Approved Consent and Assent Forms

- Investigators must always use the most current, IRB approved versions of consent and assent documents for obtaining and documenting informed consent and assent.

- The CHLA IRB or Reviewing IRB reviews and approves all materials to be used as part of the informed consent process, including advertising and recruitment materials, to assure that potential participants will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits of study participation.

- **IMPORTANT NOTE:** Informed consent documents that have been approved by the CHLA IRB or an external Reviewing IRB will include approval and expiration dates, or version approval dates. When informed consent documents are amended or revised, CHLA IRB or external Reviewing IRB approval is required before they can be used.

## Conducting the Informed Consent Conference

Obtaining consent involves explaining the research, assessing comprehension, and using consent and assent documents as a guide for the verbal explanation of the study. Principal Investigators are responsible for assuring that all investigators obtaining consent are qualified and appropriately trained to explain the research and assess participant comprehension.

- **Step 1- Explaining the Research**

Investigators should use these steps for orienting the potential participant and/or parent(s)/guardian(s)/representative(s) to the purpose of the research and why they might wish to participate:

1. Allow sufficient time to read the consent and assent forms in advance of the consent conference.
    - "Sufficient time" can range from minutes to days, depending on how long it reasonably takes to evaluate the procedures, risks, potential benefits, and alternatives to participation.
2. Meet with the participant and/or parent(s)/guardian(s)/representative(s) and explain the study verbally, providing all pertinent information (e.g., purpose, procedures, risks, benefits, alternatives to participation).
3. Allow ample opportunity to ask questions and answer any questions they may have.

- **Step 2 - Assessing Participant Comprehension**

Investigators (not participants) have the responsibility for ensuring that a potential participant understands the research and the risks and benefits involved. Investigators should use these steps to assess participant/parent/guardian/representative understanding:

1. Answer questions but also ask questions to further the discussion and elicit questions from the potential participant/parent(s)/guardian(s)/representative(s). This will prompt them to think more carefully about the study.
2. Assess comprehension using open-ended and non-directive questions. Open-ended questions are those that begin with “who,” "what," "when," "where," “why,” and "how often," or "please describe.”
3. Avoid or limit close-ended questions that ask for “yes” or “no” answers.
4. Based upon the above, decide whether the potential participant/parent(s)/guardian(s)/representative(s) adequately understand the study.

**Examples of open-ended questions:**

- "Describe in your own words the purpose of the study."

- "Would you explain to me what you will have to do if you are in the study?"
- "Would you describe the alternatives to participation in this study?"
- "What more would you like to know about this study?"
- "What is the possible benefit to you if you participate in this study?
- "What are the possible risks?"
- "How long does your participation in this study last?"
- "Why are you eligible to participate in this study?"
- "When does your first study visit happen?"
- "Where will the study take place?"
- "Who do you contact if you have questions or experience side effects?"

**Examples of closed-ended questions:**

- "Do you understand what we are asking you to do?"
- "Do you have any questions for me?"
- "Do you understand that there are some risks to taking this drug?"
- "Do you need any more information to decide whether to participate?"

## Documenting the Informed Consent Conference

In most cases the federal regulations require that informed consent be documented, but they also provide for some important exceptions. In some circumstances, the IRB may approve a waiver of documentation of informed consent.

- Documenting informed consent occurs after explaining the research and assessing participant/parent/guardian/representative comprehension.

- At minimum, it involves obtaining the signature(s) of the participant and/or parent(s)/guardian(s)/representative(s) as well as the person obtaining consent.

- The signature of the person obtaining consent indicates s/he has explained the research to the participant, ensured that the participant and/or parent(s)/guardian(s)/representative(s) understand the research and they freely consent to participate.

- The participant and parent(s)/guardian(s)/representative(s) should always be provided with a copy of the signed and dated consent and assent forms to use as continual reference for items such as procedure risks and/or side effects, questions and for emergency contact information.

**Required Signatures for Documentation of Informed Consent**

1. The parent(s)/guardian(s)/representative(s) and participant (when required by the IRB) must sign and date the consent and assent forms at the time of the consenting process and only after all questions are answered and s/he agree to participate in the study.
    - ☐ Rare exceptions include blind or illiterate participants and participants unable to consent for themselves.
2. The person who has oriented and obtained consent from the participant must also sign and date the consent form. This signature cannot pre-date the participant's signature.

**Witness Signatures:** Witness signatures are required by federal regulations in very limited circumstances and can be required by the IRB to assure an adequate informed consent process for some research studies. **Examples:**

- ☐ An adult participant has decision-making capacity, but cannot read, speak, or is blind.
- ☐ The participant's parent(s)/guardian(s)/representative(s) cannot read, speak or is blind.
- ☐ The participant and/or participant's parent(s)/guardian(s)/representative(s) cannot read, speak or understand English.

The witness must be impartial and cannot be a member of the study team, or a family member of the participant. The witness must sign and date the consent form at the time the consenting process occurs. A signature of the witness means:

- ☐ The requirements for informed consent have been satisfied.
- ☐ Consent is voluntary and freely given by the participant and/or parent(s)/guardian(s)/representative(s).

Refer to the Investigator Guidance document, Consenting Subjects with Limited English Proficiency, for information about interpreters serving as witnesses.

**Other Documents that May Require Review and Signature**

<u>HIPAA Research Authorization</u>

If the IRB requires a HIPAA research authorization the CHLA HIPAA Research Authorization form must also be signed and dated at the time written consent for participation in the study is obtained. The CHLA HIPAA Research Authorization form is available in several languages on the CHLA IRB website.

<u>California Experimental Subject Bill of Rights (ESBOR)</u>

The California Health & Safety Code, Section 24172, describes a "Bill of Rights" that must be provided to all participants of a medical experiment for which there is real or

foreseeable risk of biomedical harm. The ESBOR form is available in several languages on the CHLA IRB website.

## Providing New Information ("Re-Consent") to Research Participants

- Federal regulations require that when applicable significant new findings and information is identified that may relate to a participant's willingness to continue participation, this information is shared with participants.

- When new information becomes available, the investigator must submit an amendment to the IRB describing how new information will be shared with participants and/or parent(s)/guardian(s)/representative(s), and how providing the new information will be documented. New information can be presented in various formats:

  - ☐ Revised consent document
  - ☐ Consent form addendum (template available on the CHLA IRB website)
  - ☐ Memo or other communication to participants and/or parent(s)/guardian(s)/representative(s)
  - ☐ Verbally by phone or in person

- Documentation that the new information was provided should be described in the study research records.

## Alternative (Remote) Consent Conference Procedures

- It may not be possible in some situations to have an in-person discussion of the study with the participant and/or parent(s)/guardian(s)/representative(s), yet the criteria for a waiver of documentation of informed consent cannot be met.

- Alternative (remote) consent conference procedures must be described in the IRB application or protocol document. When approved by the IRB, obtaining and documenting written informed consent in these instances must involve a process as follows:

  - ☐ The potential participant and parent(s)/guardian(s)/representative(s) receive copies of the consent and assent forms in advance of the remote consent conference discussion.
  - ☐ The investigator obtains consent remotely as described above for conducting the informed consent conference.

- ☐ If the potential participant and/or parent(s)/guardian(s)/representative(s) agree to participation, documentation of consent and assent must be achieved as described above (e.g., DocuSign, US mail, scanned document sent by email).
- ☐ Consent and assent forms must be returned to the investigator for counter-signature before any research procedures begin (some exceptions may apply).

- When the research involves the discussion of Protected Health Information, the remote application/platform used must be HIPAA compliant.

- When research is FDA regulated (i.e., clinical investigations of test articles – drug and devices) the remote application/platform used for documenting consent must be 21 CFR Part 11 compliant (Electronic Records). Contact the Sponsor to discuss acceptable remote applications/platforms for obtaining and documenting informed consent and assent.

## Obtaining Informed Consent from Participants Outside of California

- When planning to conduct research outside of California, Investigators are responsible for being aware of the informed consent and HIPAA requirements of other states or countries. This is especially important for research that involves children and/or the use of legally-authorized representatives, as DHHS and FDA regulations rely on local laws for determining who meets their definitions of “children” and “legally-authorized representatives”.