



Human Subject Protection Program  
Investigator Guidance  
April 29, 2020

**Consent from Adults that Require a Legally Authorized Representative**

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**Introduction**

This guidance document provides information about obtaining informed consent for adults unable to consent for themselves. This guidance applies to the following situations:

- Adults who have cognitive impairments such as intellectual disabilities, dementia, or psychosis that are enduring or that may worsen with time.
- Adults whose medical condition may render them temporarily unable to provide informed consent as a consequence of severe pain, confusion, or impaired consciousness due to events such as life-threatening illness or trauma.

Investigators should consider if this guidance applies to their research. This guidance would apply in the following scenarios:

- Research studies that intend to enroll adult subjects who might be unable to consent for themselves.

- Children in research studies who reach the age of majority (per CA Law, i.e., age 18, married, joined the armed forces, legal emancipation) who might be unable to consent for themselves.

If an adult subject is unable to provide consent, consent from a legally authorized representative (surrogate) must be obtained per CA law to participate, or to continue participation in a research study.

## Definitions

- **Assent** means an adult's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- **Capacity to Consent:** The ability of the individual to understand the choices presented, to appreciate the implications of choosing one alternative or another, and to make and communicate a decision (e.g., whether or not to participate in a study).
- **Legally Authorized Representative (LAR):** An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures(s) involved in the research.
- **Surrogate Consent:** The use of an LAR with reasonable knowledge of the research participant described under California law (Health & Safety Code 24178).

## Determining Capacity to Consent

- Whenever possible, investigators should attempt to obtain informed consent directly from the research participant.
- In the event participants may qualify for surrogate consent, the IRB application should specify/describe:
  - Whether the participants may have medical condition may render them temporarily unable to provide informed consent and/or cognitive impairments such as mental retardation, dementia, or psychosis.
  - The criteria for identifying participants who may be unable to consent.
  - Who will conduct the assessment for decisional capacity.
  - The method by which capacity will be evaluated.

- While there are no standardized measures for determining capacity to consent, participants should be assessed on their abilities to understand and to express a reasoned choice concerning the:
  - Nature of the research and the information relevant to participation.
  - Consequences of participation for their own situation, especially concerning their health condition.
  - Alternatives to participation.

### Obtaining Assent from Adults

- Adults participants unable to consent for themselves should be involved in the consent process if they are able to “assent” by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may or may not be able to provide a written assent.
- A research participant who regains the cognitive ability to consent must be re-consented using the standard consenting procedure and offered these options:
  - Remain in the study.
  - Withdraw from the study and allow use of collected data/specimens.
  - Withdraw from the study, including withdrawal of collected data and specimens from further research use. **NOTE:** Data already collected must be retained if the study is FDA regulated.
- Assent is not required from adults who do not have the capacity to assent.

### Identifying a Surrogate Per California Law

California law (Health and Safety Code Sec. 24178) allows surrogate consent for research (medical experiments) that relate to the **cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research participants**. There are two hierarchies of surrogate decision makers for non-emergency and emergency environments.

## **IMPORTANT NOTES:**

- Any questions about the complying with this law and/or identification of the highest priority surrogate should be directed to CHLA legal counsel.
- For research outside California, a determination of who is a legally authorized representative must be made in consultation with CHLA legal counsel.

## **Non-Emergency Room Environment**

In a non-emergency room environment, surrogate consent may be obtained from any of the following potential surrogates who have reasonable knowledge of the participant, in the following descending order of priority:

- The person's agent designated by an advance health care directive
- The conservator or guardian of the person having the authority to make health care decisions for the person
- The spouse of the person
- The domestic partner of the person as defined in Section 297 of the California Family Code
- An adult son or daughter of the person
- A custodial parent of the person
- Any adult brother or sister of the person
- Any adult grandchild of the person
- An available adult relative with the closest degree of kinship to the person

## **IMPORTANT NOTES:**

- When there are two more available persons available to serve as surrogates, the decision of the person with the highest priority, as determined by the list above, takes precedence and cannot be superseded by the consent of a person with lower priority.
- If there are two or more potential surrogates with the same priority and they disagree about participation in the research, then consent for the research cannot be given.

In non-emergency settings, investigators are responsible for ensuring that the surrogate:

- Has reasonable knowledge of the research participant;

- Is familiar with the participant's degree of impairment;
- Is willing to serve as the substitute decision maker;
- Understands the risks, potential benefits, procedures, and available alternatives to research participation;
- Makes decisions based on the research participant's known preferences, and where the preferences are unknown, makes decisions based upon the surrogate's judgment of what the subject's preferences would be.

## **EMERGENCY ROOM ENVIRONMENT**

In an emergency room setting, the order of priority does not apply, nor does the surrogate have to show reasonable knowledge of the research participant. Surrogate consent may be obtained from any of the following:

- The person's agent designated by an advance health care directive
- The conservator or guardian of the person having the authority to make health care decisions for the person
- The spouse of the person
- The domestic partner of the person as defined in Section 297 of the California Family Code
- An adult son or daughter of the person
- A custodial parent of the person
- Any adult brother or sister of the person

### **IMPORTANT NOTE:**

- In an emergency room environment, no surrogate may be utilized if there is a disagreement whether to consent among any available surrogates.

## **Obtaining Consent from the Surrogate**

- Obtaining and documenting surrogate consent must follow the CHLA investigator guidance document, *Obtaining and Documenting Informed Consent and Assent*.
- Potential surrogates should be told the nature of ongoing decisions during the study regarding the subject's participation, decision to participate in certain procedures,

changes to the study, and other aspects of the study to ensure that the surrogate will be willing to undertake these ongoing responsibilities.

- A surrogate's decision making capacity should be assessed only when the investigator has reason to believe that the surrogate's decision-making capacity may be impaired.
- Surrogates are prohibited from receiving any financial compensation for providing consent. This does not prohibit the surrogate from being reimbursed for expenses they may incur related to the surrogate's participation in the research.
- In non-emergency settings: Potential surrogates must be advised that if a higher-ranking surrogate is identified at any time, the investigator will defer to the higher ranking surrogate's decision regarding the subject(s) of higher degree of surrogacy, the investigator is responsible for contacting this person(s) to determine if s/he wants to serve as surrogate.
- In the event a research participant has been initially consented by a surrogate, and a surrogate of higher priority subsequently notifies the investigator of that relationship to the subjects, the investigator must defer to the higher priority surrogate's decision regarding whether the subject will continue to participate or to withdraw from the study. Re-consent would be required.
- In the event that the surrogate dies, a new surrogate must be identified. Re-consent would be required.
- **Consent is an ongoing process.** All applicable criteria that would trigger re-consent of a research participant in any study also applies to participants whose consent has been provided by a surrogate.