

 INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-013 SOP: Legally Authorized Representatives, Children, and Guardians				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	OIA-013	11/9/2023	B. Mooso	G. Firestein	1 of 2

1 PURPOSE

- 1.1 This procedure establishes how to determine whether an individual meets these Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) definitions:
 - 1.1.1 Legally authorized representative
 - 1.1.2 Children
 - 1.1.3 Guardian
- 1.2 This process begins when investigators and/or the study team identify a child or an adult potential human subject who is unable to consent and have determined that a legally authorized representative or guardian is required to enroll the subject into the study.
- 1.3 This process ends when a legally authorized representative or guardian is identified and available and the consent process is begun, or when it is determined that a legally authorized representative or guardian is unable to be identified and/or available and the potential human subject will not be considered for study enrollment.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 REQUIREMENTS

- 3.1 The IRB must have specifically approved the protocol to allow the use of surrogate consent for adults unable to consent or to allow the enrollment of children.
- 3.2 Legally authorized representatives or guardians are not required to be physically present to provide consent; however, they must have appropriate means to conduct the informed consent process according to *OIA-090 SOP: Informed Consent Process for Research* and *OIA-091 SOP: Written Documentation of Consent*. If the study is FDA regulated, any electronic consent method used must be [21 CFR Part 11](#) compliant.
- 3.3 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a legally authorized representative.
 - 3.3.1 When research is conducted in California, legally authorized representatives are defined by California statute¹ and University of California policy.² Investigators must use the “Investigator Certification of Surrogate Decision Makers for Potential Subject’s Participation in University of California Research” in reference 7.6 below to document the legally authorized representative’s information and surrogate decision maker capacity.
 - 3.3.2 For research outside California, a determination of who is a legally authorized representative is to be made with consultation from appropriate institutional counsel. Contact appropriate institutional counsel if there is conflict among legally authorized representatives.
 - 3.3.3 Contact appropriate institutional counsel if the subject is involuntarily committed.
 - 3.3.4 Legally authorized representatives may not be compensated for the subject’s study participation. Legally authorized representatives may receive reimbursement for study related expenses (e.g. travel, parking, etc.).
- 3.4 Unless the IRB has waived the requirement to obtain consent, when research involves children, permission must be obtained from parent(s) or guardian(s).
 - 3.4.1 Consent may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care.³
 - 3.4.2 DHHS and/or FDA’s Subpart D^{4,5} applies to all federally funded, FDA-regulated research involving children.
 - 3.4.3 When research is conducted in California, all individuals under the age of 18 years are children. Exceptions exist for individuals under age 18 years who are emancipated

¹ [California Health and Safety Code 24178](#)

² [University of California Research Guidance Memo Surrogate Consent for Research RPAC-21-01](#)

³ This is the DHHS and FDA definition of guardian.

⁴ [45 CFR 46 Subpart D](#)

⁵ [21 CFR 50 Subpart D](#)

UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-013 SOP: Legally Authorized Representatives, Children, and Guardians				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	OIA-013	11/9/2023	B. Mooso	G. Firestein	2 of 2

minors, managing their own financial affairs, or are undergoing procedures for which parental consent is not ordinarily required (e.g., pregnancy care, sexually transmitted disease (STD)/sexually transmitted infection (STI) care, etc.). Contact appropriate institutional counsel for more information about exceptions that may apply.

- 3.4.4 For research outside California, a determination whether or not a potential human research participant is a child is to be made with consultation from appropriate institutional counsel.
- 3.4.5 Legally authorized representatives and/or guardians may receive compensation when their child participates in a study; however, such compensation should be proportionate with expenses related to the child's participation (e.g. travel, time away from work, and/or childcare) and should not be so significant as to create a sense of coercion or undue influence.

4 RESPONSIBILITIES

- 4.1 Investigators are to follow this procedure when obtaining permission for adults unable to consent or children to take part in research.

5 PROCEDURE

- 5.1 Determine whether a legally authorized representative or guardian is available to conduct the consent process.
 - 5.1.1 If yes, conduct the consent process with the legally authorized representative or guardian according to the IRB-approved study procedures and/or *OIA-090 SOP: Informed Consent Process for Research*.
- 5.2 If a qualified legally authorized representative or guardian is not available, continue to make reasonable efforts to identify an appropriate representative or guardian.
 - 5.2.1 If no qualified legally authorized representative or guardian can be found, do not enroll the adult unable to consent or the child into the study.

6 MATERIALS

- 6.1 *OIA-001 SOP: Definitions*
- 6.2 *OIA-090 SOP: Informed Consent Process for Research*
- 6.3 *OIA-091 SOP: Written Documentation of Consent*

7 REFERENCES

- 7.1 [21 CFR Part 11](#)
- 7.2 [21 CFR 50.3](#)
- 7.3 [45 CFR 46.102](#)
- 7.4 [45 CFR 46.402](#)
- 7.5 [California Health and Safety Code Section 24170-24179.5](#)
- 7.6 [University of California Research Guidance Memo Surrogate Consent for Research RPAC-21-01](#)