



SOP: LARs, Children, and Guardians				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-013	1-8-2020	T. Bechert	J. Ogden	1 of 3

## 1 PURPOSE

- 1.1 This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:
- 1.1.1 Legally Authorized Representative
  - 1.1.2 Children
  - 1.1.3 Guardian

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised “Legally Authorized Guardian” to “Legally Authorized Representative” (1.1.1) consistent with the definition in HRP-001 SOP: Definitions
- 2.2 Added an introductory paragraph (3.1) to describe California law surrogate consent for research.

## 3 POLICY

- 3.1 When research is conducted in California with respect to medical experiments that relate to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research participants, an investigator may obtain surrogate informed consent if the following requirements apply.
- 3.1.1 For purposes of obtaining informed consent required for medical experiments in a non-emergency room environment, if a person is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from a surrogate decision maker with reasonable knowledge of the subject in the following order of importance:
    - 3.1.1.1 The person’s agent pursuant to an advance health care directive
    - 3.1.1.2 The conservator or guardian of the person having the authority to make health care decisions for the person
    - 3.1.1.3 The spouse
    - 3.1.1.4 An individual as defined in section 297 of the California Family Code
    - 3.1.1.5 An adult son or daughter of the person
    - 3.1.1.6 A custodial parent of the person
    - 3.1.1.7 Any adult brother or sister of the person
    - 3.1.1.8 Any adult grandchild of the person
    - 3.1.1.9 An available adult relative with the closest degree of kinship to the person
    - 3.1.1.10 When there are two or more available persons who may give surrogate informed consent and who are in the same order of priority; if any of those persons expresses dissent as to the participation of the person in the medical experiment, consent shall not be considered as having been given. When there are two or more available persons who are in different orders of priority, refusal to consent by a person who is a higher priority surrogate shall not be superseded by the consent of a person who is a lower priority surrogate.
  - 3.1.2 For purposes of obtaining informed consent required for medical experiments in an emergency room environment, if a person is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from a surrogate decision maker who is any of the following persons
    - 3.1.2.1 The person’s agent pursuant to an advance health care directive
    - 3.1.2.2 The conservator or guardian of the person having the authority to make health care decisions for the person
    - 3.1.2.3 The spouse



SOP: LARs, Children, and Guardians				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-013	1-8-2020	T. Bechert	J. Ogden	2 of 3

- 3.1.2.4 An individual as defined in section 297 of the California Family Code
- 3.1.2.5 An adult son or daughter of the person
- 3.1.2.6 A custodial parent of the person
- 3.1.2.7 Any adult brother or sister of the person
- 3.1.2.8 When there are two or more available persons, refusal to consent by one person shall not be superseded by any other of those persons. Surrogate decision makers shall exercise substituted judgment, and base decisions about participation in accordance with the person's individual health care instructions, if any and other wishes to the extent known to the surrogate decision maker. Otherwise, the surrogate decision maker shall make the decision in accordance with the person's best interests
- 3.1.3 The use of surrogate informed consent for adults unable to consent is limited only to research that meets the definition of "medical experiment" under the California Health and Safety Code. "Medical Experiment" research conducted in California will require the distribution of the Experimental Subject's Bill of Rights at the consent conference.
  - 3.1.3.1 For research that does not meet the definition of "medical experiment" and for which no waiver of consent is granted by the IRB, adults unable to consent may not be enrolled unless they have a court appointed guardian a court-issued letter indicating the guardian has the authority to make decisions regarding research participation.
- 3.1.4 Subject to certain restrictions, a legally appointed guardian (a person whose court-issued letter includes the authority to consent on behalf of the child to general medical care of a child) meets this definition. This legally appointed guardian supersedes all other surrogates for the purposes of research consent.
- 3.1.5 For research outside California, a determination of who is a legally authorized representative is to be made with consultation from legal counsel.
- 3.2 DHHS and FDA's Subpart D applies to all research involving children.
  - 3.2.1 When research is conducted in California all individuals under the age of 18 years are children with exceptions such as emancipated and self-sufficient minors and in certain treatment circumstances.
    - 3.2.1.1 Emancipated minors may give consent to participate in any type of research even if the research does not involve treatment. To be emancipated...the minor must meet one of the following requirements
      - 3.2.1.1.1 Have entered into a valid marriage (whether or not it has been dissolved)
      - 3.2.1.1.2 Be on active duty with the armed forces
      - 3.2.1.1.3 Have received a court declaration of emancipation
    - 3.2.1.2 California statutes authorize certain un-emancipated minors to consent to research involving specific types of medical treatment. These types of treatment include:
      - 3.2.1.2.1 Outpatient mental health treatment
      - 3.2.1.2.2 Prevention/treatment of pregnancy
      - 3.2.1.2.3 Medical care related to diagnosis/treatment of a communicable reportable disease or condition
        - 3.2.1.2.3.1 This includes care involving the diagnosis, prevention or treatment of a sexually transmitted disease (for subjects age 12 and older)
      - 3.2.1.2.4 Care for rape
      - 3.2.1.2.5 Care for sexual assault



SOP: LARs, Children, and Guardians				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-013	1-8-2020	T. Bechert	J. Ogden	3 of 3

- 3.2.1.2.6 Care for alcohol or drug abuse
- 3.2.1.3 Another category includes “minors living separate and apart”. These individuals may consent to research involving medical or dental care if they are
  - 3.2.1.3.1 Age 15 or older
  - 3.2.1.3.2 Living separately and apart from his/her parent/guardian and regardless of the duration of the separate residence
  - 3.2.1.3.3 Managing their own financial affairs, regardless of the source of the minor’s income
- 3.2.2 For research outside California, a determination of who is a child is to be made with consultation from legal counsel.
- 3.3 Unless the IRB has waived the requirement to obtain consent, when research involves children 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<sup>1</sup>. Before obtaining permission from an individual who is not a parent, contact legal counsel.
- 3.4 With respect to medical experiments that relate to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research participants, investigators may obtain surrogate informed consent if the following requirements apply:
  - 3.4.1 When subjects have a disease or condition for which the procedures involved in the research hold out a prospect of direct benefit to the individual subject that is unavailable outside the research context.
  - 3.4.2 When the objectives of the trial cannot be met by means of study of subjects who can give consent personally.

**4 RESPONSIBILITIES**

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

**5 PROCEDURE**

- 5.1 None

**6 MATERIALS**

- 6.1 None

**7 REFERENCES**

- 7.1 45 CFR §46.102, 45 CFR §46.402
- 7.2 21 CFR §50.3

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<sup>1</sup> This is the DHHS and FDA definition of “guardian”