SOP: LARs, Children, and Guardians

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 (LAR)

1.1.2. Children

1.1.3. Guardian

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a LAR.

3.1.1. When research is conducted in California the following individuals meet this definition:

3.1.1.1. A “legally authorized representative” means "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 procedure(s) involved in the research."

3.1.1.2. In California, individuals under the age of 18 years old are considered minors. Because in California some people under 18 years of age can consent for themselves to some research procedures, not all “minors” meet the federal criteria for being “children.”

3.1.1.3. California Health & Safety Code § 24178 identifies the individuals who are legally authorized in California to provide surrogate consent for research.

3.1.1.4. For purposes of obtaining informed consent required for medical experiments i*n 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 SDM with reasonable knowledge of the subject, who shall include any of the following persons, in the following descending order of priority:

3.1.1.4.1. The agent named in the potential research participant’s advance health care directive. The conservator or guardian of the potential research participant, with authority to make healthcare decisions for the potential participant.

3.1.1.4.2. The spouse of the potential research participant.

3.1.1.4.3. The registered domestic partner of the potential research participant as defined in Section 297 of the Family Code.

3.1.1.4.4. An adult child of the potential research participant.

3.1.1.4.5. A custodial parent of the potential research participant.

3.1.1.4.6. An adult sibling of the potential research participant.

3.1.1.4.7. An adult grandchild of the potential research participant.

3.1.1.4.8. An available adult relative with the closest degree of kinship to the potential research participant, whose relationship to the potential participant does not fall within one of the above listed categories (e.g., aunt; uncle; cousin; etc.).

3.1.1.4.9. The investigator is responsible for making a reasonable effort to determine if that individual is available to serve as surrogate. 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 participation in the research. When there are two or more available persons who may provide surrogate consent and who are in the same order of priority (e.g., an adult son and daughter of the potential participant), if any of those persons in the same order of priority expresses dissent as to the participation of the person in the medical experiment, consent shall not be considered as having been given.

3.1.1.5. 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 SDM who is any of the following persons:

3.1.1.5.1. The agent named in the potential research participant's advance health care directive.

3.1.1.5.2. The conservator or guardian of the potential research participant, with authority to make health care decisions for the potential participant.

3.1.1.5.3. The spouse of the potential research participant.

3.1.1.5.4. The registered domestic partner of the potential research participant as defined in Section 297 of the Family Code.

3.1.1.5.5. The adult child of the potential research participant.

3.1.1.5.6. A custodial parent of the potential research participant.

3.1.1.5.7. An adult sibling of the potential research participant.

3.1.1.5.8. In emergency room research settings, no surrogate consent may be utilized if there is a disagreement whether to consent among any available surrogates.

3.1.1.5.9. SDMs described in this section 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 SDM. Otherwise, the SDMs shall make the decision in accordance with the person's best interests. In determining the person's best interests, the SDM shall consider the person's personal values and his or her best estimation of what the person would have chosen if he or she were capable of making a decision per Cal. Health & Safety Code § 24178(g).

3.1.1.5.10. A surrogate decision-maker is prohibited from receiving financial compensation for providing consent per Cal. Health & Safety Code § 24178(i).

3.1.1.5.11. Section 3.1.1.4. and 3.1.1.5. above do not apply to any of the following persons, except as otherwise provided by law:

3.1.1.5.11.1. Persons who lack the capacity to give informed consent and who are involuntarily committed pursuant the California Welfare and Institutions Code § 5000 *et seq*; or

3.1.1.5.11.2. Persons who lack the capacity to give informed consent and who have been voluntarily admitted or have been admitted upon the request of a conservator pursuant to Chapter 1 (commencing with Section 6000) of Part 1 of Division 6 of the California Welfare and Institutions Code.

3.1.1.6. Required Documentation. In all cases involving adult patients who are incompetent or lacks decision-making capacity for healthcare decisions and consent of a

Surrogate Decision-Maker is utilized, the Principal Investigator, shall document in the medical record:

3.1.1.6.1. The basis for their determination that the individual lacks decision-making capacity;

3.1.1.6.2. The investigator must detail a decision-making capacity assessment which the IRB reviews and approves.

3.1.1.6.3. If the determination that the prospective participant lacks decision making capacity is based on a diagnosis of mental illness, the researcher obtains consultation with a psychiatrist or licensed psychologist.

3.1.1.6.4. The identity of the SDM and the rationale for the selection of the individual as SDM, which shall be documented on the Investigator Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California Research form. A copy of the form should be provided to the SDM. In addition, the researcher must keep the original, signed form in the research records with the signed informed consent document.

3.2. For research outside California, a determination of who is a LAR is to be made with consultation from legal counsel.

3.3. DHHS and FDA's Subpart D applies to all research involving children.

3.3.1. When research is conducted in California all individuals under the age of 18 years are children. Exceptions exist for minors as follows.

3.3.2. Minors may consent for themselves to medical care related to the prevention or treatment of pregnancy, but not necessarily to sterilization or abortion [California Family Code Section 6925; Health and Safety Code Section 123450 for abortion].[1]

3.3.2.1. Minors 12 years of age or older have the legal right to consent on their own behalf, for:

3.3.2.1.1. Mental health treatment or counseling on an outpatient basis or residential shelter services (in limited circumstances) [California Family Code Section 6924].

3.3.2.1.2. Medical care related to the diagnosis or treatment of infectious, contagious, or communicable diseases that are required to be reported to the local health officer or a related sexually transmitted disease [California Family Code Section 6926].

3.3.2.1.3. Medical care related to the diagnosis or treatment of the condition and collection of medical evidence about alleged rape or sexual assault [California Family Code Section 6927].

3.3.2.1.4. Medical care and counseling related to the diagnosis and treatment of an alcohol or drug-related problem [California Family Code Section 6929].

3.3.2.2. Self-sufficient minors who are:

3.3.2.2.1. 15 years of age or older;

3.3.2.2.2. living separately from their parents/guardians; and

3.3.2.2.3. managing their own financial affairs have the legal right to consent on their own behalf to medical or dental care [California Family Code 6922].

[1] American Academy of Pediatrics v. Lungren (1997) 16 Cal.4th 307. **A minor may consent to an abortion without parental consent and without court permission.** California Health and Safety Code remains unchanged.

3.3.2.3. Emancipated minors, those who are:
3.3.2.3.1. married or divorced
3.3.2.3.2. on active duty in the U.S. armed forces *or* emancipated by the court; and
3.3.2.3.3. have the legal right to consent on their own behalf to medical, dental, or mental health treatment. They also have extensive other rights to enter into legal and business arrangements, and so can consent to be included in other research (e.g., interviews, surveys) [California Family Code 7000-7143].
3.3.2.4. Capacity to consent depends upon:
3.3.2.4.1. The age, ability, experience, education, training, and degree of maturity and judgment of the minor. A minor between the ages of fourteen (14) and eighteen (18) may have such capacity, but a minor under the age of fourteen (14) would rarely have such capacity;
3.3.2.4.2. The conduct and demeanor at the time consent is to be given;
3.3.2.4.3. The totality of the circumstances;
3.3.2.4.4. The nature of the proposed research procedures and their risks, probable consequences, benefits, and alternatives to the treatment; and
3.3.2.4.5. The minor's ability to appreciate the nature, risks, consequences, benefits, and alternatives of the proposed research procedures.
3.3.3. Contact legal counsel for more information.
3.3.4. For research outside California, a determination of who is a child is to be made with consultation from legal counsel.

3.4. Unless the IRB has waived the requirement to obtain consent, when research involves children consent may only be obtained from biologic or adoptive parents, guardian, an individual legally authorized to consent on behalf of the child to general medical care[i]. Before obtaining permission from an individual who is not a parent, contact legal counsel.

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

[i] DHHS and FDA definition of “guardian.”