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1 PURPOSE

- 1.1 This policy establishes how to determine whether an individual meets these 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 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 legally authorized representative.
 - 3.1.1 When research is conducted in California the following individuals are legally authorized representatives:
 - 3.1.1.1 Individual authorized to make surrogate health care decisions
 - 3.1.1.2 Spouse
 - 3.1.1.3 Domestic partner
 - 3.1.1.4 Adult child
 - 3.1.1.5 Other individuals defined in California Health and Safety Code Section 24170-24179.5¹. Contact legal counsel for more information.
 - 3.1.2 For research outside California, a determination of who is a legally authorized representative is to be made with consultation from legal counsel.
 - 3.1.3 Contact legal counsel if there is conflict among legally authorized representatives.
 - 3.1.4 Contact legal counsel if the subject is involuntarily committed.
 - 3.1.5 Legally authorized representatives may not be compensated.
- 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. Exceptions exist for individuals under age 18 years who are emancipated, managing their own financial affairs, or are undergoing procedures for which parental consent is not ordinarily required. Contact legal counsel for more information.
 - 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 care². 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
- 7.3 California Health and Safety Code Section 24170-24179.5

¹ <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=24001-25000&file=24170-24179.5>

² This is the DHHS and FDA definition of “guardian”