

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 Indiana 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 this order of priority: (1) A spouse; (2) an adult child (or majority of adult children); (3) a parent; (4) an adult sibling (or majority of adult siblings); (5) a grandparent (or majority of grandparents); (6) an adult grandchild (or majority of adult grandchildren); (7) the nearest other adult relative in the next degree of kinship who is not listed above; (8) an adult friend who has maintained regular contact with the individual and is familiar with the individual's activities, health, and religious or moral beliefs; or (9) the individual's religious superior if the individual is a member of a religious order if:

3.1.1.2.1 There is no guardian or other representative

3.1.1.2.2 The guardian or other representative is not reasonably available or declines to act; or

3.1.1.2.3 The existence of the guardian or other representative is unknown to the health care provider; or

3.1.1.3 The following individuals may not provide consent:

3.1.1.3.1 A spouse who is legally separated or has a petition for dissolution, legal separation, or annulment of marriage that is pending in court.

3.1.1.3.2 An individual who is subject to a protective order or other court order to avoid contact with the individual that is unable to make their own decisions.

3.1.1.3.3 An individual who is subject to a pending criminal charge in which the ill individual was the alleged victim.

3.1.2 When research with minors is conducted in Indiana the following individuals meet this definition:

3.1.2.1 A judicially appointed guardian of the person or an appointed representative

3.1.2.2 A parent or individual in loco parentis if:

- 3.1.2.2.1 There is no guardian or other representative as described in section 3.2.1.1
- 3.1.2.2.2 The guardian or other representative is not reasonably available or declines to act; or
- 3.1.2.2.3 The existence of the guardian or representative is unknown to the healthcare provider
- 3.1.2.3 An adult sibling of the minor if:
 - 3.1.2.3.1 There is no guardian or other representative
 - 3.1.2.3.2 A parent or an individual in loco parentis is not reasonably available or declines to act;
 - 3.1.2.3.3 A parent or an individual in loco parentis is unknown to the health care provider
- 3.1.2.4 A grandparent of the minor if:
 - 3.1.2.4.1 There is no guardian or other representative
 - 3.1.2.4.2 A parent, an individual in loco parentis, or an adult sibling is not reasonably available or declines to act
 - 3.1.2.4.3 A parent, individual in loco parentis, or adult sibling in unknown to the healthcare provider
- 3.2 For research outside Indiana, 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 Indiana all individuals under the age of 18 years are children. Exceptions exist for:
 - 3.3.1.1 Emancipated minors who are:
 - 3.3.1.1.1 14 years of age;
 - 3.3.1.1.2 not dependent on a parent for support;
 - 3.3.1.1.3 living apart from the minor's parents or from an individual in loco parentis; and
 - 3.3.1.1.4 managing the minor's own affairs
 - 3.3.1.2 A minor who is or has been married
 - 3.3.1.3 A minor who is in the military service of the United States; or
 - 3.3.1.4 A minor who is authorized to consent to health care by any other statute
 - 3.3.1.5 Voluntary and noncompensatory blood donation where a person is 17 years of age
 - 3.3.1.6 Voluntary and noncompensatory blood donation where a person is 16 years of age and has obtained written permission from his/her parent
 - 3.3.2 Contact legal counsel for more information.
 - 3.3.3 For research outside Indiana, 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 or guardian.
 - 3.4.1 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 AAHRPP elements I.1.G, I-9, II.4.B