1. PURPOSE
   1. This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:
      1. Legally Authorized Representative
      2. Children
      3. Guardian
2. REVISIONS FROM PREVIOUS VERSION
   1. None
3. POLICY
   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.
      1. When research is conducted in Indiana the following individuals meet this definition:
         1. A judicially appointed guardian of the person or an appointed representative;
         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:
            1. There is no guardian or other representative
            2. The guardian or other representative is not reasonably available or declines to act; or
            3. The existence of the guardian or other representative is unknown to the health care provider; or
         3. The following individuals may not provide consent:
            1. A spouse who is legally separated or has a petition for dissolution, legal separation, or annulment of marriage that is pending in court.
            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. An individual who is subject to a pending criminal charge in which the ill individual was the alleged victim.
      2. When research with minors is conducted in Indiana the following individuals meet this definition:
         1. A judicially appointed guardian of the person or an appointed representative
         2. A parent or individual in loco parentis if:
            1. There is no guardian or other representative as described in section 3.2.1.1
            2. The guardian or other representative is not reasonably available or declines to act; or
            3. The existence of the guardian or representative is unknown to the healthcare provider
         3. An adult sibling of the minor if:
            1. There is no guardian or other representative
            2. A parent or an individual in loco parentis is not reasonably available or declines to act;
            3. A parent or an individual in loco parentis is unknown to the health care provider
         4. A grandparent of the minor if:
            1. There is no guardian or other representative
            2. A parent, an individual in loco parentis, or an adult sibling is not reasonably available or declines to act
            3. A parent, individual in loco parentis, or adult sibling in unknown to the healthcare provider
      3. For research outside Indiana, a determination of who is a Legally Authorized Representative is to be made with consultation from legal counsel.
   2. DHHS and FDA’s Subpart D applies to all research involving children.
      1. When research is conducted in Indiana all individuals under the age of 18 years are children. Exceptions exist for:
         1. Emancipated minors who are:
            1. 14 years of age;
            2. not dependent on a parent for support;
            3. living apart from the minor’s parents or from an individual in loco parentis; and
            4. managing the minor’s own affairs
         2. A minor who is or has been married
         3. A minor who is in the military service of the United States; or
         4. A minor who is authorized to consent to health care by any other statute
         5. Voluntary and noncompensatory blood donation where a person is 17 years of age
         6. Voluntary and noncompensatory blood donation where a person is 16 years of age and has obtained written permission from his/her parent

Contact legal counsel for more information.

* + 1. For research outside Indiana, a determination of who is a child is to be made with consultation from legal counsel.
  1. 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[[1]](#footnote-1).

1. RESPONSIBILITIES
   1. Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.
2. PROCEDURE
   1. None
3. MATERIALS
   1. None
4. REFERENCES
   1. 45 CFR §46.102, 45 CFR §46.402
   2. 21 CFR §50.3
   3. IC-16-36-1

1. This is the DHHS and FDA definition of “guardian” [↑](#footnote-ref-1)