HRP-013 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

**SOP: LARs, Children, and Guardians**

1. **PURPOSE**
   1. This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:
      1. Legally Authorized Representative (LAR)
      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 minors or adults unable to consent, permission must be obtained from a LAR.
      1. When research is conducted in the Commonwealth of Virginia, the list below indicates the individuals who may serve as LAR , in the specified decreasing order of priority:
4. the parent or parents having custody of a prospective subject of human research who is a minor;
5. the agent appointed under an advance directive as defined in § 54.1-2982 of the Code of Virginia, executed by the person who is the prospective subject of human research, provided the advance directive authorizes the agent to make decisions regarding the person's participation in human research;
6. the legal guardian of a prospective subject of human research;
7. the spouse of a prospective subject of human research, except where a suit for divorce has been filed and the divorce decree is not yet final;
8. an adult child of a prospective subject of human research;
9. a parent of a prospective subject of human research when the individual is an adult;
10. an adult brother or sister of a prospective subject of human research; or
11. any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject of human research to such person's participation in the particular human research. [[1]](#footnote-1)
    * + 1. Attorney-in-fact. Any person authorized by law or regulation, including appointment under a durable power of attorney, to consent on behalf of a prospective subject to that subject's participation in human research. The attorney-in-fact shall not be employed by the person, institution or agency conducting the human research. No official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.[[2]](#footnote-2)
      1. Additional Considerations.[[3]](#footnote-3)
         1. If two or more persons who qualify as legally authorized representatives and have equal decision-making priority inform the Principal Investigator (PI) or attending physician that they disagree (with each other) as to participation of the prospective subject in human research, the subject shall not be enrolled in the human research that is the subject of the consent.
         2. In the case of persons suffering from organic brain diseases causing progressive deterioration of cognition for which there is no known cure or medically accepted treatment, the implementation of experimental courses of therapeutic treatment to which a legally authorized representative has given informed consent shall not constitute the use of force, unless prior knowledge of participant refusal is known.
      2. Legally emancipated minors (with legal documentation to verify such status) are permitted to make all decisions concerning research participation as would someone 18 and older who is also decisionally-capable. Contact legal counsel for more information.
      3. For research conducted outside Virginia, consult legal counsel to determine who is a LAR. Determinations regarding who can serve as a LAR are based on the law of the jurisdiction in which the research is being conducted.
         1. For studies approved on or after January 21, 2019 (or converted to the new regulations) that are NOT FDA or DoJ regulated, the 2018 Common Rule includes the following additional language regarding LARs: “If there is no applicable law addressing the issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research.”
    1. DHHS and FDA’s Subpart D applies to all research involving children.
       1. For research conducted in Virginia, individuals under the age of 18 years are children, unless legally emancipated as previously described.
          1. If the research on a specific treatment involves only treatments or procedures for which minors may legally consent to certain treatments, the participants under age 18 would not meet the definition of “children” as defined in 45 CFR 46.402(a). In this situation, participants may provide their own informed consent, and parental permission (or a waiver thereof) is not needed[[4]](#footnote-4).
          2. If a proposed activity includes any intervention or interaction, apart from those specific treatments, for which the subject has not yet reached the legal age of consent, that person must be considered a child.
          3. Consult with legal counsel and/or the HRPP if there are questions about the treatments or procedures for which a minor may provide their own consent, or the scope of research activities in a study.
       2. Unless the IRB has waived the requirement to obtain consent, when research involves a child, consent may only be obtained from biologic or adoptive parents or guardian, which is an individual who is authorized under applicable state law to consent on behalf of the child to general medical care[[5]](#footnote-5).
       3. Before obtaining permission from an individual who is not a parent or legal guardian, consult with legal counsel.
       4. For research conducted outside Virginia, consult with legal counsel to determine who is a child.
    2. The IRB must specifically approve the use of a LAR for adults or children in court-appointed or state custody.
12. **RESPONSIBILITIES**
    1. Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.
13. **PROCEDURE**
    1. None
14. **MATERIALS**
    1. None
15. **REFERENCES**
    1. 45 CFR §46.102, 45 CFR §46.402
    2. 21 CFR §50.3
    3. 12VAC5-20-10
    4. VA Code Ann. § 32.1-162.18 (2016)
    5. VA Code § 54.1-2969
    6. AAHRPP elements I.1.G, I-9, II.4.B

1. 12VAC5-20-10. [↑](#footnote-ref-1)
2. 12VAC5-20-10. [↑](#footnote-ref-2)
3. For limitations on LARs in Virginia, see VA Code Ann. § 32.1-162.18 (2016). [↑](#footnote-ref-3)
4. VA Code § 54.1-2969. [↑](#footnote-ref-4)
5. This is the DHHS and FDA definition of “guardian.” [↑](#footnote-ref-5)