

SOP: LARs, Minors, and Guardians

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1 PURPOSE

- 1.1 This policy establishes how to determine which individuals meet the following HHS and FDA definitions:
 - 1.1.1 Legally Authorized Representative (LAR)
 - 1.1.2 Minors
 - 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 an LAR.
 - 3.1.1 When research involving adults unable to consent is conducted in Virginia, the following individuals meet this definition:
 "LAR" means, in the following specified order of priority, (i) the agent appointed under an advance directive, as defined by Virginia law in §54.1-2982, executed by the prospective subject, provided the advance directive authorizes the agent to make decisions regarding the prospective subject's participation in human research, (ii) the legal guardian of a prospective subject, (iii) the spouse of the prospective subject, except where a suit for divorce has been filed and the divorce decree is not yet final, (iv) an adult child of the prospective subject, (v) a parent of the prospective subject when the subject is an adult, (vi) an adult sibling of the prospective subject or, (vii) any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research. Any person authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research shall include an attorney-in-fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. 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 an LAR."
 - 3.1.2 For research outside Virginia, a determination of who is an LAR is to be made with consultation from legal counsel.
- 3.2 HHS and FDA's Subpart D applies to all research involving minors.
 - 3.2.1 When research is conducted in Virginia, an unemancipated individual below the age of 18 is considered a 'minor' for research purposes and must have a parent(s) or a legal guardian (either of which are considered an LAR in Virginia) give permission for participation in research. The minor provides assent according to his or her capabilities. For minors the LAR is generally the parent or parents having custody of a perspective subject who is a minor. In cases where the minor is under court-appointed or state custody, an LAR, who is not the parent or legal guardian, provides permission on behalf of the minor.
 - 3.2.2 Minors are not required to have an LAR if they are emancipated minors. Definitions of emancipated minors include: 1) declared to be emancipated by a court; OR any of the following: 2) self-supporting and/or not living at home; 3) married; 4) pregnant or a parent; 5) in the military. Contact Virginia Tech legal counsel for more information.
 - 3.2.3 For research conducted outside of Virginia, a determination of who is a minor is to be made with consultation from Virginia Tech legal counsel.
- 3.3 Unless the IRB has waived the requirement to obtain consent, when research involves minors consent may only be obtained from biologic or adoptive parents or an individual legally



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authorized to consent on behalf of the minor to general medical care¹. Before obtaining permission from an individual who is not a parent, contact Virginia Tech legal counsel.

4 RESPONSIBILITIES

- 4.1 Investigators are to follow this policy when obtaining permission for adults unable to consent or minors 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 Code of Virginia § 54.1-2982

¹ This is the HHS and FDA definition of “guardian”