

SOP: LARs, Children, and Guardians				
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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 Contact Legal Services if there is any question about LAR.

3.2 DHHS and FDA's Subpart D applies to all research involving children.

3.2.1 When research is conducted in Ohio all individuals under the age of 18 years are normally considered children, unable to provide consent.

3.2.2 For research outside Ohio, a determination of who is a child is to be made with consultation from Legal Services.

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 care¹. Before obtaining permission from an individual who is not a parent or LAR, contact Legal Services.

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

REVISION HISTORY:

12/26/18: Revised 3.2.1 with J. Jarosch comments.

¹ This is the DHHS and FDA definition of "guardian"