



HRP-013 | 12/4/2024

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

1.2 None

3 POLICY

1.3 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a LAR.

1.3.1 When research is conducted in Massachusetts the following individuals meet this definition:

3.1.1.1 For medical research and "minimal risk" (as defined under the applicable regulations) non- medical research:

1.3.1.1.1 Health care agent. Massachusetts law provides for proxy consent for medical decisions to be given on behalf of an individual who does not have the capacity to consent. The law allows a competent adult to appoint a designated person as his or her "health care agent." M.G.L. c. 201D. If the person then becomes incapacitated, and is in need of medical care, the health care proxy becomes empowered to make medical decisions on his or her behalf. If no health care agent has been appointed in advance, then medical care providers are authorized by the law to accept consent from "responsible parties," under common law principles, usually meaning the individual's next-of-kin. M.G.L. c. 201D, §16. It is generally accepted in Massachusetts that if research involves the provision of medical care, a health care agent, whether appointed or holding that status by virtue of being a "responsible party," may consent to that treatment and to the accompanying research.

1.3.1.1.2 Guardian. Under Massachusetts law, a guardian is an individual, organization or agency, if any, that has been appointed legal guardian of the person found to be incompetent by a court of competent jurisdiction.

1.3.2 For research outside Massachusetts, a determination of who is a LAR is to be made with consultation from legal counsel.

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

1.4.1 When research is conducted in Massachusetts all individuals under the age of 18 years are children. Exceptions exist for:

1.4.1.1 Emancipated minors, defined as individuals who meet one of the following criteria:

- 1.4.1.1.1 Married/widowed/divorced individual;
- 1.4.1.1.2 A parent;
- 1.4.1.1.3 A member of the armed forces;
- 1.4.1.1.4 An individual living apart from parents and managing his or her own finances; or
- 1.4.1.1.5 A female who is pregnant or believes herself to be pregnant, unless the procedures involved in the research include abortion as described in 3.2.3 below.

1.4.2 Individuals under the age of 18 when the research procedures are limited to:

- 1.4.2.1 Diseases dangerous to the public health;
- 1.4.2.2 Drug dependency (other than alcohol dependency)
- 1.4.2.3 Pregnancy, unless the procedures involved in the research include abortion as described in 3.2.3 below.

1.4.3 Exception: If the research procedures involve abortion, a female under the age of 18 who is not and has never been married meets the definition of children.

1.4.4 Contact legal counsel for more information.

1.4.5 For research outside **Massachusetts**, a determination of who is a child is to be made with consultation from legal counsel.

1.5 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.

Under Massachusetts law, a child's guardian is an individual, organization or agency, if any, that has been appointed through a court process as legal guardian for that child. For research outside Massachusetts, a determination of who meets the definition of guardian for a child is to be made with consultation from legal counsel.

4 RESPONSIBILITIES

1.6 Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.

5 PROCEDURE

1.7 None

6 MATERIALS

1.8 None

7 REFERENCES

1.9 45 CFR §46.102, 45 CFR §46.402

1.10 21 CFR §50.3

1.11 AAHRPP elements I.1.G, I-9, II.4.B