Harvard University Area

SOP: Legally Authorized Representatives, 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 See HRPP Toolkit Tracking Spreadsheet

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 Legally Authorized Representative (LAR).

3.1.1 When research is conducted in Massachusetts, the following individuals meet these definitions:

For research that involves medical treatment:

3.1.1.1 A "health care agent" as defined in M.G. L. c. 201D. with authority to make health care decisions pursuant to a health care proxy; or

3.1.1.2 In instances in which no health care proxy has been executed, a "responsible party" designated by a health care provider under common law principles.

3.1.1.3 A "guardian" as defined in M.G.L. c. 190B § 5-101; however, the health care decision of a health care agent takes precedence over that of a guardian.

For minimal risk non-medical research:

3.1.1.4 A "guardian" as defined in M.G.L. c. 190B, § 5-101. ("a person who has qualified as a guardian of a minor or incapacitated person pursuant to court appointment and includes a limited guardian, special guardian and temporary guardian, but excludes one who is merely a guardian ad litum.")

3.1.1.5 In light of existing statutory and case law, it is unclear whether the IRB may approve a study that involves consent by a LAR for an incapacitated adult to participate in non-medical research in Massachusetts that presents more than minimal risk. For all such determinations, before approving the study, the IRB should consult with legal counsel to determine that the individuals proposed to serve as LAR meet the federal definition of "Legally Authorized Representative."

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

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

3.2.1 When research is conducted in Massachusetts, all individuals under the age of 18 years are children. Massachusetts law recognizes two instances when teenagers under the age of 18 may have the legal capacity to consent to medical treatment. These are the emancipated minor and mature minor rules. Note that these rules concern individuals in their capacity as patients, not as subjects in research, and also that they apply only to persons in Massachusetts. Contact legal counsel for more information.

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

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 care[1]. Before obtaining permission from an individual who is not a parent, contact legal counsel.

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

3.4 Massachusetts Uniform Statutory Will Act (the "Will Act") and Parents or Guardians of Minor Children

3.4.1 In general, and as more fully explained below, parents and guardians may provide consent to participation in research for their minor children or wards. The definition of who is a parent or guardian differs in some respects under federal and Massachusetts laws. The Massachusetts Uniform Statutory Will Act (the "Will Act") indirectly defines "parent" in its definition of "child." See M.G.L. c. 191B, § 1(1). Under this law, the "parent" is the biological or adoptive mother or father of a child. However, a father of a child who is not married to the child's mother may not always be considered a parent; his status would depend on whether he openly treats the child as his offspring or on whether a court has made a paternity determination. Under the Will Act, the term "parent" does not include step-parents who have not formally adopted the child, foster parents, grandparents, or other relatives. In general, the term "guardian" is widely understood to mean a person lawfully invested with the power, and charged with the duty, of taking care of and managing the property and rights of someone who is considered incapable of administering his or her own affairs. This definition includes a person who legally has responsibility for the care and management of the person or estate or both of a child during his or her minority. Parents are usually considered the guardians of their minor children under Massachusetts law. For example, with respect to children, the Department of Mental Retardation defines "guardian" in its regulations concerning research as "a natural or adoptive parent, or the individual or agency with legal guardianship of the person." 115 CMR 10.02.

3.4.2 Legal guardianship in Massachusetts usually is created through a court process, most often through the Probate Court, M.G.L. c. 201 § 2, although parents may designate another adult to be a guardian without having to invoke a court proceeding. This kind of guardian, once appointed, is also referred to as a "standby proxy," whose authority becomes enforceable when the parent dies, becomes incapacitated or is unavailable to care for the child. M.G.L. c. 201 §§ 2B – 2D. The Department of Social Services (DSS) or other state agencies may become the legal guardian of children it takes into custody. The IRB will make a determination based on the risk/benefits to determine whether to accept DSS, or other agency consent for children in their custody.

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