



## SOP: Legally Authorized Representatives, Children, and Guardians

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### 1 PURPOSE

1.1 In the conduct of research with certain human populations, special rules govern the process for securing permissions. This policy establishes which individuals meet the following definitions (under the applicable Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) laws and regulations) for research:

- 1.1.1 Legally authorized representative
- 1.1.2 Children
- 1.1.3 Guardian

### 2 REVISIONS FROM PREVIOUS VERSION

2.1 None

### 3 POLICY

3.1 **Legally authorized representative for research in MA.** Under DHHS and FDA laws and regulations, a "legally authorized representative" is an individual or other party authorized to consent on behalf of a person under the age of legal consent. Unless the Institutional Review Board (IRB) has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a legally authorized representative. When research is conducted in Massachusetts the following individuals meet this definition:

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

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.

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.

3.1.2 For all other research conducted in Massachusetts, the Office of the General Counsel shall be consulted to determine whether or not the individuals proposed to serve as legally authorized representatives meet the Federal definition of "legally authorized representative."

3.2 **Legally authorized representative for research outside MA.** For research conducted outside Massachusetts, the Office of the General Counsel shall be consulted to determine which individuals meet the Federal regulatory definitions (DHHS and FDA) of "legally authorized representative."

3.3 **Children in MA.** Pursuant to applicable Federal laws and regulations (DHHS and FDA), only those persons who are legal adults can consent to treatment or procedures involved in research. When

persons are younger than the age of legal consent, they are deemed "children" and parental permission (biological or adoptive) must be obtained to participate in research. In Massachusetts, all individuals under the age of 18 are "children" with the following exceptions:

3.3.1 Emancipated minors, defined as individuals who meet one of the following criteria, are not "children":

3.3.1.1 married/widowed/divorced individual;

3.3.1.2 a parent;

3.3.1.3 a member of the armed forces;

3.3.1.4 an individual living apart from parents and managing his or her own finances;  
or

3.3.1.5 a female who is pregnant or believes herself to be pregnant, unless the procedures involved in the research include abortion as described in 3.3.3 below.

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

3.3.2.1 Diseases dangerous to the public health;

3.3.2.2 Drug dependency (other than alcohol dependency).

3.3.2.3 Pregnancy, unless the procedures involved in the research include abortion as described in 3.3.3 below.

3.3.3 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."

3.4 **Children outside MA.** For research conducted outside of Massachusetts, the Office of the General Counsel shall be consulted to determine who meets the definition of "children."

3.5 **Guardian.** Consent may also be given by a child's 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 conducted outside of Massachusetts, the Office of the General Counsel shall be consulted to determine who meets the definition of "guardian" for a child.

#### **4 RESPONSIBILITIES**

4.1 Investigators must 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