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| POLICY: Legally Authorized Representatives Children and Guardians | | | |
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1. PURPOSE

1.1. This policy describes the [Organization]'s determination of which individuals are:

- 1.1.1. <Legally Authorized Representatives> (LARs)
- 1.1.2. <Children>
- 1.1.3. <Guardians>

2. POLICY

2.1. When research is conducted in Massachusetts, the following individuals are <Legally Authorized Representatives>:

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

- 2.1.1.1. 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.
- 2.1.1.2. 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.

2.1.2. 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 are considered <Legally Authorized Representatives>."

2.2. For research outside Massachusetts, the Office of the General Counsel determines which individuals are <Legally Authorized Representatives>

2.3. When research is conducted in Massachusetts, individuals under the age of 18 years are <Children> with the exception of:

- 2.3.1. Emancipated minors, defined as individuals who meet one of the following criteria, are not <Children>:
 - 2.3.1.1. married/widowed/divorced individual;
 - 2.3.1.2. a parent;
 - 2.3.1.3. a member of the armed forces;
 - 2.3.1.4. an individual living apart from parents and managing his or her own finances; or
 - 2.3.1.5. a female who is pregnant or believes herself to be pregnant, unless the procedures involved in the research include abortion as described in 2.3.3 below.
- 2.3.2. Individuals under the age of 18 when the research procedures are limited to:

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- 2.3.2.1. Diseases dangerous to the public health;
- 2.3.2.2. Drug dependency (other than alcohol dependency).
- 2.3.2.3. Pregnancy, unless the procedures involved in the research include abortion as described in 2.3.3 below.
- 2.3.3. 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>.
- 2.4. For research outside Massachusetts, the Office of the General Counsel determines which individuals are <Children>.
- 2.5. Individuals who can document that they are legally authorized to consent on behalf of the child to general medical care may serve as a <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. Before obtaining permission for a child to take part in research from someone who is not a parent, contact the Office of the General Counsel.

3. REFERENCES

- 3.1. None