

Legally Authorized Representatives

Clinical research involving human subjects is conducted under the auspices of the Dana-Farber/Harvard Cancer Center in compliance with federal regulations for the protection of human subjects in research. These regulations can be found at 45 CFR Part 46, as well as in Title 21 of the Code of Federal Regulations, which governs research regulated by the Food and Drug Administration. All regulations may be accessed through the website of the Dana-Farber Office for Human Research Studies (OHRS). <http://www.dfhcc.harvard.edu/ohrs/>

Central to conducting research involving human subjects is the requirement for informed consent. The federal regulations require the following: "Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or **the subject's legally authorized representative.**" (45 CFR Part 46.116).

Research conducted in Massachusetts: If an investigator is not able to obtain informed consent from the subject, it is critical that the investigator confirm that the person providing informed consent on behalf of that person is qualified to serve as the subject's legally authorized representative under Massachusetts law. The U.S. Department of Health and Human Services' Office for Human Research Protections has routinely cited institutions for obtaining informed consent from individuals who are not appropriately qualified to act as legally authorized representatives under the applicable state law.

The following is intended as guidance as to who may serve as a legally authorized representative in the Commonwealth of Massachusetts. This OHRS Information Sheet is based upon guidance provided to OHRS by the Office of the General Counsel.

The following is a list of situations in which an individual may make medical decisions on behalf of another individual and thus may serve as a legally authorized representative under Massachusetts law:

- (1) With respect to adult patients, priority among family members is as follows: i) spouse; ii) adult child; iii) parent; iv) sibling; v) other relative; vi) close friend. Such family decisions are not necessarily legally binding; the authority for such decisions is found in Massachusetts case law.
- (2) With respect to children, a parent of a minor child or a person with legal custody of a minor.
- (3) An individual who is making decisions based upon court-appointment as a guardian.
- (4) An individual who is making decisions based upon a signed health-care proxy.
- (5) An individual who is making decisions based upon a durable power of attorney that includes health care directives.

As a general matter, when the subject is a minor (less than 18 years of age), permission (informed consent) must be obtained from the subject's parents(s) or court appointed guardian, both of whom are considered legally authorized representatives. There are exceptions under Massachusetts law:

- a. emergency exception (M.G.L. Chapter 112 §12F)
- b. emancipated minor stature (M.G.L. Chapter 112 §12F)

- c. drug dependent minor (M.G.L. Chapter 112 §12E)
- d. voluntary treatment for mental illness in Department of Mental Health units (M.G.L. Chapter 123 §10)
- e. common law mature minor rule: Baird v. Attorney General, 371 Mass. 741 (1977)

In these specific cases of:

Abortion (M.G.L. Chapter 112 §12S): this statute states that unless a minor is married, widowed, or divorced, she cannot consent for an abortion; but rather, she would need parental or guardian permission in order to obtain legally effective informed consent.

Children under Department of Social Services (DSS) care or custody (110 CMR 11.00): this statute states that the DSS may not provide consent on behalf of children under their care or custody for extraordinary treatments including clinical research. For participation in clinical research, permission must be obtained from the minor's parent or parents as appropriate per federal regulations.

Research conducted outside of Massachusetts: Where research is conducted outside the Commonwealth of Massachusetts, investigators should consult with the Office of the General Counsel for guidance on who may serve as a "legally authorized representative" or "guardian." Investigators should also consult with the Office of the General Counsel for guidance on the definition of "child."