



SOP: Legally Authorized Representatives, Children, and Guardians				
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HRP-013	11/30/18	F. Conte	J. Weinstein, JD, Senior Vice President and General Counsel; M. Jeka, JD; Senior Vice President - University Relations and General Counsel	1 of 2

**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
  - 1.1.2 Children
  - 1.1.3 Guardian

**2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None

**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.
  - 3.1.1 When a participant is determined to be mentally incapacitated to give informed consent, the following individuals may consent to treatment on behalf of the subject, and are to be approached in the order listed below:
    - 3.1.1.1 Adults:
      - 3.1.1.1.1 The health care proxy, upon proper invocation of the health care proxy
      - 3.1.1.1.2 Legally appointed guardian or conservator
      - 3.1.1.1.3 Spouse
      - 3.1.1.1.4 Adult children (majority consensus encouraged)
      - 3.1.1.1.5 The participant’s parent (consensus encouraged)
      - 3.1.1.1.6 Adult siblings (majority consensus encouraged)
    - 3.1.1.2 Minors: In the case of a minor child, less than 18 years of age, consent should be obtained:
      - 3.1.1.2.1 From either the mother or father (consensus encouraged)
      - 3.1.1.2.2 From the parent with legal custody
      - 3.1.1.2.3 From the legally appointed guardian
      - 3.1.1.2.4 If custody or guardianship has not been established, an effort should be made to secure consent from both parents.
    - 3.1.1.3 Exceptions include the following; contact legal counsel for more information:
      - 3.1.1.3.1 Emergency exception (M.G.L. Chapter 112 §12F)
      - 3.1.1.3.2 Emancipated minor stature (M.G.L. Chapter 112 §12F)
      - 3.1.1.3.3 Drug dependent minor (M.G.L. Chapter 112 §12E)
      - 3.1.1.3.4 Voluntary treatment for mental illness in Department of Mental Health units (M.G.L. Chapter 123 §10)
      - 3.1.1.3.5 Common law mature minor rule: Baird v. Attorney General, 371 Mass. 741 (1977)
      - 3.1.1.3.6 Abortion (M.G.L. Chapter 112 §12S)
      - 3.1.1.3.7 Children under Department of Social Services care or custody (110 C MR 11.00)
  - 3.1.2 For research outside the Commonwealth of Massachusetts, a determination of who is a legally authorized representative is to be made with consultation from legal counsel.
- 3.2 DHHS and FDA’s Subpart D applies to all research involving children.



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3.2.1 When research is conducted in the Commonwealth of Massachusetts, all individuals under the age of 18 years are children. Exceptions exist for the following; contact legal counsel for more information:

- 3.2.1.1 Emergency exception (M.G.L. Chapter 112 §12F)
- 3.2.1.2 Emancipated minor stature (M.G.L. Chapter 112 §12F)
- 3.2.1.3 Drug dependent minor (M.G.L. Chapter 112 §12E)
- 3.2.1.4 Voluntary treatment for mental illness in Department of Mental Health units (M.G.L. Chapter 123 §10)
- 3.2.1.5 Common law mature minor rule: Baird v. Attorney General, 371 Mass. 741 (1977)
- 3.2.1.6 Abortion (M.G.L. Chapter 112 §12S)
- 3.2.1.7 Children under Department of Social Services care or custody (110 CMR 11.00)

3.2.2 For research outside the Commonwealth of 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<sup>1</sup>. Before obtaining permission from an individual who is not a parent, contact legal counsel.

**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

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<sup>1</sup> This is the DHHS and FDA definition of “guardian”