



POLICY: Legally Authorized Representatives Children and Guardians			
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1. PURPOSE

1.1. This policy describes Drexel University'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 Pennsylvania the following individuals are **Legally Authorized Representatives**:

2.1.1. If the subject is not a mentally incapacitated individual:

- 2.1.1.1. A health care agent appointed by the subject in a power of attorney;
- 2.1.1.2. A court-appointed guardian authorized to consent to the subject's participation in the protocol in a current court order issued within the subject's jurisdiction;
- 2.1.1.3. Spouse or domestic partner (unless an action for divorce is pending) and adult children of the subject who are not the children of the spouse or domestic partner;
- 2.1.1.4. An adult child;
- 2.1.1.5. Natural or adoptive parent;
- 2.1.1.6. Adult brother or sister.
- 2.1.1.7. An adult grandchild
- 2.1.1.8. An adult who has knowledge of the subject's preferences and values, including, but not limited to, religious and moral beliefs, to assess how the principal would make health care decisions. Unless related by blood, marriage, or adoption, the adult may not be the principal's attending physician or other health care provider nor an owner, operator or employee of a health care provider in which the principal receives care.

2.1.2. If the subject is a mentally incapacitated individual, the only legally authorized representative is a court having jurisdiction over such matters.

2.1.3. If the subject is diagnosed with a mental illness there are no legally authorized representatives.

2.1.4. When there are two or more available legally authorized representatives at the same level of priority, consent shall not be considered as having been given if any of those persons expresses dissent.

2.1.5. When there are two or more LARs with different orders of priority, consent by a lower priority LAR cannot supercede refusal by an LAR of higher priority.

2.1.6. If the LAR is a health care agent pursuant to a power of attorney and a court later determines that the subject is incapacitated, and appoints a guardian to make health care decisions for the LAR, the health care agent is then accountable to the guardian as well as the subject.



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- 2.1.7. LARs may provide authorization for use and disclosure of the subject's Protected Health Information ("PHI") under the Health Insurance Portability & Accountability Act of 1996 ("HIPAA") and its implementing regulations.
- 2.2. For research outside Pennsylvania, legal counsel determines which individuals are **Legally Authorized Representatives**
- 2.3. When research is conducted in Pennsylvania individuals: Under DHHS and FDA regulations "children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Since Pennsylvania law generally requires parental or guardian consent for medical treatment of any individual under the age of eighteen (18) years old, Subpart D of the DHHS must be followed and parental or guardian consent is required except in the following circumstances:
- 2.3.1. A child who:
- 2.3.1.1 Has graduated from high school;
 - 2.3.1.2. Has been married;
 - 2.3.1.3. Has been pregnant; or
 - 2.3.1.4. Suffer from the use of a controlled or harmful substance.
- 2.3.2. A child who is emancipated by court order with regard to medical treatment. Pennsylvania does not have specific statutes or regulations that address emancipation. Emancipation is provided by a court on a cases-by-case basis for a particular purpose (e.g. financial control of assets, marriage, and medical treatment). Each county has developed its own procedures for a minor to petition a court for a judicial decree of emancipation. In the event a child is claiming emancipation for purposes of participating in research, the judicial decree of emancipation should be required and Human Research Protection should be consulted prior to consenting the child.
- 2.3.3. For the following circumstances, Human Research Protection should be consulted prior to submitting the research to the Institutional Review Board.
- 2.3.3.1. Protocols enrolling children 14-17 years of age where the research procedures are limited to mental health examination and treatment.
 - 2.3.3.2. Protocols enrolling children who participate in research where the research procedures are limited to medical and health services to identify and/or treat (i) pregnancy (excluding abortion) or (ii) venereal and other diseases reportable under Pennsylvania Law. A list of reportable diseases can be found on the Pennsylvania Department of Health website.

For research outside Pennsylvania, legal counsel determines which individuals are **Children**.

- 2.4. 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**. Before obtaining permission for a child to take part in research from someone who is not a parent, contact legal counsel.

3. REFERENCES



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- 3.1. [45 CFR §46.102](#)
- 3.2. [21 CFR §50.3](#)
- 3.3. [35 P.S. §§ 10101-10103](#)
- 3.4. [71 P.S. §1690](#)
- 3.5. [5 P.S. § 7103](#)
- 3.6. [18 Pa. C.S.A. § 3201](#)