



SOP: Children and Guardians

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1 PURPOSE

1.1 This policy establishes legal counsel's opinion of which individuals meet the following DHHS and FDA definitions when the research is conducted in Pennsylvania:

- 1.1.1 Children
- 1.1.2 Guardian

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 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:

3.1.1 A child who:

- 3.1.1.1 Has graduated from high school;
- 3.1.1.2 Has been married;
- 3.1.1.3 Has been pregnant; or
- 3.1.1.4 Suffer from the use of a controlled or harmful substance.

3.1.2 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.

3.1.3 For the following circumstances, Human Research Protection should be consulted prior to submitting the research to the Institutional Review Board.

- 3.1.3.1 Protocols enrolling children 14-17 years of age where the research procedures are limited to mental health examination and treatment.
- 3.1.3.2 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.

3.2 For research outside Pennsylvania, a determination of who meets the DHHS and FDA definitions of "children" is to be made with consultation from Human Research Protection.

3.3 Under DHHS and FDA regulations a "guardian" means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. When research involves children and parental permission is required, consent may only be obtained from parents (biologic or adoptive) or a guardian as defined by DHHS and FDA regulations.

4 RESPONSIBILITIES

4.1 Investigators are to follow this policy when determining who should consent with regard to a children taking part in research.

5 PROCEDURE

5.1 None

6 MATERIALS

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6.1 None

7 REFERENCES

7.1 35 P.S. 10101-10105

7.2 45 CFR §46.102, 45 CFR §46.402

7.3 21 CFR §50.3