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 Legally authorized representative
1.1.2 Children
1.1.3 Guardian

2 REVISIONS FROM PREVIOUS VERSION

2.1 Updated logo and date in header, updated listed for legally authorized representatives and clarified position on emancipated minors; replaces version 12/27/12.

3 POLICY

3.1 Under DHHS and FDA regulations a “Legally Authorized Representative” means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. 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.

3.2 Pennsylvania law requires the informed consent of the subject or the subject’s authorized representative before the administration of an experimental medication, the use of an experimental device, or the use of an approved medication or device in an experimental manner. Pennsylvania law authorizes substituted consent to the performance of experimental biomedical or behavioral medical procedure or participation in any biomedical or behavioral experiment by the subject’s court-appointed guardian pursuant to a court order issued after fact finding. Finally, Pennsylvania statutory law further authorizes a person named in the subject’s power of attorney to consent to medical, therapeutic and surgical procedures.

3.3 While Pennsylvania statutory law does not explicitly authorize substituted consent in the absence of a power of attorney or court-appointed guardian, case law strongly supports substituted consent by close family members when subjects lack capacity to make medical decisions. When the subject is unable to give informed consent and has no court-appointed guardian or health care power of attorney, Pennsylvania administrative code allows for the selection of a “health care representative” to make necessary treatment and care decisions.

3.4 The following individuals, in descending order of priority, may be considered Legally Authorized Representatives of the subject and capable of providing surrogate consent for research:

3.4.1 A court-appointed guardian
3.4.2 A health care agent appointed by the subject in a power of attorney
3.4.3 If neither of the above are designated, the investigator may obtain the informed consent of a “healthcare representative” in the order listed below:

3.4.3.1 Spouse (unless an action for divorce is pending)
3.4.3.2 Adult child (18 years of age or older), or if the subject has more than one adult child, a majority of the adult children who are reasonably available for consultation
3.4.3.3 Natural or adoptive parent
3.4.3.4 Adult brother or sister or if the subject has more than one adult sibling, a majority of the adult siblings who are reasonably available for consultation

1 In 28 Pa. Code §103.22
3 In 20 Pa.C.S.A. §5461
3.4.3.5  Adult grandchild or if the subject has more than one adult grandchild, a majority of the adult grandchildren who are reasonably available for consultation

3.4.3.6  Any other available adult relative related through blood or marriage known and documented to have made decisions for the subject in prior health care settings

3.4.3.7  An adult individual with significant personal relationship with the subject to warrant their authority outside the currently accepted legal spousal relationship

3.5  For research outside Pennsylvania, a determination of who meets the DHHS 45 CFR 46 Subpart D, and FDA definitions of “Legally Authorized Representative” is to be made with consultation from legal counsel.

3.6  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. Subpart D of the DHHS must be applied if and only if an individual involved in the research meets this definition. Under Pennsylvania law, persons under the age of eighteen (18) meet this definition of “children”.

3.7  Pennsylvania law does not have an emancipation statute. Instead, each county in the Commonwealth of Pennsylvania has its own procedures for emancipation. A minor can be considered emancipated for one purpose (for example, obtaining birth control) but not for others. Unless a minor has been emancipated by court order, which should be confirmed by requesting a copy of the order, a minor should not be considered emancipated for purposes of consenting to participation in research.

3.8  For research outside Pennsylvania, a determination of who meets the DHHS and FDA definitions of “children” is to be made with consultation from legal counsel.

3.9  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. When research is conducted in any jurisdiction and permission for a child to participate in research is to be obtained from an individual other than biological or adoptive parents, the individual providing such permission must provide written documentation of the legal ability to consent to the child’s general medical care. A copy of this documentation is to be kept with the consent document in the investigator’s files.

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

1  In 28 Pa. Code §103.22


3  In 20 Pa.C.S.A. §5461