



SOP: Legally Authorized Representatives

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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 of legally authorized representative when the research is conducted in Pennsylvania.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

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. When research is conducted in Pennsylvania the following individuals meet this definition in the following order of priority:
 - 3.1.1 If the subject is not a mentally incapacitated individual:
 - 3.1.1.1 A health care agent appointed by the subject in a power of attorney;
 - 3.1.1.2 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;
 - 3.1.1.3 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;
 - 3.1.1.4 An adult child;
 - 3.1.1.5 Natural or adoptive parent;
 - 3.1.1.6 Adult brother or sister.
 - 3.1.1.7 An adult grandchild
 - 3.1.1.8 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.
 - 3.1.2 If the subject is a mentally incapacitated individual, the only legally authorized representative is a court having jurisdiction over such matters.
 - 3.1.3 If the subject is diagnosed with a mental illness there are no legally authorized representatives.
 - 3.1.4 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.
 - 3.1.5 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.
 - 3.1.6 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.
 - 3.1.7 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.
- 3.2 For research outside Pennsylvania, a determination of who meets the DHHS and FDA definitions of "legally authorized representative" is to be made with consultation from legal counsel.



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4 RESPONSIBILITIES

4.1 Investigators are to follow this policy when obtaining permission for adults unable to consent to take part in research.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 None

7 REFERENCES

7.1 45 CFR §46.102

7.2 21 CFR §50.3

7.3 54 Pa. C.S.A. § 54