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 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 individuals that meet this definition are those defined in the Hospital Informed Consent Policy.
   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.
   3.3 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 meet this definition. When research is conducted in Pennsylvania all individuals under the age of 18 years meet this definition without exceptions.
   3.4 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.
   3.5 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