1. PURPOSE
   1. This policy establishes legal council’s opinion of which individuals meet the following DHHS and FDA definitions when the research is conducted in Maryland and other jurisdictions:
      1. Legally authorized representative
      2. Children
      3. Guardian
2. REVISIONS FROM PREVIOUS VERSION
   1. None
3. POLICY
   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.
      1. When research is conducted in Maryland the following individuals meet this definition:
         1. A person who is determined, consistent with the Health Care Determinations Act (HCDA), to have health care decision-making authority for the participant: a health care agent
         2. A guardian of the person who is serving as a surrogate under the HCDA
         3. One of the other surrogates named in the HCDA
         4. A person who holds a specific power of attorney addressing research, if there is not an appointed guardian of the person, or the guardian of the person
      2. When research is conducted in a Veteran’s Administration facility, the following individuals meet this definition in the following order of priority:
         1. Spouse
         2. Child who is 18 years of age or older
         3. Parent
         4. Sibling who is 18 years of age or older
         5. Grandparent
         6. Grandchild who is 18 years of age or older
   2. For research outside Maryland, a determination of who meets the DHHS and FDA definitions of “legally authorized representative” is to be made with consultation from legal counsel.
   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 Maryland all individuals under the age of 18 years meet this definition with the following exceptions:
      1. Emancipated minors when the research involves the minor’s medical treatment or advice. Emancipated minors are individuals under the age of 18 years who meet one of the following criteria:
         1. Married/widowed/divorced
         2. A parent
         3. A member of the armed forces
         4. Living apart from parents and managing his or her own finances
         5. In the case of a female who is pregnant or believes herself to be pregnant, unless the procedures involved in the research include abortion and the individual has not and has never been married
      2. Individuals under the age of 18 years when the research procedures are limited to treatment or advice to the individual concerning one or more of the following:
         1. Drug abuse
         2. Alcoholism
         3. Venereal disease
         4. Pregnancy
         5. Contraception other than sterilization
         6. Injuries due to an alleged assault or rape
      3. Individuals aged 16 or 17 years when the research procedures are limited to diagnosis or treatment to the individual related to a mental or emotional disorder.
   4. For research outside Maryland, a determination of who meets the DHHS and FDA definitions of “children” is to be made with consultation from legal counsel.
   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
   1. Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.
5. PROCEDURE
   1. None
6. MATERIALS
   1. None
7. REFERENCES
   1. 45 CFR §46.102, 45 CFR §46.402
   2. 21 CFR §50.3