1. PURPOSE
   1. This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:
      1. Legally Authorized Representative
      2. Children
      3. Guardian
2. REVISIONS FROM PREVIOUS VERSION
   1. None
3. POLICY
   1. 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 Pennsylvania the following individuals meet this definition (in order of precedence):
         1. Spouse/Common-Law-Spouse[[1]](#footnote-2)
         2. Adult children
         3. Adult grandchildren
         4. Parents
         5. Brothers or sisters
         6. Nephews or nieces
         7. Grandparents
         8. Uncles or aunts
         9. Cousins
         10. Step-Children
         11. Relatives or next-of-kin or previously deceased spouse
         12. Any other relative
      2. For research outside Pennsylvania, a determination of who is a Legally Authorized Representative is to be made with consultation from legal counsel.
   2. DHHS and FDA’s Subpart D applies to all research involving children.
      1. When research is conducted in Pennsylvania all individuals under the age of 18 years are children. Contact legal counsel for more information.
      2. For research outside Pennsylvania, a determination of who is a child is to be made with consultation from legal counsel.
   3. Unless the IRB has waived the requirement to obtain consent, when research involves children consent may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care[[2]](#footnote-3). Before obtaining permission from an individual who is not a parent, contact legal counsel.
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

1. Pennsylvania law does not recognize any Common Law marriage that was contracted after January1, 2005 [↑](#footnote-ref-2)
2. This is the DHHS and FDA definition of “guardian” [↑](#footnote-ref-3)