1. PURPOSE
   1. This policy describes the [Organization]’s determination of which individuals are:
      1. <Legally Authorized Representatives> (LARs)
      2. <Children>
      3. <Guardians>
2. POLICY
   1. An individual is deemed to have capacity when the following conditions exist:
      1. Understands the potential material benefits, risks and alternatives involved in a specific proposed health care decision.
      2. Makes that health care decision on his/her own behalf.
      3. Communicates that health care decision to any other person.
   2. When research is conducted in ­­­­­­­Pennsylvania the following individuals are <Legally Authorized Representatives>:
      1. Agent – An Agent is someone selected by the principal (i.e. patient), when the principal had capacity, in an advance health care directive (i.e. Power of Attorney or Living Will).
      2. Guardian – A Guardian is someone who is appointed by the Court to make decisions on behalf of an incapacitated person. A Guardian will have a Court Order designating them as the Guardian for the person who lacks capacity.
      3. Health Care Representative – A person who is at least 18 years of age can be a health care representative and may make a health care decision for an individual whose attending physician has determined that the individual lacks capacity. Health Care Representatives may be used after determination that there is no guardian appointed by the court, there is no Health Care Power of Attorney or a Health Care Power of Attorney is not reasonably available. Any member of the following classes, in descending order of priority, who is reasonably available, may act as Health Care Representative:
         1. The spouse, unless an action for divorce is pending.
         2. An adult child.
         3. A parent.
         4. An adult brother or sister.
         5. An adult grandchild.
         6. An adult who has knowledge of the patient's preferences and values, including, but not limited to, religious and moral beliefs, to assess how the patient 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.

\*\*An individual with a higher priority who is willing to act as a health care representative may assume the authority to act even if another individual has previously acted on behalf of the patient.

\*\*If those with equal priority are evenly divided concerning the health care, so long as the class remains evenly divided, no decision shall be deemed made until such time as the parties resolve their disagreement. The health care provider is not prohibited by the disagreement from providing health care treatment in accordance with accepted standards of medical practice.

\*\*Regardless of the patient’s mental or physical capacity, a patient may countermand a health care decision made by the health care representative that would withhold or withdraw life-sustaining treatment at any time and in any manner by personally informing the attending physician.

* 1. For research outside ­­­­­­­Pennsylvania legal counsel determines which individuals are <Legally Authorized Representatives>
  2. When research is conducted in ­­­­­­­­­­­­­­Pennsylvania individuals under the age of 18 years are <Children> with the following exceptions, which must be confirmed through consultation with legal counsel:
     1. An individual who:
        1. Has graduated from high school;
        2. Has been married;
        3. Has been pregnant; or
        4. Suffers from the use of a controlled or harmful substance.
        5. Is emancipated by court order with regard to medical treatment. Emancipation is provided by a court on a cases-by-case basis for a particular purpose (e.g. financial control of assets, marriage, and medical treatment). Each county has developed its own procedures for a minor to petition a court for a judicial decree of emancipation. In the event a child is claiming emancipation for purposes of participating in research, the judicial decree of emancipation should be required and Human Research Protection should be consulted prior to consenting the child.
  3. For research outside ­­­­­­­Pennsylvania legal counsel determines which individuals are <Children>.
  4. Individuals who can document that they are legally authorized to consent on behalf of the child may serve as a <Guardian>. Before obtaining permission for a child to take part in research from someone who is not a parent, contact legal counsel.

1. REFERENCES
   1. 45 CFR §46.102, 45 CFR §46.402
   2. 21 CFR §50.3
   3. 35 P.S. 10101-10105
   4. 54 Pa. C.S.A. § 54