1. PURPOSE

1.1. This policy describes legal counsel’s determination of which individuals meet the following DHHS and FDA definitions when the research is conducted in the District of Columbia:

1.1.1. <Legally Authorized Representative> (LAR)
1.1.2. <Children>
1.1.3. <Guardian>

2. POLICY

2.1. 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.

2.1.1. When research is conducted in the District of Columbia, the following individuals may serve as a <Legally Authorized Representatives>:

2.1.1.1. An attorney in fact appointed through a durable power of attorney, unless prohibited from doing so, or

2.1.1.2. A substitute health care decision maker. The following individuals may become substitute health care decision makers to consent to research (with an order of priority under the law):

2.1.1.2.1. The patient’s court-appointed guardian, conservator, or intellectual disability advocate, if consent is within the scope of the court’s order;
2.1.1.2.2. The patient’s spouse or domestic partner;
2.1.1.2.3. The patient’s parent;
2.1.1.2.4. The patient’s adult sibling.

2.1.1.2. For research outside the District of Columbia, a determination of who meets the DHHS and FDA definitions of <legally authorized representative> is to be made with consultation from legal counsel. This consultation will be facilitated by the IRB staff.

2.2. 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 must be applied if and only if an individual involved in the research meet this definition.

2.2.1. When research is conducted in the District of Columbia and Virginia, individuals under the age of 18 years are <Children> with the exception of:

2.2.1.1. Emancipated minors or minors residing apart from his or her parents and managing his or her own personal and financial affairs;
2.2.1.2. Individuals who have entered into a valid marriage, whether or not it has been terminated;
2.2.1.3. Individuals on active duty with any of the United States armed forces.
2.2.2. For research outside the District of Columbia and Virginia, legal counsel determines which individuals are <Children>.

2.3. Unless the IRB has waived the requirement to obtain parental permission, when research involves children, parental permission may only be obtained from biologic or adoptive parents or a <Guardian> who is legally authorized to consent on behalf of the child to general medical care. Before obtaining permission from an individual who is not a parent, contact legal counsel.

3. REFERENCES

3.1. None