VANDERBILT UNIVERSITY

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SOP: LARs, Children, and Guardians

1 PURPOSE

1.1 This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:

1.1.1 Legally Authorized Representative (LAR)

1.1.2 Children

1.1.3 Guardian

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a LAR.

3.1.1 When research is conducted in Tennessee the following individuals meet this definition:

3.1.1.1 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."

3.1.1.2 If there is no applicable law addressing this issue, LAR means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research.

3.1.1.3 In the case of an individual who lacks decision-making capacity, the individual’s legally authorized representative may be designated in order of preference as one of the following:

3.1.1.3.1 Court-appointed Conservator or Guardian of the individual with authority to make health care decisions for the individual;

3.1.1.3.2 Person named in an individual’s power of attorney inclusive of ability to consent to the research, including a Durable Power of Attorney for Health Care (DPAHC) where applicable;

3.1.1.3.3 If the individual does not have a court-appointed guardian or conservator and does not have a person authorized to act under as power of attorney, then both of the following must be true for an alternative adult to serve as the LAR for the individual:

(i) The LAR must be an individual who:

(ii) Has exhibited special care and concern for the individual,

(iii) Is familiar with the individual’s personal values, and

(iv) Is reasonably available to serve as a LAR.

(v) It appears as though the individual can make research-related decisions in accordance with the individual’s instructions, if any,

and other wishes, if known. If the individual has not given instructions, and specific wishes are not known, the LAR can make a determination of the individual's desires or best interests in light of the individual's personal values and beliefs to the extent they are known. This person may include, in order of descending preference, the individual's spouse, adult child, parent, adult sibling, or other adult relative of the, or another adult who satisfies the requirements listed above.

3.1.2 For research outside Tennessee, a determination of who is a LAR is to be made with consultation from legal counsel.

3.2 DHHS and FDA's Subpart D applies to all research involving children.

3.2.1 Children means 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.

3.2.2 When research is conducted in Tennessee all individuals under the age of 18 years are children. Contact legal counsel for more information or to discuss when exceptions might apply.

3.2.3 For research outside Tennessee, a determination of who is a child is to be made with consultation from legal counsel.

3.3 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 guardian.

3.3.1 Parent means a child's biological or adoptive parent.

3.3.2 Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

3.3.3 Before obtaining permission from an individual who is not a parent, contact legal counsel.

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

7.3 AAHRPP elements I.1.G, I-9, II.4.B