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 1/1/21

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 an LAR. [See NJ State Statute 26:14-1 to 14-5 Access to Research Act.]

- 3.1.1 When research is conducted in New Jersey the following individuals meet this definition:
  - 3.1.1.1 Adults
    - 3.1.1.1.1 The guardian of the subject with the authority to make health care decisions;
    - 3.1.1.1.2 The health care representative pursuant to an advance directive for health care;
    - 3.1.1.1.3 The spouse or civil union partner
    - 3.1.1.1.4 A domestic partner;
    - 3.1.1.1.5 An adult son or daughter
    - 3.1.1.1.6 A custodial parent;
    - 3.1.1.1.7 An adult brother or sister
    - 3.1.1.1.8 An adult grandchild; or
    - 3.1.1.1.9 An available adult relative with the closest degree of kinship
  - 3.1.1.2 Minors: In the case of a minor child, less than 18 years of age, consent should be obtained:
    - 3.1.1.2.1 From either the mother or father
    - 3.1.1.2.2 From the legally appointed guardian
- 3.1.2 For research outside New Jersey, a determination of who is an LAR is to be made with consultation from the IRB Office.

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

- 3.2.1 When research is conducted in New Jersey all individuals under the age of 18 years are generally considered to be minors.
- 3.2.2 For research outside New Jersey, a determination of who is a child is to be made with consultation with the IRB office.

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 an individual legally

authorized to consent on behalf of the child to general medical care[1]. Before obtaining permission from an individual who is not a parent, contact the IRB office.

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 7.101 (HRP-417) CHECKLIST: Adults with Impaired Decision-Making Capacity

6.2 7.205 (HRP-416) - WORKSHEET: Children

7 REFERENCES

7.1 45 CFR §46.102, 45 CFR §46.402

7.2 21 CFR §50.3

7.3 New Jersey Title 26 Chapter 14 Access to Medical Research; Sections C.26:14-1 to 26:14-5

[1] This is the DHHS and FDA definition of “guardian”