SOP: Legally Authorized Representatives, Children, and Guardians			
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1 PURPOSE

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

1.1.1 Legally Authorized Representative

1.1.2 Children

1.1.3 Guardian

2 PREVIOUS VERSION

2.1 Revised from previous version dated 01/25/2018

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 Legally Authorized Representative.

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

3.1.1.1 When experimental treatment is being provided to an adult patient who does not have capacity to make her or his own medical decisions, consent may be obtained from the following legally authorized representatives in order of priority:

3.1.1.1.1 The court appointed guardian of the person if that guardian has the right to make healthcare decisions.

3.1.1.1.2 The agent under a Durable Power of Attorney for healthcare.

3.1.1.1.3 A surrogate under the Healthcare Surrogate Act, which includes:

3.1.1.1.3.1 the patient‘s court appointed guardian of the person if that person has the right to make healthcare decisions, the patient‘s spouse, any adult child of the patient;

3.1.1.1.3.2 a parent of the patient;

3.1.1.1.3.3 any adult sibling of the patient;

3.1.1.1.3.4 any adult grandchild of the patient.

3.1.1.2 For other research studies involving adults unable to consent, permission must be sought from the priority list above.

3.1.2 For research outside Illinois, a determination of who is a Legally Authorized Representative is to be made with consultation from the IRB Office.

3.2 DHHS and USFDA’s Subpart D applies to all research involving children.

3.2.1 When research is conducted in Illinois all individuals under the age of 18 years are generally considered to be minors.

3.2.2 For research outside Illinois, a determination of who is a child is to be made with consultation from 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].

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

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

5.1 None.

6 MATERIALS

6.1 CHECKLIST: Children (HRP-416)

6.2 CHECKLIST: Cognitively Impaired Adults (HRP-417)

7 REFERENCES

7.1 45 CFR §46.101(e)-(f), 45 CFR §46.102, 45 CFR §46.402

7.2 21 CFR §50.3, 21 CFR §103(c)

7.3 Illinois Mental Health and Developmental Disabilities Confidentiality Act

7.4 Illinois Health Care Surrogate Act