



## 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 12/01/2020

### 3 POLICY

#### 3.1 Adults:

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 procedure or intervention is part of a study and an adult who has impaired decision-making capacity is the potential participant, then consent must be obtained from the legally authorized representative. The Illinois Healthcare Surrogate Act states that the surrogate includes the following 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 the patient's spouse

- 3.1.1.1.4 any adult child of the patient;

- 3.1.1.1.5 a parent of the patient;

- 3.1.1.1.6 any adult sibling of the patient;

- 3.1.1.1.7 any adult grandchild of the patient.

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- 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, the principal investigator must determine who can serve as the Legally Authorized Representative. The investigator must understand and provide evidence of compliance with applicable regulatory and legal requirements for the conduct of research involving adults who are unable to consent.

- 3.1.3 If the adult with impaired decision-making capacity may regain capacity to understand and provide consent during their participation in the study, then the investigator must include provisions for obtaining legally effective consent from the adult participant for proceeding with their research participation.

#### 3.2 Children:

- 3.3 DHHS and USFDA's Subpart D applies to all research involving children (see exempt categories for exceptions). Minors defined as:

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

- 3.3.2 For research that is conducted outside Illinois and involves a minor, the investigator must understand and submit evidence of compliance to the IRB that all applicable regulatory and legal requirements for research involving a minor are met.



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- 3.4 Unless the IRB has waived the requirement to obtain consent, when research involves children, permission 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<sup>1</sup>.
- 3.5 If the duration of the minor's participation in a research study continues beyond the state of being a minor, the investigator must include provisions for obtaining legally effective consent from the now-adult participants for proceeding with their research participation.

#### 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 CHECKLIST: Children (HRP-416)
- 6.2 CHECKLIST: Adults with Impaired Decision Making Capacity (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

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<sup>1</sup> This is the DHHS and USFDA definition of “guardian”