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1. PURPOSE

1.1. This **policy** describes the University of Georgia’s process for determining who may serve as a legally authorized representative for the purpose of providing **consent** for the participation of the following individuals in **human research**:

- 1.1.1. Adults with diminished capacity to consent; and
- 1.1.2. Unemancipated children.

2. POLICY

2.1. *Adults with Diminished Capacity to Consent*

- 2.1.1. When an adult lacks the capacity to consent, only a legally authorized representative (LAR) for that adult can give consent for participation in research, unless the IRB has waived the requirement to obtain informed consent.
- 2.1.2. Under the DHHS and the FDA regulations, 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.
- 2.1.3. The issue of who can be an LAR is determined by the laws of the jurisdiction in which the research is conducted (e.g., local or state law).
- 2.1.4. For the purposes of these policy and procedures, when research will be conducted in Georgia, a legally authorized representative includes a person appointed as a health care agent under a power of attorney for health care or other appropriate legal document, or a court appointed guardian of the person. In the absence of an appointed individual, then the following may provide consent in the following order of priority:
 - 2.1.4.1. Spouse
 - 2.1.4.2. Any adult offspring for his/her parents;
 - 2.1.4.3. Any parent for his/her adult offspring;
 - 2.1.4.4. Any adult for his/her adult brother or sister;
 - 2.1.4.5. Any grandparent for his/her adult grandchild;
 - 2.1.4.6. Any adult grandchild for his/her grandparent;
 - 2.1.4.7. Any adult niece, nephew, aunt, or uncle related in the first degree; or
 - 2.1.4.8. In the absence of any other person authorized to provide consent herein, the IRB may consider allowing an adult close friend of the prospective subject to provide consent. The UGA IRB defines an "adult close friend" as an adult who has exhibited special care and concern for the subject, who is generally familiar with the subject's views and desires, and who is willing and able to act in the patient's best interest.



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2.1.5. For research outside the state of Georgia, a determination must be made of who meets the DHHS and FDA definitions of an LAR under the law of the site where human research will take place, and the researcher must include this information in the IRB submission. If necessary, the IRB will consult with the legal counsel for assistance.

2.2. *Unemancipated Children*

2.2.1. Under DHHS and FDA regulations, **children** are those unemancipated persons who have not attained the legal age for consent to treatments or procedures involved in the research (or clinical investigations) under the applicable law of the jurisdiction in which the research (or clinical investigation) will be conducted.

2.2.1.1. Under Georgia law, an unemancipated person under the age of 18 years is considered a child. A child is emancipated under Georgia law (and therefore capable of providing his or her own consent) if the child is 16 or 17 years of age and:

2.2.1.1.1. is legally married;

2.2.1.1.2. is on active duty with the U.S. Armed Forces; or

2.2.1.1.3. has obtained an emancipation order from a court.

2.2.1.2. For research outside the State of Georgia, a determination must be made as to who meets the DHHS and FDA definitions of an unemancipated child, and the researcher must include this information in the IRB submission. If necessary, the IRB will consult with legal counsel for assistance.

2.2.2. When research will involve an unemancipated child, a permission must be obtained from the child’s parent or legal guardian, unless the IRB has waived this requirement.

2.2.3. Under DHHS and FDA regulations, a **guardian** means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. When research involves children and permission is required, permission may only be obtained from parents (biological or adoptive) or a guardian as defined by DHHS and FDA regulations.

2.2.4. Georgia law will control research conducted in Georgia. Under Georgia law, a guardian may be appointed by the court; the power of a legally appointed guardian over a child is the same as that of a parent over a child, with the guardian standing in place of the parent, unless the court order appointing the guardian specifically states otherwise.

2.2.5. For research outside the state of Georgia, a determination must be made of who meets the DHHS and FDA definitions of a child under the law of the site where human research will take place, and the researcher must include this information in the IRB submission. If necessary, the IRB will consult with legal counsel for assistance.



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- 2.3. Investigators must follow this policy when determining the legally authorized representative for adults unable to consent for themselves or for children to take part in research.
- 2.4. For research being conducted outside Georgia, specifically in foreign countries, where the research may include adults with diminished capacity to consent and/or children, the researcher must include in the IRB submission information that describes or cites the relevant law or standards regarding LARs and/or verifies the legal age of consent.
- 2.5. The legal counsel will provide advice to assist in resolving any conflicts among applicable laws and regulations relevant to this policy.

3. PROCEDURES

- 3.1. None

4. MATERIALS

- 4.1. None

5. REFERENCES

- 5.1. 45 CFR §46.102, 45 CFR §46.402
- 5.2. 21 CFR §50.3
- 5.3. Policy and Procedure: Informed Consent Process for Research
- 5.4. Policy and Procedures: International Research