

## Human Research Protections Program (HRPP)

### Consent for the Treatment of Minors in Georgia

According to DHHS, children are 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 ([45 CFR 46.402\(a\)](#)).

According to FDA, children means persons who have not attained the legal age for consent to treatments or procedures involved in the clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted. 21 CFR 50.3(o).

Under Georgia law, the following people may consent to medical or surgical treatment for minors under age eighteen. The consent of only one person is required unless specifically requested by the HAC.

1. Any parent for his/her minor child.
2. Any person temporarily standing “*in loco parentis*,” whether formally serving or not, for the minor under his/her care.
3. In the absence of a parent, spouse, legal guardian, or person standing in *loco parentis*; any adult may consent to treatment for his/her minor brother or sister; or a grandparent for his/her minor grandchild.

Exceptions to the above rule are as follows:

1. A minor who is a parent may consent to the treatment of his/her own child.
2. Married minors may consent to treatment for themselves or their spouses.
3. Any female, regardless of her age or marital status, may consent to her own treatment in connection with pregnancy, the prevention of pregnancy, or childbirth.
4. A minor who is or professes to be afflicted with a venereal disease may consent to his own treatment.
5. A minor may consent to his own treatment for drug abuse.

When obtaining informed consent for treatment, physicians should use good judgment and inquire to satisfy themselves that the person purporting to be the guardian or in “*loco parentis*” honestly has that relationship with the minor. Research may require the additional consent of an advocate or other representative of the minor. Each of these instances will be discussed on a case-by-case basis.

Georgia law provides the following protection for good faith efforts to obtain consent for the treatment of minors: “Any person acting in good faith shall be justified in relying on the representations of any person purporting to give consent, including, but not limited to, his identity, his age, his marital status, his emancipation, and his relationship to any other person for whom the consent is purportedly given.” O.C.G.A. Section 31-9-6(c).

### Guardians in Georgia

Under DHHS, the term “guardian” means “an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.” ([45 CFR 46.402](#))

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FDA defines guardian as “an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care when general medical care includes participation in research.” For purposes of subpart D of 21 CFR Part 50, a guardian also means an individual who is authorized to consent on behalf of a child to participate in research. (21 CFR 50.3(s).)

### **Legally Authorized Representatives in Georgia**

HHS regulations at 45 CFR 102(c) define a legally authorized representative as 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.

FDA defines legally authorized representative as 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. 21 CFR 50.3(l).

Legally authorized representatives are to be well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity. They must also be told their obligation is to try to determine what the prospective participant would do if competent, or if the prospective participant’s wishes cannot be determined, what they think is in the incompetent person’s best interest.

A legally authorized representative is an individual or body authorized under applicable law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. For the purposes of this policy and procedure, a legally authorized representative includes not only a person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC), a court appointed guardian of the person, but also next-of-kin in the following order of priority unless otherwise specified by applicable state law:

- Health-care agent
- Legal guardian or special guardian
- Next-of-kin: a close relative of the subject 18 years of age or older, in the following priority:
  - Spouse
  - Adult child (18 years of age or older)
  - Parent
  - Adult sibling (18 years of age or older)
  - Grandparent
  - Adult grandchild (18 years of age or older)
  - Close friend

Consent is to be obtained from the subject or his/her legally authorized representative in circumstances that encourage and preserve the subject's free choice to participate; and the investigator communicates in language that is understandable to the subject.