

HAC Policies and Procedures

Children/Pediatric Research

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Federal regulations [21 CFR Parts 201, 312, 314 and 601 and 45 CFR 46 (OPRR) subpart d .401-409] stipulate that any research involving children or pediatric subjects in any manner must have specific approval for their participation.

What Is The Definition Of A Child?

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. In Georgia, the age of majority is 18. A child under the age of 18 is considered a minor.

Consent for the Treatment of Minors

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).

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Consent and Confidentiality: Treatment of Minors in Reproductive and Other Sexual Matters

Reproductive Issues. As noted above, a female minor may consent to her own medical and surgical treatment in connection with pregnancy, prevention of pregnancy, and childbirth. The law is silent as to the confidentiality of such information. However, implied in the law's authorization of a minor to consent to her own treatment in these matters is the expectation that her treatment information will be kept confidential.

Venereal Disease. Georgia law authorizes a minor to consent to treatment for the following three types of venereal diseases, syphilis, gonorrhea, and chancroid. The Code is silent as to other types of sexually transmitted disease (except AIDS, not addressed here. The Code addresses AIDS separately, with its own provisions for consent to testing, confidentiality, reporting, etc.). However, case law has acknowledged genital herpes as a venereal disease despite its omission from this section of the Georgia Code.

Georgia law provides that a physician may use his/her judgment concerning disclosure of the diagnosis and treatment of a minor's venereal disease to certain persons, as follows:

Upon the advice and direction of a treating physician, or, if more than one, of any one of them, a member of the medical staff of a hospital or public clinic or a physician licensed to practice medicine and surgery **may, but shall not be obligated to, inform the spouse, parent, custodian, or guardian of any such minor as to the treatment given or needed.** Such information may be given to or withheld from the spouse, parent, custodian, or guardian without the consent of the minor patient and even over the express refusal of the minor patient to the providing of such information. [Emphasis added.] O.C.G.A. Section 31-17-7(b).

Mandatory Reporting Law for Child Abuse

Medical personnel having reasonable cause to believe that a child under age eighteen (18) has been abused are legally required to report that abuse. Child abuse means: (A) physical injury or death inflicted upon a child by a parent or caretaker other than by accidental means; provided, however, that physical forms of discipline may be used as long as there is no physical injury to the child; (B) neglect or exploitation of a child by a parent or caretaker thereof; (C) sexual abuse of a child; or (D) sexual exploitation of a child. (The statute further defines sexual abuse and exploitation; Contact the Office of Legal Affairs at (706) 721-4018 with questions.) Such reports should be made orally as soon as possible by telephone, and followed up by a written report to the State of Georgia Department of Human Resources, or, absent such agency, to the police or district attorney.

Sexual abuse as defined in the mandatory reporting law does not include consensual sex acts between minors of the opposite sex, or between a minor and an adult who is not more than five (5) years older than the minor. See O.C.G.A. Section 19-7-5(b) (3.1).

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Good faith immunity protection is provided for those who report child abuse. Conversely, the knowing and willful failure to report a suspected case of child abuse is a misdemeanor crime.

Is a Children's Assent Document Required In Addition To Parental And/Or Legal Guardian Informed Consent Document?

Yes.

May We Label The Children's Assent Document A Student's Assent Document If We Are Working With Children In The School Systems?

Yes.

Can Protocols Involving Children Be Reviewed Using The Expedited Procedure for Initial Review?

Protocols that involve children as research subjects usually require full review for initial review. However, protocols that do not increase any risk to the child may be eligible for expedited review after the initial review. The review level of amendments, advertisements, continuing review, etc. will be determined by the HAC Chairperson or designee.

Who Decides If the Protocol Using Children Can Be Reviewed Via the Expedited Procedure?

The HAC Chairperson or designee determines the level of review.

What About Waiver Of Consent For Pediatric Subjects?

There are specific requirements and exceptions to the consent requirements in these situations and the research team should contact the HAC Administrative Office.

Are There Other Tools Available?

For more information, visit the web link of the American Academy of Pediatrics Policy Statement for the Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations (RE9503) at <http://www.aap.org/policy/00655.html>.

Who Do I Contact if I Have Any Questions?

For additional guidance, contact the HAC Administrative Office at HAC@mcg.edu or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

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(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

Although the above listing indicates the staff's primary PI assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.