

DePaul University IRB Guidance-

Research Involving Pregnant Minors and Children of Minors

Background

Under the federal regulations governing human subject research [45 CFR 46116], except when the consent is waived, an investigator may not involve a subject in a research project without obtaining the legally effective informed consent of that subject or the subject's legally authorized representative. A "legally authorized representative" is an individual or judicial body or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in the research. In other words, the legal guardian may be the biological parent, a court appointed guardian, or a state agency such as the Department of Child and Family Services (DCFS). The applicable law would refer to Illinois state law, if the research is being conducted in Illinois. A researcher should keep in mind that if subjects are being recruited and enrolled in states other than Illinois, the laws of that state would be applicable and may substantially differ from Illinois law. If your research involves the recruitment and enrollment of children in states other than Illinois, contact the Office of the General Counsel for guidance on applicable state law.

Research Involving Minors

Under the federal regulations [45 CFR 46 Subpart D], research involving minors (children as defined by the local law where the research is taking place) must meet additional requirements for IRB approval, as a measure of added protection for minors because they are considered a vulnerable population (i.e., particularly vulnerable to coercion or undue influence, and potentially lacking the decisional capacity to consent for themselves). Under Subpart D, the researcher must obtain permission from the child's legally authorized representative and assent (a child's affirmative agreement to participate in research) from the child. Under Illinois law, the legal age or age of consent (i.e., the age when a person may make a legally binding decision such as entering into contracts or consenting to medical care and treatment) is age 18. The DePaul IRB requires assent for children ages 7-17, so assent is not required for children from 0-6, and at age 18, consent becomes the appropriate procedure.

Illinois law does not directly address when minors can consent to research participation. There are state laws that address consent to medical treatment or therapy, and it is reasoned that if a person can consent to medical treatment or therapy, they can also consent to medical treatment that involves research. In these instances, guidance from the Office of Research Protections (OHRP) indicates that if the research solely involves treatments or procedures for which a minor can give consent outside the research context, then the minors are not considered children under Subpart D and may provide their own informed consent for the research.

Pregnant Minors

Under Illinois law, there is a difference between a mature minor and an emancipated minor.

Mature Minor: "Mature minor" means a person 16 or 17 years old who has demonstrated the ability and capacity to manage his/her own affairs and to live wholly or partially independent of his parents or guardian. This is someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (*e.g.*, consenting to medical care).

Emancipated Minor: "Emancipated Minor" means any minor 16 or 17 years old who has been completely or partially emancipated under the Illinois Emancipation of Minors Act. This is a legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law, but who are entitled to treatment as if they had by virtue of assuming adult responsibilities, such as self-support, marriage or procreation.

Many people mistakenly believe that any minor who is pregnant or who may be working and supporting themselves is an emancipated minor. However, under Illinois law emancipation is a legal status that may be granted by the court if a minor files a petition for emancipation. A minor being legally emancipated may actually be rare in real life. A minor may be considered a mature minor and may be able to provide consent for herself in situations specifically defined by local law, in this case Illinois law. If you intend to conduct research with this population, then you should obtain documentation of the subject's age, and/or legal status to ensure you are meeting state law requirements.

In Illinois, a pregnant minor generally cannot consent for herself, except in the following specific instances.

- A pregnant minor may consent to research where (1) she seeks "medical or surgical treatment"; (2) the research *solely* involves medical or surgical treatment; and (3) the medical or surgical treatment—as well as the research—are performed by (a) a licensed physician, (b) a physician's assistant who was delegated authority by a licensed physician, or (c) an advanced practice nurse with contractual authority from a licensed physician. (See 410 ILCS 210/1-2).
- A pregnant minor may consent to research if she is emancipated (*i.e.*, she is 16 or 17 years old and a court has declared her emancipated). (See 750 ILCS 30/5(a)).
- A pregnant minor may consent to research where (1) she seeks "counseling or treatment" for a sexually transmitted disease, addiction, alcoholism or intoxication, or for a family member who abuses drugs or alcohol; (2) the research *solely* involves the counseling or treatment for the condition, and it does not extend beyond counseling or treatment for the condition; and (3) the pregnant minor is between the ages of 12 and 18. (See 410 ILCS 210/4).

- A pregnant minor may consent to research where (1) she is the victim of criminal sexual assault or abuse; (2) she seeks “medical care or counseling” related to the diagnosis or treatment of any disease or injury arising from the criminal offense; (3) the research *solely* involves medical care or counseling related to the diagnosis or treatment of any disease or injury arising from the criminal offense; and (4) the medical care or counseling—as well as the research—are performed by (a) a hospital, (b) a licensed physician, (c) an advanced practice nurse, (d) a physician assistant, or (e) other medical personnel. (See 410 ILCS 210/3).
- A pregnant minor may consent to research where (1) she seeks birth control services or information; (2) the research *solely* involves the provision of birth control services or information; and (3) the provision of birth control services or information—as well as the research—are performed by a licensed physician. (See 325 ILCS 10/1).

Children of Minor Parents

In the case of the child of a minor parent, generally no one can provide consent under Illinois law to conduct research with the child. The law, however, has two limited exceptions:

- A minor parent may consent to research on his/her child where (1) the minor parent seeks “medical or surgical treatment” for their child; (2) the research *solely* involves medical or surgical treatment on the child; and (3) the medical or surgical treatment—as well as the research—are performed by (a) a licensed physician, (b) a physician’s assistant who was delegated authority by a licensed physician, or (c) an advanced practice nurse with contractual authority from a licensed physician. (See 410 ILCS 210/1-2).
- A minor parent may consent to research on their child if the minor parent is an emancipated minor (i.e., the minor parent is 16 or 17 years old declared emancipated by a court). (See 750 ILCS 30/5(a)).

DePaul IRB Review of Protocols Involving Pregnant Minors or Children of Minors

The DePaul IRB policy is to look at each research protocol individually on a case per case basis and determine which state laws may or may not apply. When possible, a waiver of parental permission may be granted for research protocols. If the research protocol does not qualify for a waiver of parental permission, then the IRB may determine that a pregnant minor or a minor parent might have the capacity or legal authority to provide consent for participation in research under a particular state law.