Informed Consent for Minors in Research Studies

Modified: January 2017

Background:

The Common Rule generally requires informed consent from those who participate in research studies. The Common Rule defines children as 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.

Although Florida law specifically addresses consent for medical treatment, it does not separately address consent for participation in a research study that involves medical treatment. In the absence of specific law or regulations addressing consent for research, UF follows the Florida law for consent to medical treatment when determining legally effective informed consent for research studies under the Common Rule.

Minors who are emancipated may consent to participate in research, and minors who seek certain treatments may consent to participate in research.

Q: What are the ways a minor may be emancipated?

In Florida, minors may be fully emancipated by marriage, even if they later become divorced or widowed, or by court order. Fully emancipated means that the minor may make all decisions some 18 years of age or older may make, including participating in research.

Minors who are unwed and pregnant are emancipated for purposes of consenting to medical or surgical procedures for herself related to her pregnancy. Unwed minor mothers are emancipated for purposes of consenting to medical or surgical procedures for her child. For more information on consenting unwed pregnant minors or unwed minor mothers, see the Guidelines. [Link to guidelines on unwed pregnant minors and unwed minor mothers]

Q: What treatments can a minor consent to?

In Florida, if a minor seeks treatment for the following conditions, the minor has the same capacity as an adult to consent to diagnosis and treatment of those conditions.

1. Voluntary admission to a substance abuse treatment facility
2. Medical examination or treatment for STDs, including HIV

A minor may also consent to donate blood without compensation.

Q: What types of studies may a minor be allowed to consent to participate?

Since minors may consent to certain treatments, when those treatments are in the research context, a minor may be allowed to consent to participate in research studies which offer the prospect of direct benefit to the minor for these particular services or treatments. Minors may also be allowed to consent to participate in research studies which involve no more than minimal risk.
However, approval of a particular study or consent procedure is always under the purview of the individual IRB. Even if a particular consent process were permitted under Florida law, the IRB may not approve it, or may approve it with more restrictive protections.