Research Involving Unwed Minors and Unwed Minor Mothers

Modified: March 2018

Background:

The IRB office is frequently asked whether or not young women who are younger than 18 years of age and pregnant, or those who have recently delivered their babies can sign informed consent that is legally effective for participation in research.

Q: What are the federal requirements for research involving unwed pregnant minors and unwed minor mothers?

The federal regulations do not specifically address research involving unwed pregnant minors or unwed minor mothers; however, under DHHS and FDA regulations “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. Subpart D of the DHHS human research protection regulations must be applied if and only if an individual involved in the research meets this definition.

Q: Can unwed pregnant minors consent to their own participation in research?

Yes, unwed pregnant minors and unwed minor mothers may consent in specific limited circumstances. Florida Law allows unwed pregnant minors to consent “to the performance of medical or surgical care or services relating to her pregnancy.” Thus, unwed minor mothers may consent to research if the medical or surgical services involved in the research relate to her pregnancy. If, however, the medical or surgical care or services involved in the research do not relate to her pregnancy, the natural or adoptive parent or legal custodian must provide consent. In the absence of natural or adoptive parents or a legal custodian, other individuals are permitted under Florida Law to provide consent. Please refer to HRP Policy 021 on Legally Authorized Representatives for those individuals authorized under Florida Law to consent for minors.

Q: Can unwed minor mothers consent to their child’s participation in research?

Florida Law also allows unwed minor mothers to consent to the performance of medical or surgical care or services for her child. Therefore, unwed minor mothers may also consent to their child’s participation in research if it involves medical or surgical care or services for her child.

It is important to note, because the authorization of the minor mother to consent for her child only extends to the performance of medical or surgical care or services for her child, she would not be permitted, under Florida Law, to consent to research conducted under 45 CFR 46.406 and 45 CFR 46.407.

Q: Can the IRB approve a waiver or alteration of informed consent when the research involves unwed pregnant minors or unwed minor mother?
There may be some cases where the IRB can waive or alter the requirement of informed consent under the federal regulations. For such a waiver, the IRB must find and document that:

(1) the research constitutes no more than minimal risk to the subjects;

(2) the waiver or alteration of consent will not adversely affect the rights and welfare of the subject;

(3) the research could not practicably be carried out without the waiver or alteration; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waivers will be considered on a case-by-case basis.