Minors and Pregnancy Testing for Research Purposes Only

Modified: June 2017

Background:

If you are conducting a study which involves menstruating minors, in which a negative pregnancy test is required as part of exclusion criteria, and the pregnancy test is not part of the standard of care for that patient, the minor has the right to consent to that pregnancy test without the knowledge of her parents. The lower age range to require a pregnancy test is not a fixed number, and may be specified in the sponsor’s protocol.

There is no statute regarding this specific consent issue, but rather court cases upholding a minor’s right to privacy, including a right to exercise her constitutional right to make her own reproductive decisions. Based on those court decisions, a minor has a right to privacy as it relates to whether she is pregnant or not, and thus we can only tell the parent if the minor consents to allow that disclosure.

Q: What is the suggested process to ask for consent from a minor in this situation?

- The investigator or approved study staff meet with the female minor in private
- The investigator or approved staff use the “ICF for Pregnancy in Minors” consent form [ICF for Pregnancy Test in Minors for Research Purposes Only](#) as a guide to the discussion.
- The minor is told that she may be qualified for a research study, but in order to determine this, she would have to have a negative pregnancy test.
- The minor is told that she has the right to have a pregnancy test and receive the results without her parents’ knowledge.
- If the minor wants to hear more, then she must agree to and sign the “Consent for Pregnancy Test” form in which she agrees to have a pregnancy test, and also agrees to waive the right to receive the results without her parents’ knowledge.
  - If the minor agrees, and signs the Consent for Pregnancy Test, the proposed study is then presented to the parent(s) and the minor, and the results of the pregnancy test are shared with the minor and her parent(s).
  - If the minor does not agree and does not sign the consent, the conversation ends, the parent(s) are never notified of the potential study.