



POLICY STATEMENT REGARDING PREGNANCY TESTING

04/30/2009

The Duke University Health System (DUHS) Institutional Review Board (IRB) has determined that all females of child-bearing potential being considered for participation in a research study where a possibility of harm to a fetus exists must be found to have a negative pregnancy test before undergoing any study-related activities that might harm the fetus. The test must measure the concentration of human Chorionic Gonadotropin (“hCG”) in human serum that was collected no more than 48 hours before initiation of risky study activities, such as the administration of the study drug or placement of the study device. In certain circumstances, if the 48-hour window for serum pregnancy testing is not practicable for the conduct of the research, the IRB may approve a timeframe greater than 48 hours, provided that the female subject is practicing appropriate contraceptive measures at the time of the pregnancy test (found to be negative) and continuing through the initiation of risky study activities. For example, if the protocol requires a pregnancy test at the initial screening visit in order to document eligibility, but the first dose of study drug will not occur for two weeks, if the female of childbearing potential has been practicing appropriate contraception prior to and during this two week period, a repeat serum pregnancy test would not necessarily be required by the IRB. Note that such a plan must be approved by the IRB at the time of initial protocol review, or while reviewing an amendment specifically requesting such a plan.

If the risky study activity will continue for more than one day, or the consequences of the study activity may cause risk to the fetus beyond that one day, appropriate contraceptive measures must be maintained until all known risks to the fetus have ended.

The pregnancy test must be conducted and analyzed by a College of American Pathologists (“CAP”)-accredited laboratory, not necessarily affiliated with DUHS.

After the initial serum pregnancy test, the IRB may, on a protocol-by-protocol basis, approve the subsequent use of urine pregnancy testing for female subjects who are actively participating in research studies at DUHS and who are maintaining appropriate contraceptive measures.

A urine pregnancy test for a female research subject in lieu of a serum pregnancy test is permitted only with specific approval from the IRB and only if conducted and analyzed by study staff members trained to perform the tests as described in the pregnancy testing policy for MRI directly below.

Pregnancy Testing for Research using MRI without Contrast Enhancement

The IRB will permit urine pregnancy testing for women of childbearing potential who agree to participate in research using Magnetic Resonance Imaging (MRI) without contrast enhancement, using equipment with magnets that are 4 Tesla in strength or less, provided all of the following criteria are met:

- 1) The research must not involve any study procedures or interventions where a possibility of harm to a fetus may occur, other than through the use of the MRI.
- 2) All subjects who are women of child-bearing potential must receive a urine pregnancy test on the day the subject will receive a research MRI without contrast enhancement.
- 3) The urine pregnancy test result must be negative before the MRI examination may proceed.
- 4) If the subject will be asked to have an MRI without contrast enhancement on more than one day, the study protocol must stipulate either the use of effective contraceptive measures during that portion of the study, or additional pregnancy testing must occur each day the subject will be asked to undergo such an MRI.
- 5) The person(s) who will perform the urine pregnancy test must successfully complete training as directed by the Chair of Obstetrics and Gynecology of the Duke University School of Medicine or his/her designee, to include a brief presentation describing detection of human Chorionic Gonadotropin (hCG) in early pregnancy using urine pregnancy tests, and performance by each person of testing using both positive and negative (unknown) samples.
- 6) The urine pregnancy test kits used for the research must be the commercially available test kit(s) specified by the Chair of Obstetrics and Gynecology and in routine use at DUHS.

For research using MRI **with** contrast enhancement, the IRB requires the serum pregnancy testing process as described on page 1 of this policy.

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