Pregnancy Testing in Research Studies
Involving Ionizing and Non-Ionizing Radiation
Guidance for Investigators

Background/Rationale

Special regulatory requirements govern the participation of pregnant women in research [45 CFR 46 Subpart B]. Research involving women who are or may become pregnant receives special attention from the IRB because of women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus.
http://www.hhs.gov/ohrp/irb/irb_chapter6.htm

These guidelines are not intended to be used in studies that are trying to enroll pregnant women or women attempting to become pregnant. This guidance is for research studies in which women of childbearing potential (WOCBP) participate in studies that may **inadvertently** include pregnant women. These guidelines are to assist investigators in **excluding pregnant women** in studies where pregnant women are not to be included in the study.

Definitions

Women of childbearing potential (WOCBP) is defined as any woman or adolescent who has begun menstruation. A post-menopausal woman is defined as a woman who is over the age of 45 and has not had a menstrual period for at least 12 months. The average age at menopause is approximately 51 years; though in approximately 5% of women, menopause occurs after age 55, and for another 5% or women, it may occur between 40 to 45 years (early menopause).

Ionizing radiation includes "plain films," CT scans, fluoroscopy, and administration of radioactive drugs.

Non-ionizing radiation includes MRI scans and ultrasound.

Guidelines

Non-research clinical care that includes WOCBP will conform to clinical guidelines regarding pregnancy testing of WOCBP. For example, the protocol for a research study that includes data from an x-ray that was performed as part of clinical care does not need to address the issue of pregnancy testing. However, if the research involves additional, non-clinical exposure to radiation, then the following guidelines need to be followed:

Asking about pregnancy status for WOCBP

When a woman of childbearing potential will be exposed to **ionizing radiation in a research study,** she should be asked about her pregnancy status, sexual activity, whether pregnancy is

being sought, and contraception. Investigators should document responses to these questions and perform pregnancy testing. It is recommended that in general, investigators adhere to the following specific recommendations, but these are general guidelines; the IRB reviews each protocol individually.

Recommendations for pregnancy testing based on different types of exposures to radiation:

Administration of radioactive drugs: When radioactive drugs are administered to WOCBP, the IRB requires a STAT serum β-hCG (blood pregnancy test) before administration. **A urine pregnancy test will not be acceptable in these circumstances.** Both MGH and BWH clinical chemistry laboratories offer this test 24/7. These tests are most expeditiously performed if samples are hand carried or "tubed" to the laboratories and brought to the attention of technologists in the lab.

Ionizing radiation such as radiography, CTs, fluoroscopy, **or contrast enhanced non-ionizing radiation, e.g., MRI with contrast:** If a WOCBP will be exposed to ionizing radiation or MRI with contrast, a urine pregnancy test prior to the imaging examination is usually sufficient to rule out pregnancy.

Non-ionizing radiation such as standard MRI (8 T or less), no pregnancy test is required if the woman states that she is not pregnant: If the woman thinks she could be pregnant, or her answers to the questions above suggest pregnancy is possible, a urine pregnancy test prior to the imaging examination is usually sufficient to rule out pregnancy.

_____

This guidance was developed with Dr. Ronald Callahan, Chairman, Radiation Safety Committee, MGH.