

Board Member Guidance Series

CONSIDERATIONS FOR PREGNANCY TESTING PRIOR TO RADIATION EXPOSURE FOR RESEARCH PURPOSES

Description

The IRB is responsible for considering the risks of radiation exposure for women who are pregnant and participate in research. The IRB may choose to allow a research study to follow standard of care practices for pregnancy testing when performing medical scans.

University of Utah Department of Radiology Standard of Care for All Scans (including MRI, MR with contrast, CT scans, etc.):

If the female is of reproductive age, the patient is asked to self-report whether she might be pregnant.

- 1. If the woman states she **cannot** be pregnant, the scan is scheduled and performed.
- 2. If the woman indicates **there is doubt** regarding her pregnancy status, two options are offered:
 - a. **The woman may take a pregnancy test**. If positive, she is referred to her primary care physician. If negative, the scan is scheduled and performed.
 - b. The woman may elect to have the scan **re-scheduled** until after she has a period.

We believe these standards represent good guidance for when pregnancy testing should be required in the research setting. While the IRB may require any level of testing deemed reasonable in a given case in order to protect the welfare of participants, we encourage members to use these guidelines whenever applicable when reviewing research.

Points to Address

Board Reviewer Checklist:

- 1. **Criteria for IRB Approval:** Have the risks to pregnant women and fetuses been minimized whenever appropriate by using procedures already being performed on the participants for diagnostic or treatment purposes?
- 2. **Vulnerable Populations**: Have the requirements for including pregnant women and fetuses in research been met?
- 3. **Ancillary Approvals, Radiation Safety**: If applicable, has the RDRC-HUS approved the use of radiation in the research?

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

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