Evaluation Criteria for Fenton Breast Scan Contract

Technical Criteria

1) Provide a Biomedical Research Imaging Center and Radiology Clinical Research Service Center in which all study related procedures are conducted in adherence with ICH Good Clinical Practices and Federal Regulations.
2) Inform the study participants of the process that will be performed
   a) retain identity of all study images and evaluations of breast morphology after collection.
3) Provide Pregnancy test kits that are able to provide results within 30 minutes, to prevent delays in performing the MRI scans for 25 participants.
4) Provide a high contrast MRI breast imager with dedicated breast coils to image the breast morphology, specifically:
   a) recording dense and non-dense areas,
   b) measure fat and total adipose content, and epithelial outgrowth.
   c) image 25 adolescent participants, w/o contrast. Breast MRIs with "T1 weighted" to sequences with and without fat saturation are required to provide strong tissue contrast between adipose and fibroglandular breast tissue with high spatial resolution.
5) Provide a certified radiologist who is able to:
   a) read and interpret MRIs,
   b) have PET imaging expertise,
   c) quantitate three-dimensional (3D) MRI-based assessment of total breast volume, total fibroglandular tissues,
   d) identify fatty vs stromal tissue,
   e) determine breast density using digital breast tomosynthesis, automated whole breast ultrasound, or dedicated 3D-breast computer tomography in adolescent girls.
6) A research coordinator that will be responsible for
   a) patient oversight and management.
   b) Ensure images are processed, identified according to study participant IDs provided and transmitted to NIEHS CRB.
   c) Transmit the images and evaluations to the NIEHS.
7) The ability to repeat analysis twice in 1 year, approximately 6 months apart.

Past Performance

Price