

This form is for research only. Do not use for Standard of Care Imaging

Radiology is a specialty that is at the crossroads of every aspect of clinical diagnosis, treatment and care. Radiology research must comply with CPHS (Committee for the Protection of Human Subjects), HIPAA (Health Insurance Portability and Accountability Act) regulations, as well as follow all related federal, institutional and ethical guidelines. It is important for DII to be aware of imaging being performed for research, to ensure that imaging resources are available and billing occurs appropriately. The attached approval form is required for all research studies that utilize imaging procedures, whether the research is initiated by a DII faculty member or is being conducted by members of other departments, schools, or institutions.

Please obtain approval for all research studies involving the use of Radiology and Medical Physics services (e.g., interpretation, reporting, processing, establishing imaging equipment performance/compliance etc.) that are NOT required for patient care and **are performed for research purposes only**. Any studies that involve the non-routine use of Radiology (e.g., in the assessment of a new implant or device), non-routine imaging methods or new/improved contrast methods also need departmental approval. As with standard of care imaging, all research imaging performed on MHHS imaging equipment needs to be read by a UTHealth radiologist. Please obtain research pricing for professional read fees by emailing Radiology.Research@uth.tmc.edu.

A Radiology start-up fee of **\$750** will be assessed on all industry-sponsored studies that involve research-only (non-standard of care) imaging. This fee may be waived for investigator-initiated unfunded studies and studies that involve the services of our radiologists in the role of Co-Investigator or Consultant. This fee will also not be charged on studies that are conducted on the UTHealth 3T MRI scanner.

Investigators from other departments who wish to utilize the capabilities of DII are advised to discuss potential projects with a Radiologist during the planning phase of a project, in parallel with the CPHS approval process.

Submit the form and a copy of the protocol to:

Usha N. Menon, Ph.D.
 6431 Fannin Street, MSB 2.130B
 713-500-7701
Usha.N.Menon@uth.tmc.edu

Lauren McGuire, RN, BSN
 6431 Fannin Street, MSB 2.130B
 713-500-7264
Lauren.C.McGuire@uth.tmc.edu

| | | | | | | | | | |
|---|--|---|---|---|---------------------------------------|--|---|--|--|
| Study Title: | | | | | | | | | |
| Principal Investigator: | | | | | | | | | |
| PI Contact (Phone and Email): | | | | | | | | | |
| PI Department: | | | | | | | | | |
| Study Funding source: | | | | | | | | | |
| Is a DII Faculty Radiologist listed as study personnel? | <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, enter name, role and effort: | | | | | | | | |
| List DII Radiologist services requested for this research. | <table border="0"> <tr> <td><input type="checkbox"/> Protocol Development</td> <td><input type="checkbox"/> Manuscript/Grant Preparation</td> </tr> <tr> <td><input type="checkbox"/> Read/Interpret</td> <td><input type="checkbox"/> Post-process</td> </tr> <tr> <td><input type="checkbox"/> Generate Report</td> <td><input type="checkbox"/> RECIST/RANO/Other calculations</td> </tr> <tr> <td><input type="checkbox"/> Review Imaging Protocol</td> <td></td> </tr> </table> | <input type="checkbox"/> Protocol Development | <input type="checkbox"/> Manuscript/Grant Preparation | <input type="checkbox"/> Read/Interpret | <input type="checkbox"/> Post-process | <input type="checkbox"/> Generate Report | <input type="checkbox"/> RECIST/RANO/Other calculations | <input type="checkbox"/> Review Imaging Protocol | |
| <input type="checkbox"/> Protocol Development | <input type="checkbox"/> Manuscript/Grant Preparation | | | | | | | | |
| <input type="checkbox"/> Read/Interpret | <input type="checkbox"/> Post-process | | | | | | | | |
| <input type="checkbox"/> Generate Report | <input type="checkbox"/> RECIST/RANO/Other calculations | | | | | | | | |
| <input type="checkbox"/> Review Imaging Protocol | | | | | | | | | |

| | | |
|---|---|--|
| <p>Choose all imaging/procedures in this research study.</p> | <input type="checkbox"/> X-ray <input type="checkbox"/> Ultrasound <input type="checkbox"/> Mammography <input type="checkbox"/> CT <input type="checkbox"/> MRI <input type="checkbox"/> PET <input type="checkbox"/> Bone density scan/DEXA <input type="checkbox"/> Bone Scan <input type="checkbox"/> Other Image-guided procedures including injections <input type="checkbox"/> Imaging quality/Imaging equipment performance evaluation <input type="checkbox"/> New/Modified Imaging Software <input type="checkbox"/> Modified Imaging Equipment/Unique Technical requirement <input type="checkbox"/> Calibration/Phantoms/Dosimetry/Test images <input type="checkbox"/> Other Nuclear Med, please specify below <input type="checkbox"/> Interventional Radiology, including biopsies please specify below <input type="checkbox"/> Other, please specify below Please specify: | <input type="checkbox"/> Lumbar Puncture <input type="checkbox"/> Blood Patch <input type="checkbox"/> Image-guided biopsy <input type="checkbox"/> Fluoroscopy <input type="checkbox"/> Imaging protocol <input type="checkbox"/> Medical Device Evaluation <input type="checkbox"/> Radiopharmaceuticals |
| <p>Choose all applicable scan/procedure sites for this research study.</p> | <input type="checkbox"/> MH Hospital <input type="checkbox"/> MH OPID - U Kirby <input type="checkbox"/> MH OPID - TMC <input type="checkbox"/> MHH Imaging Center – Bayshore <input type="checkbox"/> MHH Imaging Center – Bellaire <input type="checkbox"/> MH ROH <input type="checkbox"/> Peripheral Site, please specify below. <input type="checkbox"/> Other Site, please specify below. Please specify: | <input type="checkbox"/> UT 3T Center (Core Facility) <input type="checkbox"/> UTP Bellaire <input type="checkbox"/> UTP Bayshore <input type="checkbox"/> Smith Clinic <input type="checkbox"/> LBJ Hospital |
| <p>Estimated Target Enrollment (number of subjects)</p> | | |
| <p>Additional Comments</p> | | |

FOR OFFICIAL DII USE ONLY: DII Reviewer, please apply below and then click Return to PI to send the form back to the Principal Investigator via email. If you do not have digital ID, please print the form, sign and return.

Approved

Reviewer Comments:

Need More Information

DII Reviewer Digital Signature/ Name, Signature and Date