Research Request for Radiation Safety Committee Review

Main Department: Radiology
Sub Department: Radiation Safety Committee

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Keywords: Radiation Safety Committee, Radiology, Review, External Application

A) Introduction:

Human exposure to ionizing radiation from x-ray procedures or nuclear medicine studies for research purposes must be reviewed to determine if exposure is considered standard of care or research specific. If exposure is related to research only, it must be submitted to the Radiation Safety Committee (RSC). The purpose of the document is to provide step by step guidance on the Radiation Safety Committee Submission process. Radiation Safety consideration applies to all Maine Medical Center Campuses. This includes SMHC. The following tests are eligible for review:

- Diagnostic
- Fluoroscopy
- Interventional Radiology
- Cardiac Cath Lab / Electrophysiology (EP) Lab
- PET Scan
- CT Scan
- Nuclear Medicine
- Dual-energy x-ray absorptiometry (DXA) or bone densitometry*
MMC Radiology does not perform Bone density testing. Therefore, a Radiology Research Checklist request does not need to be submitted; however, if bone density test is not standard of care, it IS subject to Radiation Safety Committee Review.

B) Things to think about:
   - What radiology tests are required
   - Where will testing be performed
   - Are the tests standard of care, research, or both
   - Where should I send the Radiation Safety Committee Review application
   - What is the expected review time
   - Is radiation specific language required in the ICF

C) Process:
   1. Identify which radiology tests are required.
   2. Confirm testing is above standard of care i.e. "If the patient were not enrolled in this study or protocol, would the imaging be ordered?" If the answer is "no", then the imaging is not considered to be standard of care.
   3. If imaging is not standard of care, complete the Radiation Safety Committee Application
   4. Submit the completed Radiation Safety Committee Application along with required documents below to: Lindsey Berkowitz, Radiation Safety Officer (RSO) at L.Berkowitz@mmc.org
      a. ICF template
      b. Protocol
      c. Flowsheet
   5. Allow for a 2 week response time
      NOTE: Approval must be obtained prior to the IRB submission
   6. Respond to and provide any additional information requested by the RSO
   7. Following RSO approval, written notification will be provided to the research staff along with recommended (if applicable) ICF radiation safety language.
   8. Update ICF with recommended RSO language
   9. Submit updated ICF to RSC for approval
   10. Submit updated ICF to sponsor for approval
   11. Submit IRB application
       a. If using WIRB, MMC, or Copernicus submit via IRBnet
       b. If using "other" IRB, submit accordingly

D) Helpful information and Links:
   - Radiation Safety Committee Application
   - IRBnet
E) **Troubleshooting:**
- N/A

F) **Key contacts:**
Lindsey Berkowitz, Dir-Imaging Physics & Radiation Safety
207-662-4332 Direct line
L.Berkowitz@mmc.org

G) **Change History:**
Use this section to track who has made edits to the process and when

**Read and Acknowledged by:**

[SIGNING THIS DOCUMENT MEANS THAT YOU HAVE READ AND ACKNOWLEDGED THIS PROCESS, CONCUR THAT IT IS CORRECT, AND AGREE TO SUPPORT THE OUTLINED STEPS ( )]

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<td>Andrew Berkowitz</td>
<td>RSO</td>
<td>Imaging Physics</td>
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