



Before You Submit: A Practical Guide to Nuclear Medicine and Radiation Safety Review in Human Research

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IRB Brown Bag | May 20th, 2026

Before You Submit

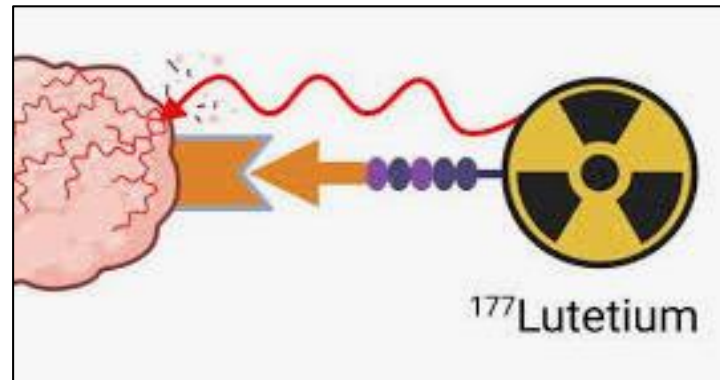
Agenda

- Introduction
- Where Nuclear Medicine Fits in Human Research
- Where Investigators Need to Submit (and When)
- How Nuclear Medicine & Radiation Safety Reviews Are Conducted
- When Further Review Is Required
- Common Issues During Submission & Review
- Practical Tips to Streamline Review
- Current Limitations & Future Direction
- Q & A

Where Nuclear Medicine Fits in Human Research

At a high level, Nuclear Medicine in research includes:

- Diagnostic imaging:
 - PET/CT, SPECT/CT
 - MUGA, planar bone scans
- Use of approved or investigational radiotracers
- Radioligand therapy (RLT) and other nuclear therapies
- Radiation dosimetry and participant exposure



Where Nuclear Medicine Fits in Human Research

Investigational vs Standard of Care (SOC)

Standard of Care (SOC)

- SOC Imaging in Research:
 - PET/CT, SPECT/CT
 - Established clinical workflows and scan protocols
- Radiotracers / Therapeutics:
 - Approved diagnostic tracers
 - Approved radiotherapeutics
- Role in research:
 - Used as baseline assessment and/or evaluate response to study therapy:
 - Imaging data may be processed and read locally

Where Nuclear Medicine Fits in Human Research

Investigational vs Standard of Care (SOC)

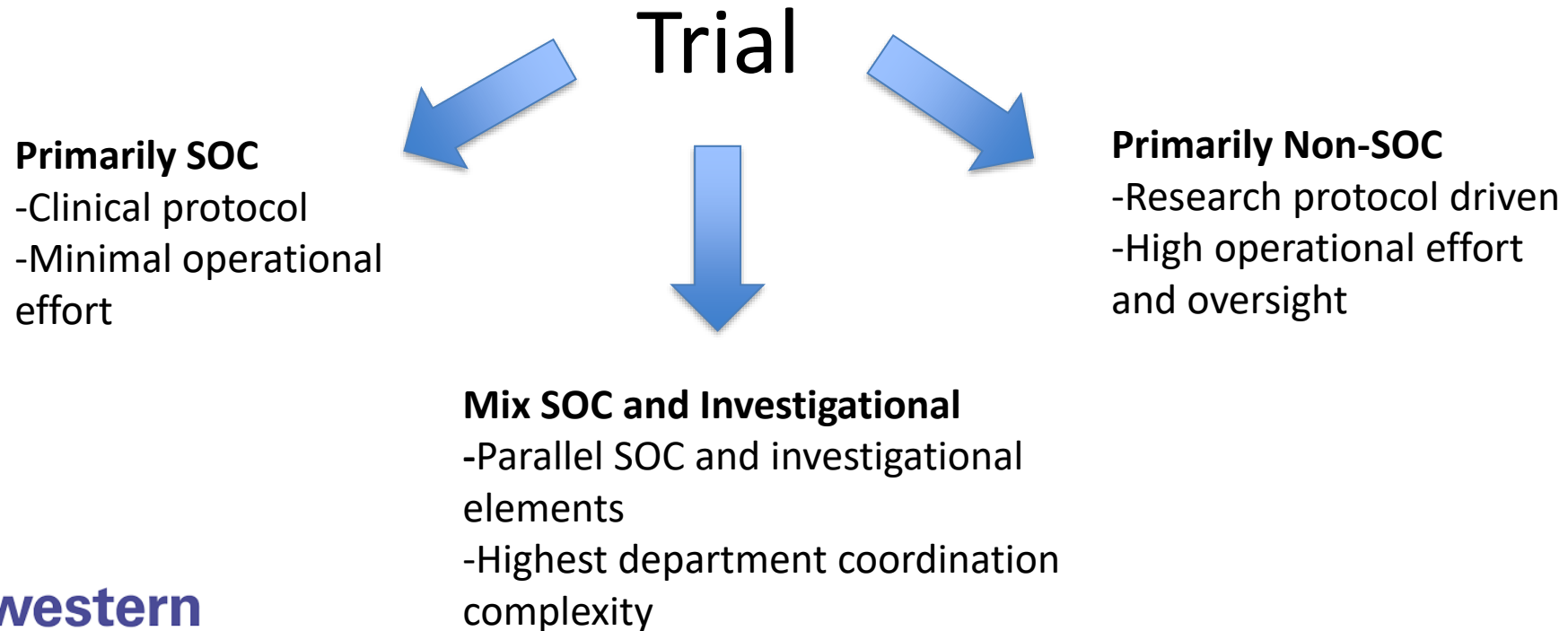
Investigational / Non-SOC Imaging and Therapies

- Investigational and non-SOC imaging in research:
 - PET/CT, SPECT/CT
 - Research specific protocol builds, custom acquisitions and reconstructions, additional timepoints
- Radiotracers / Therapeutics:
 - Investigational tracers or novel nuclear therapeutics
 - First-in-human agents
- Role in research:
 - Imaging or therapy is driven by the research protocol
 - Imaging data is typically anonymized and queried for central review

Where Nuclear Medicine Fits in Human Research

Investigational vs Standard of Care (SOC)

*Classification drives protocol builds,
staffing efforts, and operations*



Where to Submit (Investigator View)

Where Investigators Need to Submit (and When)

- Primary submission pathway:
 - Research Imaging Collaboration Office (RICO) is the primary point of contact for imaging and nuclear therapy related research
 - NU study team personnel submit study concepts and documentation through RICO
 - RICO coordinates department reviews and confirms institutional imaging services feasibility
- ✓ Key Takeaway:
 - ✓ Do not contact Nuclear Medicine for feasibility assessment unless directed
 - ✓ Early submission through RICO helps prevent redundancies and miscommunication

Where to Submit (Investigator View)

Research Imaging Collaboration Office (RICO)



RICO

- RICO provides centralized administrative review and coordination of Imaging feasibility for radiology research studies at Northwestern Memorial Hospital
- Established in Jan 2022, the Research Imaging Collaboration Office has supported more than 450 studies in collaboration with 14 departments to ensure efficient, feasible, and compliant use of Imaging resources

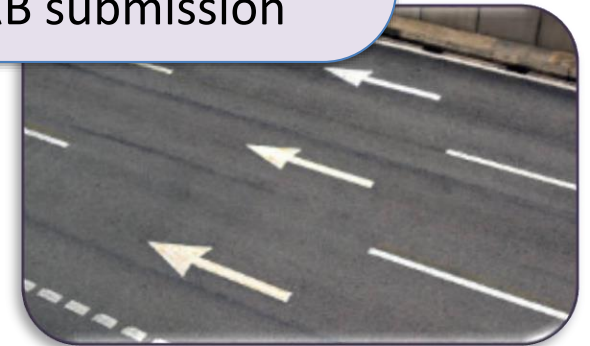
www.radiology.northwestern.edu/research/research-imaging-collaboration-office-rico/index.html

Where to Submit (Investigator View)

What Happens After RICO Submission

- Typical pathway after submission:
 - RICO reviews study scope and coordinates feasibility
 - Nuclear Medicine and Radiation Safety are engaged as needed
 - Specialized reviews by the Nuclear Medicine's Radiology Review Committee and Radiation Safety
 - Feedback is returned through communication with RICO
- ✓ Key Takeaway:
 - ✓ Review requirements are driven by study design and protocol details

RICO, Nuclear Medicine and Radiation Safety reviews are initiated independently from and proceed in parallel with IRB submission



How Nuclear Medicine & Radiation Safety Reviews Are Conducted

How Nuclear Medicine Reviews Are Conducted

- What Nuclear Medicine evaluates:
 - Imaging protocols and acquisition details
 - Radiopharmaceuticals: Approved vs. investigational
 - Operational feasibility (equipment, workflow, staffing)
 - Expected patient volume
 - Does the study require radioactive pharmacokinetics (PK)?
 - Alignment with study design and imaging requirements
- Studies are reviewed at Radiology Review Committee (R2C) meetings monthly
 - R2C is multidisciplinary team including physicians, technologists, physicists, radiation safety, and radiopharmacist

How Nuclear Medicine & Radiation Safety Reviews Are Conducted

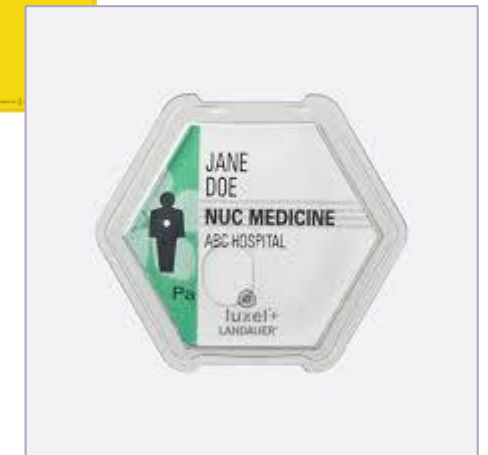
How Nuclear Medicine Reviews Are Conducted

- ✓ Key Takeaway:
 - ✓ Nuclear Medicine review focuses on whether the imaging and therapeutic components are clearly defined and feasible within clinical operations
 - ✓ Clinical operations include real world constraints like space, scheduling and ongoing department expansion

How Nuclear Medicine & Radiation Safety Reviews Are Conducted

How Radiation Safety Reviews Are Conducted

- When Radiation Safety is involved:
 - Use of ionizing radiation (e.g., X-ray, CT, Fluoroscopy)
 - MRI does not require review
 - Studies involving radiopharmaceuticals (nuclear medicine)
 - Research involves radiation exposure beyond clinical care
- What Radiation Safety evaluates:
 - Radiation exposure to participants and staff
 - Use, handling, and disposal of radioactive materials
 - Regulatory and institutional compliance
 - Radioactive materials (RAM) licensing or amendments
 - Dosimetry review and risk communication for consent documentation



How Nuclear Medicine & Radiation Safety Reviews Are Conducted

Key Components of Radiation Safety

- Radioactive Materials (RAM) License:
 - Regulatory authorization that allows an institution to possess and use radioactive materials
 - Required to ensure safe handling, storage, use and disposal of radioisotopes
 - Issued and overseen by regulatory agencies
 - Includes isotope details, intended use, approved locations and authorized users
- Why it matters for research:
 - Required for any study using radioisotopes
 - And new tracer, radiotherapy or device may require a RAM license amendment (~6 months)



How Nuclear Medicine & Radiation Safety Reviews Are Conducted

Key Components of Radiation Safety

- Dosimetry review & risk communication:
 - Focuses on research-related radiation exposure to study participants
 - Calculates the total effective dose equivalent (TEDE) to study participants
 - Provides language for the study consent form
 - Required for IRB submission and approval



When Further Review Is Required

When Further Review Is Required

- Further review is required when additional questions arise at R2C:
 - Imaging protocols exceed routine clinical care
 - Variable uptake times
 - Additional imaging at non-standard time points
 - Novel or investigational radiopharmaceuticals are involved
 - RLT or other nuclear therapeutics are included
 - Studies requiring RAM license amendments
 - Operational feasibility constraints
- ✓ Key Takeaway:
 - ✓ Requirements such as RAM licensing or complex protocols can impact feasibility and study timelines

Common Issues During Submission & Review

Common Issues

- Sponsors or CRO's contact Nuclear Medicine staff directly outside of RICO
- Multiple parallel email threads across departments and teams
- Uncertainty about whether a study has been submitted to RICO/IRB
- Misalignment between study teams, RICO, and Nuclear Medicine on study status
- Early feasibility work begins before formal submission or coordination



Common Issues During Submission & Review

Impact of Communication Gaps

- Consequences:
 - Duplicate or conflicting communications across teams
 - Time spent on feasibility work before formal submission
 - Delays from needing to clarify study status
 - Missed opportunities when studies stall before reaching review

- ✓ Key Takeaway:
 - ✓ Studies may be delayed or lost before Nuclear Medicine review begins
 - ✓ Department effort and resources may be used inefficiently

Practical Tips – Before / During / After Review

Practical Tips to Streamline Review

- **Before you submit:**
 - Route all imaging-related communication through RICO when possible
 - Engage early to assess feasibility and study requirements
 - Ensure all teams are aligned on study status and submission pathway
 - Maintain a single, coordinated communication pathway across teams
- ✓ Key Takeaway:
 - ✓ RICO serves as the central point of coordination for study submissions

Practical Tips – Before / During / After Review

Practical Tips to Streamline Review

- **During and after review:**
 - Direct communication with sponsors/CROs and study teams is expected during review
 - Ensure RICO remains informed and included in key communications
 - Maintain visibility of study status across all teams
 - Communicate timeline changes across all teams
 - Communicate protocol or study changes early

- ✓ Key Takeaway:
 - ✓ Ongoing communication is expected and supports visibility across all teams
 - ✓ Keeping RICO in the loop maintains coordination and alignment

Current Limitations & Future Direction

Current Limitations

- Current Limitations:
 - Limited infrastructure for radioactive pharmacokinetics (PK)
 - Inability to fully support certain Phase 1 or early phase studies
 - Limited staff for supporting certain Phase 1 or early phase studies
- Impact on Studies:
 - Currently, studies may require protocol adaptation or exceptions in order to select Northwestern Medicine
 - Early evaluation is critical to determine site participation

Current Limitations & Future Direction

Future Direction

- Future Direction / Nuclear Medicine:
 - Renovation of 4th floor Arkes Pavilion
 - Expansion of infrastructure to support complex early-phase trials:
 - Addition of a radioactive specimens laboratory
 - SPECT/CT and PET/CT systems
 - Uptake rooms to accommodate RLT and other nuclear therapy studies
 - Additional site personnel
 - Anticipated completion:
 - November 2026



Dedicated Nuclear Medicine space in the new tower

Contact Us

Resources and Contacts

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Radiation Safety:

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RICO:

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What we
think we do..



..what we
actually do



Questions?

