Four Years and Beyond: Progress with the Committee on Radiation

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Background

- The Protocol Review Core (PRC) within Memorial Sloan Kettering Cancer Center's (MSK) Clinical Research Administration (CRA) was established in 2018 to provide centralized oversight of protocol review committees, including the Committee on Radiation (COR).
- COR has jurisdiction over all ionizing radiation use in accordance with applicable regulations and MSK's broad scope license, which includes reviewing protocols where participants receive any investigational radiation exposure.
- PRC and COR leadership identified challenges with protocol reviews at COR such as ambiguity of review criteria, increased submission volume, and PRC operating outside of scope since COR is a unique committee reviewing clinical and non-clinical research activities subject to regulatory oversight.

Goals

- Streamline COR's review process while ensuring regulatory compliance
- Improve access to COR resources
- Align responsibilities for COR administration
- Facilitate review at future committee meetings (i.e., IRB)

Solutions Implemented

January 2018
PRC committee management established to standardize review process across institution

April 2019
Created Informed Consent template language to ensure COR's vetting of appropriate radiation risk language during review

May 2019
Clarified and updated COR review criteria to ensure regulatory compliance (Figure 1)

July 2019
Implemented expedited reviews to facilitate timely activation of protocols

October 2019
Created COR review letter template text to establish consistency and facilitate reviews and PI responses

March 2020
Developed amendment workflow (Figure 4) to ensure regulatory compliance

May 2021
Redesigned COR Clinical Research (CR) Portal Page (Figure 2) to increase transparency and improve access to resources

October 2021
SOP revisions and RACI document implemented (Figure 3) to comply with internal workflows and to separate clinical research from radiation safety responsibilities

Figure 1: Review Criteria in the Research Proposal Submission Form (RPSF)

B.11	Are any of the ionizing radiation scans in the protocol performed for research purposes only? Examples include X-ray, CT, PET, image guided biopsies, MUGA, or other nuclear medicine scans. If Yes, list the non-standard of care scans and timepoints. Please note: Non-standard-of-care scans, time points, and number of time points are subject to change after the Medicare coverage analysis is complete.
B.12	Will the patient receive radioactive materials that are not FDA approved or FDA approved but being used for a non-FDA approved indication?
B.13	Does the protocol include radiation therapy or radionuclide therapy that is not standard of care, is being used for a non-approved indication, or is performed in a non-routine manner?

If RPSF B.11 is YES, protocol will be assigned for expedited review

If RPSF B.12 and/or B.13 are YES, protocol will be assigned for full review

Figure 3: RACI (Responsible, Accountable, Consulted, Informed)

	PRC	Medical Health Physics Regulatory Specialist	Radiation Safety Officer/COR Vice Chair	COR Chair	COR members
COR Meetings					
- Schedule Meeting Dates and send Zoom invites.	R/A	C/I	C/I	C/I	I
- Book conference room for in-person meeting and order food	A/I	R/A	I	I	I
- Assign protocols to meeting date and reviewers	R/A	I	I	C	I
- Add relevant CR announcements as discussion items on agenda	R/A	I	I	I	I
- Add the following non-protocol review agenda items and notify PRC via email once entered into PIMS: Human use licenses and non-human use licenses	A/I	R	C/I	C/I	I
- Publish COR agenda and active user work (6-7 days prior to meeting date)	R/A	I	I	I	I
- Complete reviews in PIMS	A		R	R	R
- Follow up with reviewers who have pending checklists/reviews	R/A		I	I	I
- Project protocol review documents	R/A				
- Project non-protocol documents (e.g. Report from the Sub-Committee on Non-Human Use, Quarterly ALARA reports)		R/A			
- Enter real time attendance in PIMS to ensure quorum	R/A				

Figure 2: List of Resources Accessible via Clinical Research Portal

COR Review Criteria	Radiation Dosimetry Resources	Additional Resources
• Full • Expedited	• Adults • Pediatrics • Protocol Specific Language	• SOPs • Regulations • Protocol Review Resources

Figure 4: Amendment Review Criteria

Does the amendment include the addition of any of the following that increases radiation exposure for participants?

- ❑ Radioactive materials that are not-FDA approved or FDA approved but being administered for a non-FDA approved indication. Examples include diagnostic molecular imaging scans, radiolabeled antibody drugs (radiopharmaceuticals).
- ❑ Radiation therapy that is not standard of care, is being used for a non-approved indication, or is performed in a non-routine manner

If YES, please specify the radioactive material and/or radiation therapy that is being added

Outcome

- **325%** Increase in COR protocol reviews (2017-2021) as a result of clear review criteria
- **83%** % protocols reviewed via expedited process (2020) compared to 0% prior to PRC management
- **12** Median days for COR approval, which remained consistent despite significant increase in volume (2020)
- **79%** Increase in protocols 'approved as is' after CR portal redesign, including comprehensive resources, led to improved quality of submissions (2021)

Lessons Learned

- Establishing clear review criteria in the initial stage of protocol submissions was effective for ensuring regulatory compliance
- Incorporating RACI tool was critical for realigning administrative responsibilities

Future Directions

- Leverage technology to improve committee management such as:
  - Automate amendment submissions and reviews in Protocol Information Management System (PIMS)
- Continue to increase efficiencies within the review process