Abstract Title: Enhancing the Review Process for Radiation Safety in Human Subjects Research

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Describe the background of the problem:

Historically all human subjects research protocols involving ionizing radiation required review by Mount Sinai Radiation Safety Committee (RSC) before submission to the Institutional Review Board (IRB). This included submission to RSC for all cancer-related protocols even if ionizing radiation was “medically indicated” for diagnosis or clinical management of patients. This process also resulted in lengthy consent forms that discussed exposure levels for procedures that were considered standard of care for an existing cancer, disease progression or suspected medical condition.

Approximately fifty new protocols are submitted annually to the IRB by the Cancer Clinical Trials Office (CCTO). Requirements for RSC review significantly added to the regulatory workload, causing delays in study activation and also created inconsistencies across protocols and consent forms.

Provide metrics or goals hoped to be achieved with the solutions to address the problem:

The following best-practice policy was achieved

• Eliminate the need to submit to RSC protocols that did not include radiation exposure beyond standard of care practice.
• Eliminate the need to add in the consent form the risk of total radiation exposure rather than the additional exposure resulting from participation in the research.

Describe the solutions or methods implemented:

• For protocols involving only standard of care procedures: IRB form now includes PI attesting to the assertion that radiation exposure is provided as per standard of care. These attestations are reviewed by IRB to ensure RSC review has been waived appropriately.
• For protocols involving radiological procedures performed for research: Only protocols that involve radiation exposure beyond standard of care may require RSC review. RSC revised policy so that review and management of human subject research protocols are now stratified based upon the highest level of anticipated research specific radiation in mSv by subject participation-year:
  o <5 mSv: IRB reviewing such protocols have appropriate expertise to assess radiation safety, either by standing members or external consultants.
  o ≥5 mSv but <50 mSv: A Subcommittee of IRB will determine acceptability of radiation exposure.
  o >50 mSv: The protocol is referred directly to RSC for evaluation to determine acceptability of the radiation exposure.
• For those protocols employing radiation that exceeds standard of care, or for irradiation of healthy subjects, a novel interactive dosimetry table (Image I) was created to calculate total effective dose and provide standardized radiation exposure consent form language.

Describe the Outcome of the Solutions implemented or show data representing a change whether positive or negative:

The revised RSC policy impact on cancer-related clinical trials:

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The number of cancer related protocols requiring RSC review has been reduced.

IRB submission to approval dropped from 55 to 42 average days (2012-2014).

Investigators using the dosimetry table have guidance to write safer protocols.

Consistency in consent form risk has helped improve the patient consenting process.

Show lessons learned, others to involve in the future, changes to the methods to achieve a better outcome:

Institutional collaboration is critical to implement any changes in research related policy. This initiative included local experts such as our Radiation Safety Officer, IRB Chair, Medical Oncologist, Radiologist, Radiation Oncologist, and Regulatory personnel. A Compliance Attorney was consulted to advise on the NY Official Compilation of Codes, Rules and Regulations related to the control of safety of ionizing radiation and the NIH Radiation Safety Committee also provided guidelines for research radiation.

Interactive Dosimetry Table (Image I)