For Research Protocols Involving the Use or Evaluation of Diagnostic or Therapeutic Procedures that Emit Ionizing Radiation:

- Formal HUSC review/approval is required if the:
  1. research protocol involves the use or the evaluation (i.e., for safety and/or effectiveness) of a radioactive drug or a radiation-emitting device that is not currently FDA-approved for commercial marketing; including radioactive drugs or devices that are the subject of a FDA-accepted IND or IDE application or approved for clinical investigations under the FDA’s Radioactive Drug Research Committee (RDRC) process.¹
  2. research protocol addresses (i.e., in the objectives or specific aims) the evaluation (i.e., for safety and/or effectiveness) or involves the use of a FDA-approved radioactive drug for an “experimental” indication or using “experimental” procedures (i.e., an indication or procedures that are not consistent with standard clinical practice or the current FDA-approved product labeling).¹
  3. research protocol involves the evaluation (i.e., for safety and/or effectiveness) or involves the use of a FDA-approved radiation-emitting device for a therapeutic indication that is not related to cancer.
  4. research protocol involves the enrollment of individuals (e.g., healthy volunteers) who would not be undergoing the procedure (i.e., exposure to ionizing radiation) in association with the diagnosis or treatment of their disease or condition.¹

- Formal HUSC review/approval is not required if the:
  1. research protocol involves the use of a FDA-approved diagnostic procedure being performed, in a manner and frequency that is consistent with standard clinical practice, for subject screening or to evaluate the outcome of a treatment regimen. This would include diagnostic procedures for off-label uses that are routinely performed in clinical practice.¹,²,³
  2. research protocol involves the use of a FDA-approved radioactive drug for a therapeutic indication that appears in the current FDA-approved product labeling for that drug product.¹,²,³
  3. research protocol involves the use or the evaluation of a FDA-approved radiation-emitting device for a therapeutic indication that is related to cancer.¹,²,³

For Humanitarian Use Devices:

- Formal HUSC review/approval is required for all Humanitarian Use Devices that emit ionizing radiation.

For any questions related to these requirements or their application, contact the Chair of the HUSC (412-647-0736) or the University’s Radiation Safety Officer (412-624-2728).

1. All research protocols wherein the parameters (e.g., dose, dosing frequency) for performing the procedure(s) that emit ionizing radiation are defined in the protocol must include an Authorized User (i.e., a physician or dentist who has expertise and who is credentialed in the respective medical specialty) as a listed co-investigator; i.e., so as to ensure adequate notification and respective compliance with the protocol.
2. The risks of radiation exposure associated with the diagnostic or therapeutic procedure must continue to be addressed in the protocol and consent form using the standard, HUSC-accepted wording. (For diagnostic procedures refer to the University IRB website – www.irb.pitt.edu: A-Z Guidance/Radiation Guidance. For therapeutic procedures, address the specific risks currently known to be associated with the respective procedure.
3. The University of Pittsburgh IRB, at its discretion, may request formal HUSC review of the research protocol.