

REQUIREMENTS FOR THE REVIEW OF HUMAN SUBJECT RESEARCH PROTOCOLS and
HUMANITARIAN USE DEVICES BY THE HUMAN USE SUBCOMMITTEE (HUSC),
RADIATION SAFETY COMMITTEE (effective 7/1/2018)

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 agent or a 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 radiopharmaceutical or device-associated procedure 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
 - Note: HUSC review/approval is not required for research protocols that involve the use of diagnostic procedures being performed, in a manner and frequency that are 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}
 - Note: HUSC review/approval is not required for research protocols that involve the use of therapeutic procedures being performed in a manner and frequency that is consistent with standard clinical practice.^{1,2,3}
 3. research protocol involves the enrollment of individuals (e.g., healthy volunteers) who will not be undergoing the procedure in association with the diagnosis or treatment of a disease or condition.¹

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 Human Research Protection Office website – www.hrpo.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.