Radiation Safety Committee

VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

SOP No.: CR-RE-345.3	Status: Final	Version Date: 02/11/2025 Effective Date: 03/14/2025

1. PURPOSE

This Standard Operating Procedure sets forth the requirement that all clinical research protocols involving any use of radioactive materials or radiation-producing devices NOT for the participant's direct clinical benefit and not within standard of care must be reviewed, approved, and maintain reporting as required by the VCU Radiation Safety Committee (RSC). This requirement applies to any protocol to be conducted at a VCU/VCU Health facility, affiliate, or participating site.

2. REQUIREMENTS

VCU and VCU Health are committed to the safe and ethical use of all radioactive materials and radiation-producing devices utilized in research at VCU/VCU Health facilities. To that end, VCU has established a Radiation Safety Committee (RSC) to oversee the use of radioactive materials and radioactive-producing devices in humans. VCU RSC review is an institutional pre-requisite, regardless of the IRB reviewing the clinical study. RSC review and approval is required for all clinical research involving the use of radioactive materials or radiation-producing devices NOT for the participant's direct clinical benefit and not within the standard of care.

3. DEFINITIONS

Radiation Safety Committee (RSC) - The RSC is managed through the Radiation Safety Section of the VCU Office of Environmental Health and Safety (OEHS). The RSC identifies potential radiation safety problems, initiating, recommending, or providing corrective actions, and verifying the implementation of corrective actions as mandated by the VCU/VCU Health (Tappahanok) with the goal of keeping radiation doses as low as reasonably achievable for all.

Effective Dose Equivalent (EDE) - A general way of determining overall risk for exposure to radiation. It is a calculated value measured in *mSv/mrem*, which takes into account the absorbed radiation dose to all organs of the body, the relative harm level of the radiation, and the sensitivities of each organ to radiation.

Sum Effective Dose - Estimate of all ED from external and internal radiation exposure.

4. PROCESS

A. All investigators and research staff should be familiar with and comply with VCU Guidelines for IRB Protocols Involving the Use of Ionizing Radiation as found on the VCU OEHS webpage.

B. All clinical research projects involving radioactive materials and radiation-producing devices that are NOT for the direct clinical benefit of the participant and not within standard of care are required to be reviewed by the VCU RSC prior to IRB submission.

C. The PI (or designee) should consult with the Medical Physicist in VCUH Department of Radiology/Radiation Physics or Radiation Oncology for estimation of the effective Dose Equivalent(EDE).

D. The VCU Radiation Safety Officer will review estimated EDE, sum effective dose, and recommend an appropriate risk statement for inclusion into the informed consent document in the event the ICF does not cover the risk adequately

E. The PI (or designee) should submit the appropriate RSC Application (as found on the VCU OEHS website), protocol, informed consent, and all relevant documents to the OEHS Radiation Safety Section via email for review. Massey applications should include the IRB number with their submission, if available.

F. Should the RSC recommend changes to the protocol and/or consent, the updated documents require re-review by the RSC.

G. Upon receipt of the RSC approval letter, the study may be submitted to the IRB. The RSC letter should be filed in the regulatory binder.

H. RSC approval should be documented in the VCU Clinical Research Management System (VCU/VCU Health CR SOP CR-AD-120).

5. REFERENCES

- VCU
  - VCU Radiation Safety Committee
  - VCU Safety and Risk Management
  - Radiation Safety Section
  - Guidelines for IRB Protocols Involving the Use of Ionizing Radiation
  - Application-Use of Ionizing Radiation in Human Research
- VCU/VCU Health Clinical Research Standard Operating Procedures
  - CR-AD-120 - Clinical Research Management System

Review/Revision History CR-RE-345		
Version No.	**Effective Date**	**Description**
CR-RE-345.3	03-14-2025	● Revised where to submit RS application and what to include in submission ● Minor formatting edits ● References and links updated ● Updated to ICH E6(R3)
CR-RE-345.2a	07-01-2020	● Links updated
CR-RE-345.2	07-01-2020	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-RE-345.1	02-03-2018	● Original