Title: **Radioactive Drug Research Policy**	**Policy Category:** **Research**
Issuing Authority: **Office of the Vice President for Research**	**Responsibility:** **Office of Research Compliance**
Publication Date: **08/07/2023**	**Next Review Date:** **08/07/2026**

Policy Statement/Background:

None

Policy:

The Food and Drug Administration (FDA) under 21 CFR 361.1 permits **basic research** using radioactive drugs in humans **without** having an IND (approved New Investigational Drug application) when the drug is administered under the following conditions:

- The research is considered basic science research and is done for the purpose of advancing scientific knowledge. Under § 361.1(a), this type of research is:
  - intended to obtain basic information regarding the kinetics, distribution, dosimetry, and localization of a radioactive drug or regarding **human physiology, pathophysiology, or biochemistry,**
  - **not** intended for immediate therapeutic, diagnostic or similar purposes (e.g. preventive benefit to the study subject from the research), and
  - **not** intended to determine the safety and effectiveness of a radioactive drug in humans.

Research projects that meet the criteria for review in the regulations must be submitted to and approved by the Radioactive Drug Research Committee (RDRC) prior to initiation of the study.

Radioactive Drug Research Committee (RDRC)

The Radioactive Drug Research Committee (RDRC) operates in accordance with 21 CFR 361.1. The RDRC is a campus committee appointed by the Vice President for

Research in accordance with federal regulations for member composition. The RDRC has the following authority:

- To review and approve applications for radioactive drug research performed at Stony Brook University. Note: Referrals to the RDRC can also be made by the Institutional Review Board (IRB).
- To determine the value of the proposed research against research subject risk versus benefit before approving the study.
- To serve as an educational resource and provide consultation for researchers engaged in this type of research.

The RDRC has adopted operating procedures to implement this policy. These procedures serve as the governing procedures for the conduct and review of radioactive drug research carried out under the auspices of the University, in conjunction with all other federal, state, and institutional policies, as applicable.

Definitions:

None

Contact:

Additional information about this policy is available here:

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Relevant Standards, Codes, Rules, Regulations, Statutes and Policies:

- Code of Federal Regulations (21 CFR § 361.1 Radioactive drugs for certain research uses)
- Guidance Document: Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application
- Stony Brook Office of Research Compliance Website