

**HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES**

Chapter 1	Administration and Organization	Effective:	June 2000
Section 1.7	Standing Committees	Revised:	December 2015
<b>Policy 1.7.16</b>	<b>Radioactive Drug Research Committee</b>	Responsibility:	Executive Vice President for Facilities Planning and Operations

## **RADIOACTIVE DRUG RESEARCH COMMITTEE**

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### **Members**

1. One representative who is a physician in Nuclear Medicine
  2. One representative who is a Nuclear Pharmacist
  3. One representative in Radiological Sciences with experience in biophysics or radiological physics
  5. One clinical representative from Clinical Pathology, Internal Medicine, Radiation Oncology, or Diabetes
  6. One representative experienced in positron emitting tracers
  7. One representative from Hematology or Molecular Medicine
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### **Ex-Officio (with vote)**

1. One representative who is a VA Radiation Safety Officer
  2. Radiation Safety Officer, Environmental Health and Safety
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### **Chair**

The Assistant Vice President for Risk Management and Safety makes Chair and Vice Chair appointment recommendations from the membership to the Vice President for Academic, Faculty, and Student Affairs. The Vice President for Academic, Faculty, and Student Affairs will recommend to the President approval or disapproval for the appointment of the proposed Chair.

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### **Charge**

To serve in an advisory and consultative capacity to the President and the Executive Vice President for Facilities Planning and Operations. To review and approve all research involving the use of radioactive drugs and/or agents with human subjects conducted at or by employees of the UT Health Science Center at San Antonio; the South Texas Veterans Health Care System; and the University Health System. In accordance with the Food and Drug Administration (21 CFR, Part 361.1) regulations, the Radioactive Drug Research Committee (RDRC) ensures that the use of such drugs is in compliance with these regulations.

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This Committee supports the Human Research Protection Program in its review of protocols involving human participants and the use of radioactive drugs and/or agents; the Committee notifies the Institutional Review Board (IRB) upon their approval or failure to approve. Approval of the RDRC is required prior to final IRB approval.

If the drug is an Investigational New Drug (IND), or New Drug Approval (NDA) with the Food and Drug Administration (FDA), it will not be reviewed by the RDRC.

**Additional Information:** Committee meets quarterly. Workload of the Committee requires knowledge of or interest in learning FDA regulations for radioactive drug development, testing, and approval. Experience with the legal and safe use of such drugs for clinical and research purposes is highly desirable. Electronic review of protocols between meetings may be utilized by the committee.

**Term of Membership**

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Two years

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