

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 1	Administration and Organization	Effective:	June 2000
Section 1.7	Standing Committees	Revised:	April 2008
Policy 1.7.16	Radioactive Drug Research Committee	Responsibility:	Vice President for Research

RADIOACTIVE DRUG RESEARCH COMMITTEE

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
 4. One representative in Radiological Physics
 5. One representative from Clinical Pathology
 6. One representative experienced in positron emitting tracers
 7. One Hematologist
 8. One faculty member at large/past Chair
 9. One representative from Radiation Oncology
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Ex-Officio (with vote)

1. One representative who is a VA Radiation Safety Officer
 2. One Radiation Safety Officer
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Chair

The Radioactive Drug Research Committee will recommend to the Vice President for Research a Chair of the Committee. After deliberation on the recommendation, the Vice President for Research will recommend to the President approval or disapproval for the appointment of the proposed Chair.

Charge

To serve in an advisory and consultative capacity to the President and the Vice President for Research. 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

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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.

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) with the Food and Drug Administration (FDA), it will not be reviewed by the Committee. If the drug is a New Drug Approval (NDA) with the 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.

Term of Membership

Three years
