



### 1.5.13 Radioactive Drug Research Committee

Chapter 1 - Administration and Organization	Original Effective Date: June 2000
Section: 1.5 University Committees	Date Last Reviewed: February 2024
Responsible Entity: Vice President for Facilities and Capital Planning	Date Last Revised: February 2024

#### I. Purpose

The purpose of this Policy is to define membership terms and conditions, leadership selection and charge of the Radioactive Drug Research Committee.

#### II. Scope

This Policy applies institution wide to all current and prospective members of the UT Health San Antonio Radioactive Drug Research Committee and associated Environmental Health and Safety units.

#### III. Policy

The Radioactive Drug Research Committee (RDRC) is established in accordance with Food and Drug Administration (*21 CFR, Section 361.1*) regulations, the RDRC ensures that the use of such drugs is in compliance with regulations. If the drug is an Investigational New Drug (IND), or New Drug Approval (NDA) with the Food and Drug Administration (FDA), it is not reviewed by the RDRC.

The RDRC 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.

##### A. Membership

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
4. One clinical representative from Clinical Pathology, Internal Medicine, Radiation Oncology or Diabetes

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5. One representative experienced in positive emitting tracers
6. One representative from Hematology or Molecular Medicine

#### B. Ex-Officio Membership (with vote)

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

#### C. 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.

#### D. Charge

To serve in an advisory and consultative capacity to the President and the Executive Vice President for Facilities Planning and Operations in the following ways:

1. review and approve all research involving the use of radioactive drugs and/or agents with human subjects conducted at or by employees of UT Health Science Center at San Antonio; the South Texas Veterans Health Care System; or the University Health System;
2. support the Human Research Protection Program in its review of protocols involving human participants and the use of radioactive drugs and/or agents; and,
3. notify the Institutional Review Board (IRB) upon their approval or failure to approve the use of a radioactive drug or agent. Approval of the RDRC is required prior to final IRB approval.

#### E. Term of Membership

Members serve on the Committee for a term of up to two (2) years.

## **IV. Definitions**

*There are no defined terms used in this Policy.*

## **V. Related References**

### **Food and Drug Administration (FDA)**

21 CFR §361.1 Radioactive drugs for certain research uses.

## VI. Review and Approval History

- A. The approving authority of this policy is the University Executive Committee.
- B. The review frequency cycle is set for three years following the last review date, a time period that is not mandated by regulatory, accreditation, or other authority.

<b>Effective Date</b>	<b>Action Taken</b>	<b>Approved By</b>	<b>Date Approved</b>
<b>06/2000</b>	Policy Origination		
<b>12/2015</b>	Policy Revision		
<b>05/2021</b>	Policy Revision/Discretionary Edits		
<b>02/2024</b>	Policy Revision/Discretionary Edits		