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Radioactive Drug Research  
Committee (RDRC)  
Office of Safety and Business Continuity

## Radioactive Drug Research Committee (RDRC)

- **What is the purpose of the RDRC?**
  - The RDRC is chartered by the FDA under the provisions of 21 CFR § 361.1.
  - The RDRC reviews and approves certain basic research using radioactive drugs in humans without an Investigational New Drug Application (IND).
- **What types of basic research studies are reviewed by the RDRC?**
  - Research intended to obtain basic information regarding the metabolism (including kinetics, distribution and localization) of a radioactively labeled drug or regarding human physiology, pathophysiology or biochemistry
  - RDRC does NOT approve these type of research studies:
    - Research intended for immediate therapeutic, diagnostic, or similar purposes
    - Research to determine the safety and effectiveness of the radioactive drug or biological product for such purposes (i.e., to carry out a clinical trial).

## RDRRC Reference Information

- **Contact Information**

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<https://www.utsouthwestern.net/intranet/administration/safety/safety-programs/radiation/rad-subcommittees/radioactive-drug-research-committee.html>

(or: <https://tinyurl.com/mr3rrfyn>)



- RDRRC Website Quick Links
  - RDRRC Application
  - Instructions for Completing an Application
  - UTSW RDRRC Guidelines