RDRC Program

- Under the US Food & Drug Administration (FDA)
- Permits basic science research using radioactive drugs in human subjects without an Investigation New Drug (IND) Application when the drug is administered under certain conditions in addition to other requirements.
RDRC

• Review all protocols involving the research use of radioactive drugs and/or agents on human subjects at UT Health, UHS and the Audie Murphy VA.

• Required to ensure compliance with regulations mandated by the FDA. Annual FDA report.
Membership - Required

1. A physician recognized as a specialist in nuclear medicine

2. A person with special competence in radiation safety & dosimetry

3. A person qualified by training & experience to formulate radioactive drugs
Membership - Required

4. Radiation Safety Officer (RSO) UT Health

5. Radiation Safety Officer (RSO) UHS

6. Radiation Safety Officer (RSO) Audie Murphy VA
Membership - General

Individuals knowledgeable in:

1. Clinical Pathology
2. Positron Emitting Tracers
3. Internal Medicine
4. Hematology
5. Endocrinology
6. Radiation Therapy
Membership - General

6. Radiation Physics
7. Radiation Biophysics
8. Health Physics
9. Radiopharmacy
2018 - 2019 RDRC

- **Membership**: all areas of expertise are met
- **Activities**: Quarterly meetings
  - Prompt completion of annual FDA report
  - Expedited review of radioactive drug research protocols
  - Semi-annual review of protocols
  - Review of research subject dose in relation to the research protocol