Radioactive Drug Research Committee (RDRC)  
www.irb.pitt.edu/radiation-guidance

About

The University of Pittsburgh Radioactive Drug Research Committee (RDRC), established under and operating in compliance with the regulations of the U.S. Food and Drug Administration (FDA) at 21 CFR Sec. 361.1, is responsible for reviewing and approving basic research studies involving the use, in humans, of non-FDA-approved radiotracers. Examples of basic research studies that can be approved by the RDRC include clinical investigations intended to obtain basic information regarding metabolism (including kinetics, distribution, and localization) of a radiotracer or regarding human physiology, pathophysiology or biochemistry; but not intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety and/or effectiveness of the radiotracer for a diagnostic or therapeutic application. Approval by the RDRC eliminates the requirement for the submission of an Investigational New Drug (IND) application for the respective non-FDA-approved radiotracer; however the radiotracer (in its radioactive or stable form) must have been previously used in humans and the corresponding radiation dose must be below specified regulatory limits.

The primary services offered by the RDRC include the following:

- Consultation and guidance regarding the acceptability of proposed clinical investigations for review and approval under the RDRC approach;
- Review and approval (in accordance with FDA regulations at 21 CFR Sec. 361.1) of basic research studies involving the human use of non-FDA-approved radiotracers; and
- Completion of FDA-required Special Summary Reports and Annual Reports for clinical investigations approved under the RDRC approach

Contact Us

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<tr>
<th>Name</th>
<th>Title</th>
<th>Contact</th>
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| Dennis P. Swanson, R.Ph., M.S. (Nuclear Pharmacy) | Chairman                  | 412-383-1399  
  swansondp@upmc.edu |
| Michael Sheetz, M.S. | Radiation Safety Officer  | 412-624-2728  
  msheetz@pitt.edu |