AbstractID: 1286 Title: The Radioactive Drug Research Committee - Microdosing

Basic clinical research involving radiolabeled drugs at microdose, or sub pharmacologic levels, does not require an FDA Investigative New Drug (IND) application. Such research can be performed under the authority of a Food and Drug Administration (FDA) approved Radioactive Drug Research Committee (RDRC). This program, codified in 21 CFR 361.1 and established in 1975 to encourage preliminary human research, is a little known program currently consisting of 83 active committees in 2002 (the most recent year for which data is available).

RDRC research is considered basic science research. This research is intended to obtain basic information regarding the metabolism (including kinetics, distribution, dosimetry, and localization) of a radioactive drug. It is not intended for therapeutic, diagnostic, or preventive benefit to the research subject, and is not intended to determine the safety and effectiveness of the drug. These type of investigations would require an IND.

RDRC research must be conducted in a facility licensed for the use of radioactive materials in humans and conducted by qualified study investigators. The research protocols must be approved by the associated Institutional Review Board (IRB). Research subjects must be properly selected, informed, and any adverse events must be reported to the FDA. Quality assurance testing of the radioactive drugs must be performed

Both the pharmacologic dose of the radioactive drug to be administered must be low enough to not cause any clinically detectable pharmacologic effect in humans, and specified [21 CFR 361.1 (b)(3)] organ and whole body radiation dose limits must not be exceeded.