INFORMATION SHEETS

Guidance for Institutional Review Boards and Clinical Investigators
1998 Update

Frequently Asked Questions

EXCERPT

65. Do Radioactive Drug Research Committees (RDRCs) have authority to approve initial clinical studies in lieu of an IND?

No. An IND is required when the purpose of the study is to determine safety and efficacy of the drug or for immediate therapeutic, diagnostic or similar purposes. RDRCs are provided for in 21 CFR 361.1 *Radioactive Drugs for Certain Research Uses*. Radioactive drugs (as defined in 21 CFR 310.3(n)) may be administered to human research subjects without obtaining an IND when the purpose of the research project is to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a radioactively labelled drug or regarding human physiology, pathophysiology, or biochemistry. Certain basic research studies, e.g., studies to determine whether a drug localizes in a particular organ or fluid space and to describe the kinetics of that localization, may have eventual therapeutic or diagnostic implications, but the initial studies are considered to be basic research within the meaning of 21 CFR 361.1. Such basic research studies must be conducted under the conditions set forth in 21 CFR 361.1(b).

All RDRC approved studies must also be approved by an IRB prior to initiation of the studies.

66. Does FDA approve RDRCs?

Yes. An RDRC must obtain and maintain approval by the Food and Drug Administration, as outlined in 21 CFR 361.1(c). RDRCs must register with the Division of Medical Imaging and Radiopharmaceutical Drug Products, (HFD-160), Center for Drug Evaluation and Research, FDA, 5600 Fishers Lane, Rockville, Maryland 20857. The FDA contact for compliance issues is the Human Subject Protection Team (HFD-343), CDER, FDA, 7520 Standish Place, Rockville, MD 20855.
