Subject: Establishment of the Radioactive Drug Research Committee (RDRC)

Definitions:
1. Radioactive Drug: Any substance defined as a drug under the Federal Food, Drug and Cosmetic Act that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. Included are any non-radioactive reagent kit or nuclide generator that is intended to be used in the preparation of a radioactive drug and "radioactive biological products." Drugs such as carbon-containing compounds or potassium-containing salts containing trace quantities of naturally occurring radionuclides are not considered radioactive drugs.
2. Radioactive Drug Research Committee: A sub-committee, under the Human Research Protections Program, which is responsible for the review and approval of research protocols involving human participants and the administration or use of radioactive drugs.

Policy:
It is the policy of the Human Research Protections Program (HRPP) to establish the Radioactive Drug Research Committee (RDRC) to review and approve the use of radioactive drugs in human subjects research.

I. Authority of RDRC.
The structure, authority, and functions of the RDRC are governed by the FDA Regulations at 21 CFR 361.

II. RDRC Review and Approval of Radioactive Drugs in Human Subjects Research.
A. Research protocols involving radioactive drug(s) meeting criteria as outlined in Policy XII.D and requiring IRB approval must be reviewed and approved by the full RDRC Committee.
B. Through the review process, the RDRC has the authority to approve, require modification in, or disapprove the use of radioactive drugs in human subjects research activities that fall under the jurisdiction of the IRB.
C. Research activities may not begin until both RDRC and IRB approvals have been granted.

III. Composition of the RDRC Committee.
A. The RDRC shall consist of a minimum of five (5) individuals qualified in various disciplines pertinent to the field of radiation safety and radiation dosimetry.
B. The RDRC Committee must include the following three individuals:
   1. A physician recognized as a specialist in nuclear medicine;
   2. A person qualified by training and experience to formulate radioactive drugs; and
   3. A person with special competence in radiation safety and radiation dosimetry.

IV. Reporting Requirements.
A. A summary must be provided to the FDA when:
   1. A research activity involves radiation exposure to applicable radioactive drugs (as defined in the FDA regulations or HRPP Policy XII.D) to more than 30 research participants; and/or
2. Participants exposed to these applicable radioactive drugs for research are less than 18 years of age.

B. The RDRC must submit an annual report to the Food and Drug Administration, Center for Drug Evaluation and Research.

References:
21 CFR 361