Subject: Radioactive Drug Research Committee Review

Definitions:

1. **Roentgen Equivalent in Man (REM):** The unit of measurement for a dose of an ionizing radiation that produces the same biological effect as a unit of absorbed dose (1 rad) of ordinary x-ray.

2. **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.

3. **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 to establish the Radioactive Drug Research Committee (RDRC) to review and approve the use of radioactive drugs in accordance with the FDA for use in human subject research.

I. **RDRC Review and Approval of Radioactive Drugs in Human Subjects Research.**

A. Research protocols involving radioactive drug(s) meeting criteria as stated in section II of this policy are to be reviewed by the full RDRC Committee.

B. Amendments or changes to currently approved RDRC studies must be resubmitted for consideration, including the addition of radiological procedures or radioactive drugs and/or the revision of previously approved radiological procedures or radioactive drugs. All revised RDRC applications that continue to meet the criteria as stated in section II of this policy are to be reviewed by the full RDRC Committee. All planned changes in the conduct of the study and/or changes to the informed consent document must be approved by the IRB prior to initiation.

C. Appropriate pregnancy testing is to be used to exclude pregnant women from participation in research involving radiation exposure, due to the serious risks to the fetus.

D. Through the review process, the RDRC has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction.

E. Research activities may not begin until both RDRC and IRB approvals have been granted.

II. **Approval.**

A. The RDRC may approve the use of radioactive drugs in human subjects research provided that all of the following conditions are met.

   1. The pharmacological dose is within the limits such that "the amount of active ingredient or combination of active ingredients to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings."

   2. The radiation dose of the radioactive drug is within the following limits:
(a) Whole body, active blood-forming organs, lens of the eye, and gonads: single dose 3 rem, annual and total dose commitment 15 rem.
(b) Other organs: single dose 5 rem, annual and total dose commitment 15 rem.
(c) The radiation dose shall not exceed 10 percent of these requirements for participants under 18 year of age.

3. The radiation exposure of the radioactive drug is justified by the quality of the study being undertaken and the importance of the information it seeks to obtain.

4. The study meets the other requirements set forth regarding qualifications of the investigator, proper licensure for handling radioactive materials, selecting and consent of research participants, quality of radioactive drugs used, research proposal design, reporting of adverse reactions, and subsequent approval by the IRB.

5. The RDRC has considered additional relevant aspects of the trial, such as the importance of the research, and subject safety.

B. Informed consent is to be obtained from each participant or legally authorized representative with details of the administration and safety precautions of the radioactive drug.

C. All adverse events involving the use of a radioactive drug in research are to be submitted immediately to the IRB/RDRC for review and determination (See HRPP Procedure XII.D.2). All adverse events involving the use of a radioactive drug in research must be reported quarterly and annually to the RDRC.

D. The RDRC must review all approved protocols quarterly and annually. In addition, the research is subject to continuing review requirements of the IRB.

E. All research involving the use of radiation exposure from radioactive drugs is to be conducted in accordance with all applicable HRPP policies and procedures.

References:
21 CFR 361