APPLICATION FOR THE USE OF RADIOACTIVE MATERIAL IN HUMAN SUBJECTS TO THE RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC)

1. **Project Title**:

2. **Principal Investigator**:
   Co-Investigator(s):

3. **State** in which physicians are **licensed** to practice medicine:
   (Note that a physician listed on the University of Florida radioactive materials license must be included.)

4. Information regarding the investigator's basic training and clinical experience with radioisotopes should be forwarded to the Secretary of the Radioactive Drug Research Committee prior to or at the time a proposal is submitted. Forms for submitting this information (**Preceptor/Applicant, RC-1**) are available from the Secretary's office.

5. **Abstract**: *(can be obtained from IRB Protocol)*

6. **Specific Aims**: *(can be obtained from IRB Protocol)*

7. **Background and Significance**: *(can be obtained from IRB Protocol)*

8. **Research Plan**:

   Patient Eligibility:

   A. Inclusion Criteria

      1. Describe subjects to whom the isotope is to be administered as to number, age, sex and approximate weight.

      2. A brief comment as to the disease process with attendant life and health expectancy is warranted.

   B. Exclusion Criteria

      1. Can the data needed be obtained without using radioisotopes? If so, why are radioisotopes to be used?

   Study Design:

   A. Radioisotope Characteristics:

      1. Radioisotope(s) to be used
      2. Type and energy of radiation(s) emitted
      3. Physical half-life (lives)
      4. Biological half-life (lives)
      5. Target organ(s)
      6. Critical organ(s)

B. Clinical or Laboratory Procedures:

1. Dosage to be used; to be repeated?

2. Rationale for the dosage.

3. The proposal should be supported by citation of previous animal and/or human studies which have established the assimilation, distribution, selective localization, and excretion of the radioisotope (or its derivatives) sufficiently well to permit extrapolation to man for dosage purposes.

4. Mode(s) of excretion and per cent by each route.

5. Calculated radiation absorbed dose (in rad and Gray) to target organ, active blood-forming organs, lens of the eye, gonads, and to other critical organs over the entire period of the study and calculate an effective dose (in mrem) to the whole body. Show calculations.

6. Method by which radiation absorbed dose was calculated (i.e. MIRD, ICRP).

7. Expected duration of the study.

C. How will the radioisotope be assayed prior to each dosage?

D. How will the dose to the patient be monitored during the investigation? Is bioassay required? (Include information and calculations used).

E. Describe how personnel responsible for patient care will be trained in the hazards and precautions of the management of radioactive patients.

F. In what manner will radioactive waste produced by the patients be disposed of?

G. Information shall be provided to demonstrate that the amount of material to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings. The pharmacologic dose calculations shall be based on data from published literature or from other valid human studies and should include:

1. active ingredients.

2. maximum amount administered per subject.

H. Information such as the manufacturer's certificate of lot analysis/certificate of authenticity or Principal Investigator's quality control procedure shall be provided to demonstrate that the proposed material to be administered:

1. meets appropriate chemical, pharmaceutical, radiochemical and radionuclidic standards of identity, strength, quality and purity.

2. is of a uniform and reproducible quality.

3. is sterile and pyrogen-free if radioactive material is for parenteral use.

I. Describe how adverse reactions will be reported.

J. A copy of the proposed radioactive drug label must be attached to this application.

9. **Potential Health Risks**:

Refer to the following for the appropriate risk statement. This statement must be included ***verbatim*** in the IRB Informed Consent Form, section 6, "Potential Health Risks or Discomforts".

Risk Statements for Informed Consent Form

A. Informed Consent Statement for Diagnostic Procedures using Radioactive Material

This research study involves exposure to radiation from (insert type of procedure or procedures). The amount of radiation exposure you will receive from this procedure is equivalent to an exposure to your whole body of (insert effective dose calculated in B-5 from "Study Design") mrem. A comparable exposure is equivalent to (insert number of days) days of the amount of natural background radiation exposure people in the United States receive each year. The risk from radiation exposure of this magnitude is too small to be measured directly and is considered to be low when compared with other everyday risks. The investigator will provide you with a contact person if you would like more information about radiation exposure. This contact person is (insert contact name and phone number).

B. Informed Consent Statement for Therapeutic Procedures using Radioactive Material

This research study involves exposure to radiation from (insert type of procedure or procedures). The amount of radiation exposure you will receive from this procedure will be at therapeutic doses with the intent of (insert intent of procedure). As a part of this study, vital organs and normal tissues may receive significant radiation exposure. The potential early and late side effects and the risks of these side effects occurring are as follows. (insert for all organ systems which will receive significant radiation exposure in this study a listing of the potential acute and late side effects and known risks of occurrence at the proposed radiation exposure levels). The investigator will provide you with a contact person if you would like more information about radiation exposure. This contact person is (insert contact name and phone number).

C. Informed Consent Statement for All Radioactive Material Procedures involving Potentially Pregnant Participants

This study may be hazardous to an unborn or breast-feeding child. Therefore, participants who are still menstruating and have not been surgically sterilized must have a negative pregnancy test prior to participating in this study (or studies). The results of the pregnancy test will be made available to the study participant prior to the initiation of this study. Breast-feeding mothers may not participate in this study.