THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

Radioactive Drug Research Committee

Application for Radioactive Drug Research Protocol

1. General Information

Principal Investigator:

Primary Authorized User:

Other Authorized Users:

Project Title:

Please provide a brief description of the project (This purpose statement must match the statement used on Form FDA 2915):

Number of Subjects: **Age Range:**

Number of Controls: **Age Range:**

2. Radiopharmaceutical Information

Radionuclide: **Activity (MBq):** **Scans per Subject:**

Chemical Form:

Production of Radioactive Drug:

Applicant must provide details of the preparation of the radiopharmaceutical to be used in the study. This can be a descriptive paragraph, flow chart, or other format, but it must include a detailed process by which the drug will be prepared.

Attachment Included: ☐ Yes ☐ No

Quality of Radioactive Drug:

Applicant must provide information confirming that the radioactive drug meets appropriate chemical, pharmaceutical, radiochemical and radionuclide standards of identity, strength, quality and purity. Material for parenteral use must be prepared in sterile and pyrogen-free form. Include a list of quality tests and the respective specification for each test.

Attachment Included: ☐ Yes ☐ No

2. Radiopharmaceutical Information (continued)

Radiopharmaceutical Label:

Applicant must provide an example label. The label must include the information required by 21CFR361.1.

Attachment Included: ☐ Yes ☐ No

3. Radiologic Considerations

Dosimetry of All Sources of Ionizing Radiation:

a. Provide absorbed dose calculations based on available biological distribution data from published literature or other valid studies. This dosimetry data should include calculations for the primary critical organ, secondary critical organ, whole body, bone marrow, lens of the eye, and reproductive organs. Dose limits may not exceed:
   Whole body - 3 rem/dose or 5 rem/year
   Organ dose - 5 rem/dose or 15 rem/year

   NOTE: *For research subjects under 18 yrs at last birthday, dose shall not exceed 10% of the above.*
   Radiation dose from procedures involving ionizing radiation (e.g. CT, SPECT/CT, PET/CT) that are part of the research study (i.e., would not have occurred but for study) shall also be included as well as any follow-up possibilities.
   Dose calculations shall be based on MIRD calculations of the Society of Nuclear Medicine or ICRP System. Calculations should be based on biologic distribution data available from published literature or from other valid studies. *Provide documentation of bibliographic sources*

   Attachment Included: ☐ Yes ☐ No

b. Provide manufacturer, model and serial number of instrument used to assay patient dose.
   Manufacturer:
   Model:
   Serial Number:

c. Attach a short summary detailing why the radioactive drug chosen is suitable due to half-life, types of radiation, radiation energy, metabolism, chemical properties, etc., to achieve optimal information from lowest dose to whole body or specific organs.

   Attachment Included: ☐ Yes ☐ No

4. Pharmacologic Information

The pharmacological dose shall not cause any clinically detectable pharmacological effect in human beings; or, the total amount of active ingredients including the radionuclide shall be known not to exceed the dose limitations applicable to the separate administration of the active ingredients excluding the radionuclide. Provide pharmacological dose calculations based on data available from published literature or from other valid human studies. *Provide documentation of bibliographic sources*

Attachment Included: ☐ Yes ☐ No

5. Investigator(s) Qualification

   Provide qualification of investigator to conduct studies by training and experience.

   Attachment Included: ☐ Yes ☐ No

6. Appropriate Selection of Subjects

   a. Obtain approval of Institutional Review Board of consent form which will be required from all participants. Also present for approval to RDRC.

      Attachment Included: ☐ Yes ☐ No

   b. Studies involving minors must:

      i. Present a unique opportunity to obtain information not currently available

      ii. Be without significant risk to the minor, and

      iii. Be supported with review by qualified pediatric consultants to the Radioactive Drug Research Committee.

      Attachment Included: ☐ Yes ☐ No ☐ Not applicable

   c. Female subject shall state that she is not pregnant or submit to confirmatory pregnancy test. Breast feeding must be terminated

      Attachment Included: ☐ Yes ☐ No

7. Research Protocol

Protocol must be based on sound rationale derived from appropriate animal studies or published literature.

Attachment Included: ☐ Yes ☐ No

8. Additional Committee Reviews

Provide the IRB application number:

Provide a copy of the Protocol Review committee application.

Attachment Included: ☐ Yes ☐ No ☐ Not applicable

Certification:

The statements made in this application are true to the best of my knowledge. I accept responsibility for the radiation safety aspects of this study and agree to contact the Radiation Safety Officer and/or the Chairman of the RDRC within 24 hours of any excessive radiation exposure, contamination, or adverse reactions. If required by the terms of approval, I agree to provide the Radioactive Drug Research Committee with Quarterly Progress Reports at the end of each calendar quarter and with a fully completed Form FDA 2915 (Report on Research Use of Radioactive Drug; Study Summary) at the time of initial approval, immediately after the end of each year during which the study was active, and at the completion of the study.

Responsible Physician	Department Chairman
Date	Date