

# Application for New Radioactive Drug Research Protocol

## Radioactive Drug Research Committee

### Duke University Medical Center

Complete this Application in its entirety, including signatures. Attach a descriptive protocol for the proposed research, including specific details which address items 3 – 9. Return the Application and protocol to the Secretary of the Radioactive Drug Research Committee.

<b>TITLE:</b>		
<b>1. Principal Investigator</b>		
Name:		
Department:		
Campus Box:	Phone:	E-mail:
<b>2. Investigator Authorized for Human Use of Radioactive Material (if different from Item 1)</b>		
Name:		
Department:		
Campus Box:	Phone:	E-mail:
<b>3. Proposed Radioactive Drug (Radionuclide/Form):</b>		
<b>4. Route of Administration (parenteral, oral, etc):</b>		
<b>5. Maximum Quantity of Radioactivity Administered per Study (millicuries):</b>		
<b>6. Radiation Dose from Radioactive Drug</b>		
Attach summary of computations of dose, or a copy of a reference from the literature. Complete the table(s). Do not omit any information. If lens of eye dose not available, so state.		
<b>a. Organ /Tissue</b>	<b>b. Rem per Millicurie</b>	<b>c. Rem per Study</b>
Blood-forming Organs		
Gonads		
Lens of Eye		
Critical Organ (specify)		
Effective Dose Equivalent		
<b>7. Radiation Dose From Associated Procedure(s):</b> <input type="checkbox"/> PET Transmission Scan <input type="checkbox"/> CT <input type="checkbox"/> DEXA <input type="checkbox"/> X-ray <input type="checkbox"/> Other (specify)		
<b>a. Organ / Tissue</b>	<b>b. Rem per Study</b>	<b>Total Rem per Study (Sum of 6c and 7b)</b>
Blood-forming Organs		
Gonads		
Lens of Eye		
Critical Organ (specify)		
Effective Dose Equivalent		
<b>(CONTINUE ON NEXT PAGE)</b>		

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<b>8. Pharmacological Dose, Toxicity, Adverse Reactions and Side Effects</b>	
a. Amount of active compound administered (milligrams, micrograms):	
b. "No Observed Effect Level" (NOEL) (milligrams, micrograms):	
c. Attach reference(s) to demonstrate that no clinically detectable pharmacologic effects will occur in humans following administration of the amount of drug stated in 8a.	
<b>9. Drug Quality</b>	
a. <u>Sterility</u> : Attach documentation of sterility of preparation to be administered to research subjects.	b. <u>Non-pyrogenicity</u> : Attach documentation demonstrating that preparation to be administered to research subjects is pyrogen free.
<b>10. Research Subjects</b>	
Minors : <input type="checkbox"/> Yes <input type="checkbox"/> No	Pregnant Women: <input type="checkbox"/> Yes <input type="checkbox"/> No
<b>11. Statement of Understanding</b>	
I / We understand that (a) adverse reactions to the drug described in this protocol shall be reported to the Duke Radioactive Drug Research Committee; (b) sterility and non-pyrogenicity must be documented as required; (c) quarterly and annual reports listing the number of subjects studied and any adverse reactions shall be submitted to the Duke Radioactive Drug Research Committee; (d) approval of the Duke Institutional Review Board shall be obtained before proceeding with human tests; (e) failure to adhere to any pertinent Institutional policies, or regulations of the United States Food and Drug Administration, will result in termination of this protocol.	
<b>12: Signature(s):</b>	<b>Date(s):</b>

Print, sign, date and return this form with all supporting documentation to:

**Secretary**  
**Radioactive Drug Research Committee**  
**Box 3155**  
**Duke University Medical Center**  
**Durham, NC 27710**