

Application for Use of Radioisotopes in Human Research

The Institutional Review Board (IRB) requires that the Radiation Safety Committee (RSC) review all research involving the use of radioactive material in human subjects. Both IRB and RSC approval are necessary prior to beginning this procedure/research. If more than one radioisotope procedure is involved, please complete a separate form for each procedure. Submit the application to Radiation Safety at UT Southwestern, mail code 9053. For additional information call Radiation Safety at (214) 648-2250.

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|------------------------------|----------------------------------|--------------------------|
| Items needed for submission: | RSC Form RSC-021 | 1 original and 12 copies |
| | IRB Form NR1 | 13 copies |
| | Project Summary | 13 copies |
| | Consent Form | 13 copies |
| | Protocol/ Investigators Brochure | 2 copies |

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| Activity Title: |
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|-------------------------|------------|
| Principal Investigator: | Phone: |
| Contact Person: | Phone: |
| Department/Division: | Mail Code: |

| Radioisotope Procedure | | | |
|--|-------------------------------|--------------------------------------|----------------------|
| Procedure: | | Radio-pharmaceutical: | |
| Radioisotope: | | Activity per Procedure (mCi): | |
| Number of Participants Requested | Patients: | Patient Controls: | Non-Patient/Normals: |
| Number of Procedures per | Patients: | Patient Controls: | Non-Patient/Normals: |
| Age Range: | Sex: Female, Male, Both Sexes | Duration of Project: | |
| Whole Body (Effective) Dose (mrem): | | | |
| Critical Organ: | | Critical Organ Absorbed Dose (mrad): | |
| Reproductive Organ and Absorbed Dose (mrad): | | Testes: | Ovaries: |
| Dosimetry Reference (must be included): | | | |

What special precautions are being taken? Is the issue of pregnancy being addressed? _____

Would the patient receive radioactive material if not enrolled in this study? Yes _____ No _____

Is the radiopharmaceutical to be used an FDA approved drug? Yes _____ No _____

Is it being used for the FDA approved procedure? Yes _____ No _____

If not an FDA approved drug what is the IND number and Phase? IND #: _____ Phase: _____

Name of sponsor IND number was issued to? Sponsor: _____

Which physician is certified to administer radiopharmaceuticals? _____

Where will the procedure be performed? Bldg: _____ Room: _____

SIGNATURES

Investigator Signature: _____ Date: _____

Department Chairman: _____ Date: _____

RSC Chairman: _____ Date: _____

Radiation Safety Officer: _____ RSC Approval Date: _____
(UTSWMC)