Instructions for Completion of the

APPLICATION FOR NON-ROUTEINE ADMINISTRATION OF RADIONUCLIDES OR RADIATION TO HUMANS

The Medical Radiation Subcommittee of the Temple University Radiation Safety Committee, Radioactive Drug Research Committee and the Radiation Safety Department are charged with the oversight of non-routine administration of radionuclides and radiation to humans. This includes diagnostic, therapeutic, and research usage. The committee is also responsible for notifications to the US FDA of any adverse events. The enclosed application MUST be completed prior to any non-routine administration. Questions and reports of adverse effects should be forwarded to the Radiation Safety Department at 215-707-2520.

Items

1, 2  Self explanatory
3  Insert the name of the Investigator/User authorized in the use of the radioactive substance or machine. This person will be chiefly responsible for compliance and reporting to the committee. This person must be authorized by Temple University Radiation Safety Committee. Please contact the Radiation Safety Officer for questions.

4  The protocol must include a detailed description of the radionuclide or other radiation to be utilized. The consent form should describe the amount of radiation and potential effects of the radiation in terms understandable to the subjects. The radiation dose may be given in reference to standard tests (such as “the amount of radiation in 2 standard chest x-rays”) or in relationship to standard treatments (such as “twice the radiation of a routine cardiac catheterization” or “the amount of radiation used to treat brain cancers in non-research settings”). The short term side-effects and potential long-term side effects should be clearly defined. Any specific late monitoring should also be given. Trivial doses not expected to cause adverse effects should be stated to be trivial, rather than being omitted. Investigators with questions about wording on the consent are urged to call the radiation safety office before submitting the protocol in order to speed the approval process.
5  Self explanatory.

6  Insert source, body site, amount of radiation and additional information as noted on form

7  The protocol should have a description of the dosimetry to vital organs, and the expected elimination.
   SEE BELOW FOR ADDITIONAL INFORMATION.

8  Include site and room/area, if known (example, Temple University Hospital, Clinical Research Unit). The chosen site must be approved by the Radiation Safety Office to deal appropriately with shielding, spills, accidents.

9  Examples include chemotherapy agents which affect toxicity, screening/follow-up diagnostic x-rays. Radiation used as part of routine medical care should be listed in this section.

10 Self explanatory; A statistical section in the protocol outlining the number of subjects required to achieve the power of analysis is suggested.

11 Self explanatory

12 Certain Non-routine uses of radiation must be reviewed by the Temple University Medical Radiation Subcommittee and must be reported annually (or at the completion of the study) to the FDA. These include:
   a) Studies with greater than 29 patients studied at Temple University (or Temple affiliate site)
   b) Studies involving subjects under the age of 18
   c) Studies using non-FDA approved radiopharmaceuticals (if applicable, list IND number)

13,14 Self explanatory
INFORMATION ON DOSIMETRY AND RADIATION ELIMINATION
(question7)

I. EXPOSURE FROM DIAGNOSTIC PROCEDURES

A. Radiopharmaceuticals

The following are the preferred sources of dosimetry information:

1) For an approved radiopharmaceutical to be administered to adults by
   the usual route of administration, a copy of the package insert
   containing dosimetry information should be provided.

2) For a radiopharmaceutical which is approved for use in adults but will
   be administered to children, radiation dosimetry for various ages/body
   sizes of children should be obtained from a reputable source e.g., Oak
   Ridge Institute of Nuclear Studies.

3) For an approved radiopharmaceutical to be administered by a
   nonstandard route of administration, appropriate dosimetry
   calculations should be submitted. The submission can consist of a
   detailed article is available. The information should include the
   expected biodistribution and kinetics of the radiopharmaceutical,
   determined either in humans or in two animal species, only one of
   which may be a rodent. All of the administered radioactivity should
   be accounted for. Assumptions and calculations must be performed by
   a person knowledgeable in dosimetry calculations, and presented in
   sufficient detail to permit evaluation by the committee

4) For an investigational radiopharmaceutical, the information requested
   in item 3) above will be required. In addition, the following
   information may also be required:

a) copy of IND (if on has been submitted to FDA).

b) Source of drug/methods of manufacture. This should be comparable
   to an IND submission and should consist of detailed standard
   operating Procedures if prepared in-house.

c) A statement of the purity/quality requirements of components and final
   products, and testing methods used to determine ppurity/quality.
   Includes chemical purity, radiochemical purity, radiochemical purity,
   sterility, nonpyrogenicity, potency and specific radioactivity.

d) Toxicity information
B. Fluoroscopy

The dose rate and maximum beam on time should be given. Doses provided should include expected skin entrance exposure, estimated midline exposure, and gonadal doses. The unit should be identified by model and serial number.

C. Other x-ray

Provide expected skin entrance exposure, estimated midline exposure, and gonadal doses.

II. RADIATION THERAPY DOSES

A. Sealed implants or HDR

Give doses to target tissue.

B. External beam

Give doses to target tissue. If fractionated, state number of fractions and dose/fraction.

C. Unsealed radiopharmaceuticals

Provide the same type of information as for diagnostic radiopharmaceuticals.
APPLICATION FOR NON-ROUTINE ADMINISTRATION OF RADIONUCLIDES OR RADIATION TO HUMANS

Principal Investigator _______________________________
Date _____________________

1) Title of study:

2) Co-Investigators:

3) Authorized Radiation User (title, department):

4) Enclose a copy of the Protocol and the Informed Consent Form. See instructions for details regarding required consent descriptions of radiation dosing.

5) What is the primary Use of Radiation?
   [] Diagnostic  [] Therapeutic  [] other (describe)

6) What are the primary Sources of radiation for research purposes and in what amount?
   [] Radionuclide___________ Amount ________________
   [] Sealed source___________ Amount ________________
   [] X-ray_________________
     [] Standard radiograph: Site/Number___________
     [] CT: Site/Number__________
     [] Bone densitometry: Site/Number______________
   [] Fluoroscopy______________
     Site/Number/Number Spot films__________________
     Fluoro on-time __________ Magnification__________
     Typical kVp _____________ Cine-mode______________
   []Other (specify)______________________________
7) Does the protocol contain information on dosimetry and radiation elimination

[ ] Y (indicate page numbers)_________________

[ ] N (why)______________________________

8) Where will the primary radiation be administered?

9) Are other substances used in the protocol that may interfere with the elimination, add to the overall radiation exposure, or affect the toxicity? List:

Are other sources of radiation used in the protocol for purely clinical purposes? List:

10) Human Subjects to be Studied:

(please indicate how numbers chosen)

Number Overall: Age Range:

Number with Disease: Number Without Disease:

Gender: # Males _____ # Females ______

11) a. Will pregnant women be enrolled in the study? [ ] Yes [ ] No

If yes, why? __________________________

b. Will women of child bearing age be enrolled? [ ] Yes [ ] No

If yes, describe method to identify pregnancy? ______________________

c. Will study subjects be asked to use some form of contraception for the duration of the study? [ ] Yes [ ] No

If yes, what form(s)? ______________________________

If no, why not? ______________________________
12) Does this Radiation Use require reporting to the FDA?  
[ ] Yes  [ ] No  See instruction sheet for details

13) Is this study part of a multi-institutional trial?  [ ] Y  [ ] N
Is this study sponsored? [ ] Y(sponsor name) ____________________ [ ] N
Is this study part of a grant proposal? [ ] Y (deadline) __________ [ ] N

14) Certification: I affirm that each person who will use radioisotope and/or radiation producing machines under the authorization for this project has or will have received training in both the general (University wide) and specific (laboratory/procedure based), if any, radiation safety requirements for the safe conduct of the work. I will also comply with reporting schedules, including prompt notification of any unexpected toxicities and annual reports, to the Medical Use Subcommittee.

Printed Name of Principal Investigator

__________________________________________  ____________________________
Signature of Principal Investigator              Date

Printed Name of Authorized Radiation User  
(if different from PI)

__________________________________________  ____________________________
Signature of Authorized Radiation User  
(if different from PI)                Date