

Instructions for Completion of the

APPLICATION FOR NON-ROUTINE 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 if 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 one 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 purity/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