**Application for Human Use of Ionizing Radiation in Research**

**(university of north carolina - Form ua-1b)**

# PART I: General Information.

**Title of Project:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Biomedical IRB Project Number:**\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Telephone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_

## Mailing Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Authorized Physicians:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Co-Investigators and Staff:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Indicate all sources of radiation to be used in this project**

\_\_Radiopharmaceutical \_\_ Bone mineral analyzers (DEXA, QCT)

\_\_ Diagnostic x-ray machines \_\_ Bone mineral analyzers (radioactive source)

\_\_ Radiotherapy machines \_\_ Fluoroscopy

\_\_ Other

**Number of Studies per Subject** \_\_\_\_\_\_\_\_\_\_\_\_ **Subject Age**\_\_\_\_\_\_\_\_\_\_\_

**Subject Sex**\_\_\_\_\_\_\_\_\_\_\_ **Total Number of Subjects**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Can the desired information be obtained more easily, accurately, or safely by other methods? Give brief explanation:

Briefly Outline Purpose of Project and/or attach summary of proposal (IRB Form HR 5):

**PART II:** Radiopharmaceuticals.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

 Radiopharmaceutical approved by FDA (standard Nuclear Medicine Procedure)

 Radiopharmaceutical covered under IND (attach copy of FDA IND approval letter)

IND Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Radiopharmaceutical and proposed study meet criteria for approval by Radioactive Drug Research Committee (RDRC): Complete and submit UNC RDRC Application instead of Part II information listed below.

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Radionuclide:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Chemical Form:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Radiations and Energies:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physical Half-Life:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Biological Half-Life: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Activity (mCi) administered/study:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Radiation dose (rads) per administration:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Route of administration:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Critical Organ\*: , Radiation Dose:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Testes\_\_\_ Ovaries Bone Marrow\_\_\_\_\_\_\_\_\_\_\_\_

Liver Kidneys Thyroid \_\_\_\_\_\_\_\_\_\_\_

Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\* Critical organ is that receiving the highest radiation dose.

**Effective Dose (rem):**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Source of dose estimate (circle one):** Sponsor, PI, Radiology Physicist, RSO

Clearly state if per administration or for total study.

Location of subjects when receiving material:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Radiation Safety Office has been contacted regarding purchase, receipt, handling, storage, and disposal of radioactive materials: Yes\_\_\_ No \_\_\_ N/A \_\_\_

Describe procedure for radiopharmaceutical dosage preparation, standardization, assessment of radionuclidic and radiochemical purity, sterility and pyrogenicity:

**PART III:** Radiation Sources (non-radiopharmaceutical).

Briefly describe the source of radiation to be used:

Who will operate the radiation source?

**Radiography**

Will UNC Medical Center Department of Radiology standard protocols be followed: Y/N

If yes, please identify the imaging protocol(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If no, provide the requested information below for each exam or projection to be used:

Body Part Projection Number of Images

How many times will this radiographic procedure be performed on the same person during the course of the experimental study:\_\_\_\_\_\_\_\_\_\_\_

**Effective Dose (rem)**:\_\_\_\_\_\_\_\_\_\_

**Source of dose estimate (circle one):** Sponsor, PI, Radiology Physicist, RSO

Clearly state if per exposure or for complete study.

**Fluoroscopy**

Fluoroscopic room(s) to be used for this study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Fluoroscopic protocol used: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Primary organs imaged: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Estimated maximum fluoroscopy time:\_\_\_\_\_\_\_\_\_minute(s)

Fluoroscopic pulse rate used (pps): \_\_\_\_\_\_\_\_\_\_\_

Estimated maximum DA/DSA time, if applicable:\_\_\_\_\_\_\_\_\_seconds

DA/DSA frame rate used (fps), if applicable: \_\_\_\_\_\_\_\_\_\_\_

Number of cone-beam CT (volume imaging) scans, if applicable: \_\_\_\_\_\_\_\_\_\_\_

How many times will this fluoroscopic procedure be performed on the same person during the course of the experimental study: \_\_\_\_\_\_\_\_\_\_\_\_\_

**Effective Dose (rem)**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Source of dose estimate (circle one):** Sponsor, PI, Radiology Physicist, RSO

Clearly state if per exposure or for complete study.

**PART IV:** Signature.

I affirm that the information provided is correct to the best of my knowledge and that I shall conduct, or supervise the described work with full regard for safety of the general public, those engaged in the work, and the radiation safety procedures as established by University of North Carolina Hospitals.

Signed\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Applicant

Signed\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Radiation Safety Officer

# Instructions: Application for Human Use of Ionizing Radiation in Research

**PART I:**

List title of project and if you already have a number assigned by the Office of Human Research Ethics–Biomedical Institutional Review Board (IRB), please indicate. For the use of radiopharmaceuticals, our license has designated specific "Authorized Users" (AU’s). A complete list of AU’s can be obtained by contacting the Chairperson of the Radiation Safety Subcommittee. For radiation sources (non radiopharmaceutical), board certified Radiologists or Radiation Oncologists are "authorized" physicians. If the principal investigator is not an authorized user, or faculty member, then such a person must be listed as a participant and indicated on the consent form as a responsible contact.

Indicate by the appropriate checks, all sources of radiation that the subject will be exposed to as part of this project. For example, if the subject is undergoing a bone mineral study, and will also receive a radiograph that would not be done as part of a

routine clinical work up, the radiation exposure from the radiograph should be included

as part of this project.

The number of studies, age, sex, and no. of subjects are needed to document the population exposure. Project outline- please briefly state the aims of the project, why the use of radiation is necessary to conduct the research, and outline the research protocol.

**PART II:**

Shaded area is to be completed for any project involving radiopharmaceuticals. For studies that meet the criteria for approval by the Radioactive Drug Research Committee (RDRC), submit a UNC RDRC Application instead of the remainder of Part II. Such studies must be basic research and meet limits on pharmacological dose and radiation dose as specified in the RDRC regulations. [Use of Radioactive Drugs in Research](https://www.ecfr.gov/cgi-bin/text-idx?SID=a1870595b66181994d78903e7bb88140&mc=true&tpl=/ecfrbrowse/Title21/21cfr361_main_02.tpl)

For all other studies involving radiopharmaceuticals, complete the remainder of Part II. The radiation dose to the organs is the total dose for the administered activity per administration. The Radiation Safety Office should be contacted and provided information about the purchase and handling of radioactive materials. The exception to this is when the procedure is handled through Nuclear Medicine.

**PART III:**

When x-ray machines are the sources of the radiation, a description of the procedure should be given to include what part(s) of the body are to be exposed, if shields are used to shield the subject, if special x-ray beam filters will be used, and what the radiation exposure dose is to the subject. It is recommended that x-ray equipment, operators and special filters or other dose reduction equipment be scheduled well in advance of the experimental study.

**Part IV:**

Applicants must sign and date the application.

**Consent Form:**

In addition to the application form, a copy of the consent form should be included. With respect to the radiation exposure to the subject, this committee has established the policy that the following information be provided to the subject:

(A) The radiation dose associated with the test must be stated in mrem or rem. A general statement that puts in perspective what that radiation dose means is considered to be useful. For suggestions about how this can be presented see

Guidelines for the Assessment of Radiation Risks.

(B) If female subjects are included in the project, there must be a statement in the consent form that precludes the participation of pregnant or possibly pregnant subjects. In some cases, project protocols may include a pregnancy test as part of the subject selection process.

(C) Subjects are discouraged from participating in more than one project that involves radiation in any one year period. In addition, subjects employed as radiation workers should not participate as healthy volunteers in research involving radiation exposure unless they are fully cognizant of their occupational radiation exposure.

Send application to the Chairman of the Radiation Safety Subcommittee:

Marija Ivanovic, Ph.D.

CB# 7510

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