Applications must be received at least 14 days prior to the UCDHS Radiation Committee meeting.

When an investigative procedure involves exposure of human subjects to ionizing radiation, Federal, State, and University regulations require prior approval by the UCDHS Radiation Use Committee and the UCD Institutional Review Board (IRB). Such approval is granted only when, in the collective judgment of the Committee, the benefits outweigh the risks. The completed form will provide information to the UCDHS Radiation Use Committee and is designed to facilitate verification of the radiation exposure calculations which, together with other information, determine the potential risks. Evaluation of potential benefits rests not only with the research goal, but also on the details of the experimental design.

Use this form when requesting an authorization to:

- Use radioactive material/radiopharmaceuticals in human research.
- Use diagnostic x-ray, fluoroscopy, or any other external radiation source in human research.

**NOTE:** Research means any procedure not routinely performed for patient diagnosis or therapy.

A draft of this form and the consent form should be prepared and faxed (734-7309) or e-mailed to the UCDHS Health Physics Office (phone 734-3355) for preliminary review. No later than 2 weeks before a committee meeting, submit an original, signed application form, consent form(s), and all attachments to the UCDHS Health Physics Office, FSSB, Suite 2500. In addition, forward an electronic version of the entire submission to the Health Physics staff person assisting you with the application.

**IMPORTANT:** This application, the Human Radiation Use Research Application, and consent forms must be typewritten and completely filled out before processing of your application can begin. Any omissions will result in unnecessary delays.

This application to use radiation in human research is required in addition to, and not as a replacement of, the Human Subjects Protocol Form. Final approval of your proposed research project rests with the Office of Human Research Protection involving clinical or physiological studies on human subjects (i.e., IRB).

A safety protocol (Form 4) must be prepared and submitted along with the Human Radiation Use Research Application to the UCDHS Health Physics office for addition to the Radiation Use Authorization or Machine Use Authorization under which the research will be performed.
GENERAL CRITERIA FOR THE USE OF RADIATION IN HUMAN RESEARCH

A. The radiation dose shall be as low as is reasonable to perform the study. X-ray procedures must use all appropriate dose limiting devices (i.e., collimation, gonadal shielding).

B. The radiation exposure is justified by the quality of the study being undertaken and the importance of the information it seeks to obtain.

C. The investigator must use adequate instrumentation and quality control for the administration, detection and/or measurement of the radiation.

D. Each investigator must be qualified by training and experience to conduct the proposed research study. This includes adequate radiation safety equipment and experience as determined by the UCDHS Radiation Safety Officer, Director of Health Physics Programs, and/or UCDHS Radiation Use Committee.

E. Subjects under the age of 18 are only permitted under special situations. It must be demonstrated to the UCDHS Radiation Use Committee that the study presents a unique opportunity to gain information not presently available and does not pose a significant risk to the subject. Furthermore, these studies must be reviewed by qualified pediatric consultants.

F. Each female research subject of childbearing age must state in writing that she is not pregnant, or be confirmed not to be pregnant, on the basis of a pregnancy test. In either case, documentation shall be maintained.

G. The number of subjects to be studied will be sufficient but not greater than the number necessary for the purpose of the study.

H. Adverse reactions must be reported to the UCDHS Radiation Use Committee immediately.

I. Before the research is instituted, a Human Radiation Use Research Application must be submitted and approved by the IRB and a Human Use RUA or MUA with study specific protocols must be in place.

J. The guidelines for consent form statements to be used when human subjects are exposed to ionizing radiation are provided in Attachment 3. The risk estimates are based on information from the International Commission of Radiological Protection Booklet Number 60, reports of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and other pertinent data. Risk estimates will be approved by the Director of Health Physics Programs, UCDHS Radiation Safety Officer or Health Physics staff.
CRITERIA FOR EVALUATING THE USE OF INTERNALLY ADMINISTERED RADIOACTIVE MATERIAL IN HUMAN RESEARCH

A. The investigator must provide an acceptable method of radioassay to ensure that the proper amounts of radiopharmaceutical is being administered (e.g., dose calibrator).

B. The responsible investigator must have a Human Radiation Use Authorization to possess radioactive material in the quantity and type described in the study. Radiation Use Authorization Amendment Request form describing any change in laboratory protocol or experimental design involving radioactive material should be completed and be included in your application. Any personnel handling radioactive material must be listed on the RUA and have a Statement of Experience on file. Personnel not on the RUA must be added by submitting an Radiation Use Authorization Amendment Request, together with a completed Statement of Experience. The principal investigator is responsible for providing the appropriate specific radiation safety training for each member of the research team involved in the project. This training must be documented and kept on file by the principal investigator.

C. The radioactive drug must be prepared in a sterile and pyrogen-free form except when given orally.

D. If the radioactive material is not an FDA approved pharmaceutical or an Investigational New Drug (IND), then it will fall under the FDA requirements for Radioactive Drug Research and the following information is required in the protocol:

1. Describe the importance of the information the study seeks to obtain: what scientific knowledge and benefits are likely to result from the study? The study must be based on sound rationale derived from appropriate animal studies or published literature. It must be of a sound design such that information of scientific value shall be obtained.

2. Provide information about the quality of the radioactive drug or material used. Chemical and radiological contaminants must be quantified.

3. Describe the research protocol design.

4. The protocol will include provisions that the Health Physics Office and the IRB shall be notified immediately of any adverse reactions experienced by any of the subjects.

5. If the number of research subjects exceeds 30 or the age of the subjects is under the age of 18 a summary report must be filed by the RDRC with the FDA. Also, the allowable radiation dose for subjects under the age of 18 shall not exceed 10% of the adult limit.

6. Submit an acceptable method for radioassay of the drug or material prior to use to assure that the dose calculations reflect the administered dose.

7. Human subjects information required to be submitted to the FDA by the RDRC:
   a. Age, sex and approximate weight
   b. Total activity of each radionuclide administered
   c. If the subject has participated in other radioactive drug research studies, report the name of the drug, date of administration, total activity of each radionuclide administered. If x-ray studies were performed, identify the x-ray procedure and an estimate of the absorbed radiation dose.

8. Adhere to the “Use of Isotopes in Human Studies Checklist” provided by Health Physics.

9. For RDRC studies, provide a complete copy of the description of study from the IRB submittal.
HUMAN RADIATION USE RESEARCH APPLICATION

A. Principal Investigator: Responsible for scientific aspect of study.

1. Name: ____________________________
   Title: ______________________________
   Address: ____________________________
   Department: _________________________
   Telephone Extension: __________________
   E-mail address: ______________________

2. Physician responsible for medical aspects of the study if the Principal Investigator is not a licensed Medical Doctor in the State of California:
   Name: ____________________________  Signature: ______________________

B. If this protocol involves the use of radioactive material, indicate current Human Use RUA under which this study will be performed. RUA #____________. If RUA is not held by the principal investigator, indicate the individual whose RUA will be responsible for this aspect of the study and have them sign below, indicating their concurrence. Their signature indicates the willingness to assume responsibility for all radiation safety activities for the project performed under their RUA.

   Name: ____________________________
   Radiation Use Authorization: ____________________________
   Address: ____________________________
   Department: _________________________
   Telephone: __________________________
   Signature: ____________________________

C. Title of Study (Be sure to use the same title on your IRB application form):

D. Brief Purpose of Study:
E. Subject Selection and Consent:

1. Indicate subject selection below:

   ■ Will normal subjects be studied? YES ____ NO ____
   Number: __________ Age Range: __________ Sex: __________
   Provide a statistical justification for the number of study subjects:

   ■ Will subjects with manifest disease be studied? YES ____ NO ____
   Number: __________ Age Range: __________ Sex: __________
   Provide a statistical justification for the number of study subjects:

   ■ Will women of childbearing potential be studied? YES ____ NO ____
   Number: __________ Age Range: __________
   □ If female subjects of childbearing potential are studied, will written evidence of non-pregnancy be obtained in the consent form? YES ____ NO ____ Not applicable ________

   ■ Will pregnant or lactating women be studied (justification required)? YES ____ NO ____

   ■ Will you be using yourself as the subject for this research? YES ____ NO ____
   If yes, please review section VIII.B.6, Self Subject Policy of this manual on page VIII-2.

2. List inclusion and exclusion criteria (be specific):

3. Indicate below the primary purpose for which the proposed procedure will be performed:
   ( ) Accumulation of scientific knowledge.
   ( ) Clinical trial of a new radiopharmaceutical product.
   ( ) Clinical trial of a new x-ray procedure.
   ( ) Benefit to health of participating subjects.

4. Will subjects be hospitalized? YES ____ NO ____

   Will normals be hospitalized? YES ____ NO ____
   If yes, describe under what circumstances, and who will assume responsibility for, any special requirements or procedures during the hospitalization (e.g., radioactive urine collection, special posting, isolation, etc.).
F. Absorbed Radiation Dose (show calculations on attached sheet):

1. List all exposure to ionizing radiation that the subject will receive during the course of this study. Indicate which exposures are part of normal patient care and which are part of the research procedure:

2. Number of Radionuclide Exams/Subject ________ Interval between exams ________

3. ICRP-103 Effective Dose Calculation
   (1 rad = 10 mGy; 1 rem = 10 mSv)

<table>
<thead>
<tr>
<th>Organ</th>
<th>( w_i )</th>
<th>rad/exam (1)</th>
<th>CED (rem)</th>
<th>CED (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Bone Marrow</td>
<td>0.12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colon</td>
<td>0.12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>0.12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stomach</td>
<td>0.12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>0.12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gonads</td>
<td>0.08</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bladder</td>
<td>0.04</td>
<td></td>
<td></td>
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<tr>
<td>Liver</td>
<td>0.04</td>
<td></td>
<td></td>
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<tr>
<td>Esophagus</td>
<td>0.04</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.04</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td>0.01</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone Surface</td>
<td>0.01</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brain</td>
<td>0.01</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salivary glands</td>
<td>0.01</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remainder(^2)</td>
<td>0.12</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

   Effective Dose

\[ \text{Effective Dose} = \sum \text{CED} \]

\[ \text{Effective Dose} = 0.12 \text{ rem} \]

\[ \text{Effective Dose} = 0.12 \text{ mSv} \]

1 Indicate total organ dose for all radiopharmaceuticals used in study.

2 \( w_i \) is arithmetic mean of 14 remainder organs: adrenals, extrathoracic region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate, small intestine, spleen, thymus, and uterus/cervix.

4. Source of formulas used in effective dose calculations for the radiopharmaceutical component:

   MIRD _________ Other ____________________________

   Reference(s) documenting biological distribution and clearance data:

5. Number of X-ray/Fluoro Exams/Subject ________ Interval between exams ________

   Effective Dose Estimate for all radiographic/fluoroscopic exams: ________ rem; ________ mSv

   Source of radiographic/fluoroscopic dose information:
   ( ) Tables: Specify source and page number.
   ( ) Measured Data: Attach data.
   ( ) Calculation: Attach calculation.

6. Total Effective Dose Estimate from all sources of ionizing radiation: ________ rem; ________ mSv

G. If the study is using radioactive materials, complete Attachment 1. If x-rays, fluoroscopy, or external radiation is involved, complete Attachment 2.
H. Consent Form: Consent forms must follow IRB format. The Radiation Risk Statement (Attachment #3) will be provided by the Health Physics Office during the review process. Attach a copy of the consent form(s) to this application.

I. List of Pertinent References (attach reprint of principal reference).

J. Certificate

Statements made in this application are true to the best of my knowledge and belief. I accept responsibility for the radiation safety aspects of this study and agree to contact the UCDHS Health Physics Office (734-3355) within 24 hours of any excessive radiation exposure, contamination, or adverse reactions.

______________________________  ______________________________
Principal Investigator                      Department Chairperson

______________________________  ______________________________
Signature                     Date                      Signature                      Date
USE OF UNSEALED RADIOACTIVE MATERIAL

A. Radionuclide: ___________________ Chemical Form: _____________________________

Route of Administration: _______________________________________________________

Dose per administration (mCi): ___________ No. of administrations: ________________

B. Will the administered radiopharmaceutical be obtained in pharmaceutical refined form for human use?
   Yes ________ No ________

C. Will the user prepare, process, or modify the drug in any way?
   Yes ________ No ________

D. Describe in detail the preparation, processing, or modification of the drug.

E. Describe the tests that will be used to establish the identity, purity, and non-toxicity of the drug.

F. Describe the manner in which batches of the drug will be assayed and tested for sterility and pyrogenicity.

G. Will the process described be carried out by, or under the supervision of, a registered pharmacist?
   Yes______ No ________ If not, state the qualifications of the individual and attach a C.V.

H. Material will be tested for radiochemical purity.  
   By User  By Manufacturer  Not applicable
   ( )  

Material will be tested for sterility. 
   ( )  

Material will be tested for pyrogenicity. 
   ( )  

01/09
I. Does the total amount of pharmacologically active ingredients cause any clinically detectable pharmacological effects in human subjects?

Yes ________ No ________

Name of non-radioactive drug: ____________________________

Maximum mass dose of non-radioactive drug administered per dose (mg): __________

No-Observed-Effect-Level (NOEL) mass dose (mg): __________

Cite reference for the above information:

---

J. Maximum amount of radioactivity to be on hand at any one time:

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>Amount (mCi)</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

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K. What method of radioassay will be employed to verify that the dose to be administered is correct?

Dose calibrator __________ Other __________ (Explain)

---

L. What criteria was used to determine the administered dose?

---

M. What count rates or are expected from the samples? ________________________________

---

N. Is the use covered by a physician-sponsored Notice of Claimed Investigational Exemption for a New Drug (IND) filed with the U.S. Food and Drug Administration? Yes ________ No ________

IND No. ________________________________

If so, attach Forms FDA 1571 and 1572 and the acknowledgment of receipt of the application from the FDA.

01/09
O. Is the use covered by a manufacturer sponsored Notice of Claimed Investigational Exemption for a New Drug (IND) filed with the U.S. Food and Drug Administration? Yes _____ No _____
IND No. __________________________
Company Name: ________________________________________________________________

If so, attach Forms FDA 1571 and 1572 and the acknowledgment of receipt of the application from the FDA.

P. Does this experiment require a change to any of the conditions of your RUA?
Yes _____ No _____
If yes, complete an RUA Amendment Request and attach it to your application.

Please note any change in:

  ( ) Responsible user.

  ( ) Type, form, maximum amount, or experimental amount of the radioactive material.

  ( ) Type of procedure (attach new or reference existing safety protocol).

  ( ) Authorized personnel (attach Statement of Experience).

  ( ) Authorized location.

Q. Indicate all locations where ionizing radiation will be used for this research study:
USE OF X-RAYS/FLUOROSCOPY OR OTHER EXTERNAL RADIATION SOURCE IN HUMAN RESEARCH

A. What type of x-ray equipment will be used in this study?

B. List techniques/methods used to minimize patient exposure:

C. Indicate all locations where ionizing radiation will be used:

D. Examination:

- Will a written order for the exam be obtained from a physician familiar with the research protocol?  
  Yes ______ No ______

- Will California state certified UCDHS x-ray technologists be performing the exam?  
  Yes ______ No ______

- Will a radiologist be performing the exam?  Yes ______ No ______

- Will a radiology resident/fellow be performing the exam?  Yes ______ No ______

- Will a physician certified x-ray supervisor and operator be performing the exam?  
  Yes ______ No ______

- Will a physician certified x-ray supervisor and operator be onsite or offsite? (Circle one)

E. Provide the following information for each research x-ray procedure you wish to perform:

<table>
<thead>
<tr>
<th>Name of Procedure</th>
<th>Typical mAs</th>
<th>Typical kVp</th>
<th>Comments</th>
</tr>
</thead>
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</tbody>
</table>
### NON-THERAPY PROCEDURES

1. The proposed study involves an effective dose of ≤ 20 mrem to a human subject. Use the following statement:
   
   This study involves a low radiation exposure that is less than other diagnostic tests using ionizing radiation. The amount of radiation exposure received in this study is below the levels that are thought to result in a significant risk of harmful effects.

2. The proposed study involves an effective dose of ≤ 5 rem (but greater than 20 mrem) to a human subject. Use the following statement:
   
   This study involves a radiation exposure that is typical of other diagnostic tests using ionizing radiation. The amount of radiation exposure received in this study is below the levels that are thought to result in a significant risk of harmful effects.

3. The proposed study involves an interventional procedure on a human subject. Use the following statement:
   
   This study involves a radiation exposure that is typical of other interventional procedures using ionizing radiation. Risks of this procedure include a slight possibility of skin reddening, temporary or permanent loss of hair or, rarely, permanent skin damage.

4. The proposed study involves an effective dose of ≥ 5 rem to a human subject. Use the following statement:
   
   This study involves a moderate radiation exposure that is higher than other diagnostic tests using ionizing radiation. The exposure to radiation from this procedure may result in a slight increase in your risk of developing cancer.

5. The proposed study involves an effective dose of ≥ 5 rem to a human subject with cancer. Use the following statement:
   
   This study involves a radiation exposure that is higher than other diagnostic tests using ionizing radiation. The exposure to radiation from this procedure might result in a slight increase in cancer risk in normal healthy individuals. However, since you already have cancer, a risk estimate cannot be accurately determined. [(If the person is undergoing radiation therapy, use this additional statement.) The amount of radiation for this research study is low compared to the radiation dose from the treatment of your cancer.]

### RADIATION THERAPY PROCEDURES

5. The exposure to radiation from this procedure has been correlated with an increase in cancer risk in normal healthy individuals. However, since you already have cancer, a risk estimate cannot be accurately determined.

### PREGNANCY

If women of childbearing age are to be included in this study, the following statement must appear with the appropriate risk statement in the consent form.

6. If you are a woman of childbearing years and are pregnant or think that you could be pregnant, please inform the investigators. Pregnant subjects may not participate in this study.

### BREAST FEEDING

Women who are breast feeding may not participate in studies when radionuclides are taken internally.

7. If you are a woman who is breast feeding a child, please inform the investigators. Women who are breast feeding may not participate in this study.