APPLICATION FOR THE USE OF RADIATION IN HUMAN SUBJECTS TO THE HUMAN USE OF RADIOISOTOPES AND RADIATION COMMITTEE (HURRC)

1. **Project Title**:

2. **Principal Investigator**:
   Co-Investigator(s):

3. **State** in which physicians are **licensed** to practice medicine:
   (Note that a physician approved by the Credentialing Committee for the use of x-ray machines must be included.)

4. Information regarding the investigator's basic training and clinical experience with radiation machines should be forwarded to the Secretary of the Human Use of Radioisotopes and Radiation Committee prior to or at the time a proposal is submitted. Forms for submitting this information (**RC-1X**) are available from the Secretary's office.

5. **Abstract**: *(can be obtained from IRB Protocol)*

6. **Specific Aims**: *(can be obtained from IRB Protocol)*

7. **Background and Significance**: *(can be obtained from IRB Protocol)*

8. **Research Plan**:

   Patient Eligibility:

   A. Inclusion Criteria

      1. Describe subjects to whom the radiation is to be delivered as to number, age, sex and approximate weight.

      2. A brief comment as to the disease process with attendant life and health expectancy is warranted.

   B. Exclusion Criteria

      1. Can the data needed be obtained without using radiation studies? If so, why are radiation studies being used?

   Study Design:

   A. Clinical Procedures:

      1. Type of radiation exam, i.e. if *Diagnostic* state type of Radiographic, Fluoroscopic, CT, or Mammography exam or type of *Radiation Oncology* procedure.

      2. Is this an exam that will be performed just once or repeated? If repeated, how many total exams for the duration of the study?

3. Rationale for the exam.

4. The proposal should be supported by citation of previous studies which have established the assimilation and distribution of the radiation (or its derivatives) sufficiently well for dosage purposes.

5. For Diagnostic procedures, calculate the effective dose (in mrem) to the whole body for each exam and calculate a cumulative dose if multiple exams are proposed for the entire period of the study. Note if contrast media will be used and describe.

6. For Radiation Oncology procedures, state the therapeutic dose level.

7. Expected duration of the study.

9. **Potential Health Risks**:

Refer to the following for the appropriate risk statement. This statement must be included ***verbatim*** in the IRB Informed Consent Form, section 6, "Potential Health Risks or Discomforts".

Note: Background radiation exposure is about 0.8 to 1 mrem per day.

Risk Statements for Informed Consent Form

A. Informed Consent Statement for Diagnostic (Radiography, Fluoroscopy, CT, or Mammography) Procedures

This research study involves exposure to radiation from x-rays. The amount of radiation you will receive from this procedure exposes a portion of your body to a higher level of radiation than the rest of your body. The risks from radiation to only part of your body are considered to be less than the risks from radiation to your whole body. The radiation exposure from this procedure is typically (insert effective dose calculated in Section 8.A.5") mrem. A comparable exposure is equivalent to (insert number of days) days of the amount of natural background radiation exposure people in the United States receive each year. The risk from radiation exposure of this magnitude is too small to be measured directly and is considered to be low when compared with other everyday risks. The investigator will provide you with a contact person if you would like more information about radiation exposure. This contact person is (insert contact name and phone number).

B. Informed Consent Statement for Radiation Oncology Procedures using Therapeutic Irradiation Dosages

This research study involves exposure to radiation from (insert type of procedure or procedures). The amount of radiation exposure you will receive from this procedure will be at therapeutic doses with the intent of (insert intent of procedure). As a part of this study, vital organs and normal tissues may receive significant radiation exposure. The potential early and late side effects and the risks of these side effects occurring are as follows. (insert for all organ systems which will receive significant radiation exposure in this study a listing of the potential acute and late side effects and known risks of occurrence at the proposed radiation exposure levels). The investigator will provide you with a contact person if you would like more information about radiation exposure. This contact person is (insert contact name and phone number).

C. Informed Consent Statement for All Radiation Procedures involving Potentially Pregnant Participants

This study may be hazardous to an unborn child. Therefore, participants who are still menstruating and have not been surgically sterilized must have a negative pregnancy test prior to participating in this study (or studies). The results of the pregnancy test will be made available to the study participant prior to the initiation of this study.