###### APPLICATION FOR THE USE OF IONIZING RADIATION IN HUMAN SUBJECTS

This application must be completed and submitted to the Human Use Subcommittee (HUS) of the All University Radiation Protection Committee (AURPC) for any study that involves the exposure of participants to ionizing radiation. It must be submitted to the HUS with a copy of the Institutional Review Board (IRB) application, the study protocol and all applicable consent and assent forms.

Send completed form to: Department of Radiation Safety, 100 Thompson Center for Environmental Management

**1. Principal Investigator**

Name:      Department:

Phone:       Address:

Email:      

Preparer/Contact name:      

Phone:       Fax:

Email:       IRB Application#:

Study Title:

Provide a description of *all* radiation that will be used in this study, and indicate whether it is standard medical care or if it is due to participation in the study (clinical vs. research). List the names and phone numbers of those individuals who will administer each type of the ionizing radiation. Attach additional pages if necessary.

Name:       Phone:

Name:       Phone:

**2.** **Condition for Exemption**

Are you giving ***only*** diagnostic radiation that is part of the patient’s standard medical care? Yes  No

If yes, your application does not require HUS review. Attach a statement indicating that none of the radiation received by the study participant is related to the study, sign this application in Section 7 and attach it to the IRB application. If no, proceed to Section 3.

**3. Types of Radiation Procedures**

Studies may combine various types of procedures that involve different applications of ionizing radiation(s). You must submit information regarding *all* of the types of radiation procedures involved in your study, so you may need to complete more than one of the following sections of this application.

Diagnostic X-ray imaging: complete Section 4 and follow additional instructions.

Therapeutic or diagnostic radiopharmaceuticals: complete Section 5.b. and follow additional instructions.

External beam and/or sealed radioactive brachytherapy: complete Section 5.c. and follow additional instructions.

**4.** **Conditions for an Accelerated HUS Review**

Studies that are limited to the conditions and categories listed below qualify for an accelerated review by the HUS chairperson and the Radiation Safety Officer. Complete this section to enable the HUS to determine if this study is exempt from a full subcommittee review.

**Study Procedures**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Radiographic Procedure** | **View** | **Dose per Exam (mSv)** | | **Number per Study**  **(max)** | **Total Dose per Study (max)** |
|  |  | **Male** | **Female** |  |  |
| **Head and Neck** |  |  |  |  |  |
| Cervical Spine | AP | 0.08 | 0.08 | 10 | 0.80 |
| Cervical Spine | Lateral | 0.09 | 0.09 | 10 | 0.90 |
| Skull | AP or PA | 0.04 | 0.04 | 10 | 0.40 |
| Skull | Lateral | 0.01 | 0.01 | 10 | 0.10 |
| **Dental** |  |  |  |  |  |
| Intraoral (bitewing) | 4 films | 0.04 | 0.04 | 10 | 0.40 |
| Full Mouth Series | 19 films | 0.15 | 0.15 | 6 | 0.90 |
| Panoramic |  | 0.09 | 0.09 | 10 | 0.90 |
| **Upper Extremities** |  |  |  |  |  |
| Hand or wrist (non-bucky) | Any | <0.001 | <0.001 | 10 | < 0.01 |
| Forearm (non-bucky) | Any | <0.001 | <0.001 | 10 | < 0.01 |
| Humerus or elbow | Any | 0.04 | 0.04 | 10 | 0.40 |
| **Lower Extremities** |  |  |  |  |  |
| Foot or ankle (non-bucky) | Any | <0.001 | <0.001 | 10 | < 0.01 |
| Femur | Any | 0.10 | 0.01 | 6 | 0.60 |
| Tibia / fibula (non-bucky) | Any | <0.001 | <0.001 | 10 | < 0.01 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Radiographic Procedure** | **View** | **Dose per Exam (mSv)** | | **Number per Study**  **(max)** | **Total Dose per Study (max)** |
| **Thorax** |  | **Male** | **Female** |  |  |
| Chest | PA | 0.02 | 0.03 | 10 | 0.30 |
| Chest | Lateral | 0.04 | 0.05 | 10 | 0.50 |
| Thoracic Spine | AP (7"x17") | 0.23 | 0.25 | 1 | 0.25 |
| Thoracic Spine | Lateral (7"x17") | 0.98 | 1.15 | 1 | 1.15 |
| Scapula | AP (one) | 0.09 | 0.09 | 10 | 0.90 |
| Shoulder | AP (one) | 0.06 | 0.06 | 10 | 0.60 |
| Bilateral Mammogram | CC and MLO |  | 0.30 | 1 | 0.30 |
| **Abdomino-Pelvic** |  |  |  |  |  |
| Abdomen | AP | 0.29 | 0.45 | 2 | 0.90 |
| Abdomen | PA | 0.20 | 0.31 | 2 | 0.62 |
| Abdomen | Lateral | 0.09 | 0.15 | 2 | 0.30 |
| Pelvis | AP | 0.28 | 0.35 | 2 | 0.70 |
| Lumbar Spine | AP (7"x17") | 0.33 | 0.47 | 1 | 0.47 |
| Lumbar Spine | Lateral | 0.49 | 0.80 | 1 | 0.80 |
| Hip | AP (one) | 1.10 | 0.43 | 1 | 1.10 |
| Hip | Lateral (one) | 0.23 | 0.25 | 1 | 0.25 |
| **DEXA, bone mineral** |  | 0.01 | 0.01 | 10 | 0.10 |

References: X-ray techniques were provided by Billy Wesp, FUMC General Radiology Manager (10/04).

X-ray doses were calculated using the methods in Handbook of Radiation Doses in Nuclear Medicine and Diagnostic X-Ray, Kereiakes and Rosenstein, CRC Press, 1980.

Dental doses (bitewing & full mouth) were obtained from the ADA adapted from Frederiksen, Texas Dental Journal, 1995; 112(2): 68-72.

Dental panoramic dose was obtained from RADAR website, Stabin, et al, http://www.doseinfo-radar.com/RADARDoseRiskCalc.html

### Study Population

* Are minors (under age 18) excluded? Yes  No
* Are pregnant women excluded? Yes  No
* Are breast-feeding women excluded if radionuclides are used? Yes  No
* Are healthy volunteers excluded? Yes  No
* Is the whole body dose less than 5 mSv? Yes  No

Is the source of the ionizing radiation exposure limited to ***one*** of the above categories

listed under **Study Procedures** and within the allowable frequencies? Yes  No

If you have answered yes to the question above, and yes to ***all*** of the questions in **Study Population**, and if there is no potential for radiochemical toxicity or adverse reactions, you may go to Section 6 for instructions on completing the patient consent form, and sign this application in Section 7.

If you have answered no to any of the questions above, proceed to the next section.

**5. Radiation Dose**

5.a. From Diagnostic X-ray Sources

Submit the calculations for the dose received from diagnostic X-ray procedures. In the calculations you must include the procedure name, (CT, radiograph, fluoroscopic, dental, etc.), type of procedure(s) (chest X-ray, whole body CT, interventional cardiac fluoroscopy, etc.), the area of the body being imaged, and the number of each type of procedure being done in the study. List all radiation procedures including those clinically indicated and those that would not be received unless the subject was included in this research study.

Each procedure must be itemized and categorized, i.e. clinical v. research, so the Subcommittee can give full consideration to the total radiation dose received by the subject. You must also provide the skin dose, bone marrow dose, gonadal dose, other affected organ dose(s) and the effective dose equivalent (all stated in mSV) per procedure. The individual performing the dose calculations and the dosimetry references used must be identified.

If you need assistance in completing the dose calculations, you may call a medical physicist in the University's Department of Radiology at 612-626-6638. You will be required to submit the same information requested in the first table below, so the medical physicist can most accurately calculate the corresponding dose(s).

List of All X-ray Procedures (must be provided by investigator)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  | Technique  (if not standard UMMC technique) | | | |  |
| Procedure name | Exams per year | Type | Area imaged | View | Standard technique | kVp | mAs | Fluoro time | Field size or scan length | Clinically indicated |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

Estimated Radiation Dose per Procedure (total for multiple procedures) in mSv

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Gonads | | Other Exposed Organs | |  |
| Procedure name (from table above) | Skin | Bone  Marrow | M | F | Organ | Dose | Effective Dose |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

Doses calculated by:       Phone:

5.b. From Therapeutic or Diagnostic Radiopharmaceutical Sources

List all radiation procedures included in this study (attach additional pages if necessary). Each procedure must be itemized and categorized, i.e. clinical v. research, so the Subcommittee can give full consideration to the total radiation dose received by the subject. If any procedure involves diagnostic X-ray, you must also complete the section above (5.a.).

Radioactive Materials Permit Holder:       Phone:

Nuclear Medicine Physician:       Phone:

Radionuclide(s) and activities (mCi):       Chemical form(s):

Route(s) of administration and location (room and building):

Is material a FDA approved nuclear medicine agent? Yes  No

If no, is it approved under an IND (investigational new drug)? Yes  No  If yes, list the number:

List the radiation doses (mSv) to the five organs that receive the highest dose from the radionuclide(s) used. Also include the dose to the blood forming organs, the gonads, and the lens of the eyes if they are not already listed, and include the whole body effective dose equivalent. If these dose calculations are obtained from a radiopharmaceutical package insert, attach a copy and adjust the doses appropriately for age, body mass, medical condition of the subjects, etc. If these doses are obtained by other means, attach the calculations and references used (including assumptions for biological half-life, source and target organs, etc.).

Organ:       dose:       (mSv) Lens of eye dose:       (mSv)

Organ:       dose:       (mSv) Bone marrow dose:       (mSv)

Organ:       dose:       (mSv) Ovary dose:       (mSv)

Organ:       dose:       (mSv) Testicle dose:       (mSv)

Organ:       dose:       (mSv) Effective dose equivalent:       (mSV)

Clinical  Research Doses calculated by:       Phone:

**For Therapeutic Sources only:** Attach a copy of the radiation safety instructions and contamination control protocol for patient care staff, and a copy of the radiation safety instructions for the patient to follow at home after release. Also attach information and references on any toxicity, side effect or contraindication for the radiopharmaceutical(s).

5.c. From Therapeutic Radiation - Accelerator, Gamma knife and/or Brachytherapy sources:

List all radiation procedures included in this study (attach additional pages if necessary). Each procedure must be itemized and categorized, i.e. clinical v. research, so the Subcommittee can give full consideration to the total radiation dose received by the subject. If any procedure involves diagnostic X-ray or radiopharmaceuticals, you must also complete the appropriate section above (5.a. and/or 5.b.).

Authorized radiation therapy physician:      Phone:

Type of radiation source:      Energy or Activity:      Frequency of treatment(s):

Number and duration of treatment(s):      /      Area of body treated:      Max. total dose:      (cGy)

Dose to other organ(s) near treatment site:  Clinical  Research

(a)       dose/treatment:      (cGy) Total organ dose:       (cGy)

(b)       dose/treatment:      (cGy) Total organ dose:       (cGy)

(c)       dose/treatment:      (cGy) Total organ dose:       (cGy)

(d)       dose/treatment:      (cGy) Total organ dose:       (cGy)

If brachytherapy, include a copy of the radiation protection precautions and procedures to be followed by physicians and other patient care staff to assure patient, staff and visitor protection and regulatory compliance where applicable.

**6. Consent Form**

A copy of the consent form for the proposed study must be included with this application. The following information must be included in the consent form:

* A statement informing participants of population groups excluded from the study (e.g. minors, pregnant women), an indication of the risk from radiation exposure if a subject becomes pregnant during the study, and the method used to assure that the subject is not pregnant prior to the administration of radiation, e.g. pregnancy test.
* A statement informing participants that they may not be eligible if they have participated in any other study within the past 12 months, and that the participant is responsible for informing the investigator of such involvement prior to the beginning of the proposed study.
* A statement of risk for the radiation dose, and if appropriate the potential for radiochemical toxicity and adverse reactions.
* If the dose is given as part of a radiation therapy procedure the statement of risk should indicate all potential side effects from the radiation including the potential for secondary cancers. You may skip the dose comparison statement outlined below.
* If the dose is not given as part of a radiation therapy procedure include a statement that expresses the whole body dose as a percent or multiple of the annual natural background dose for the State of Minnesota (~ 3 mSv/yr).

Below are two examples of a dose comparison statement. The first example may be used if the total dose from the study is less than or equal to 3 mSv and it will be presented as a *percentage* of the annual background dose in the State of Minnesota. The second example may be used if the total dose from the study is greater than 3 mSv and it will be presented as a *multiple* of the annual background dose.

The percentage/number needed to complete the risk statement can be obtained by dividing the total annual effective dose equivalent from the procedures by 3 mSv (the average natural background radiation dose level in Minnesota). The annual effective dose equivalent is the effective dose equivalent per procedure multiplied by the number of times the procedure will be performed per year. The annual effective dose equivalent for each procedure is summed to obtain the total.

Example 1. Total dose < 3 mSv

" As part of this study you will undergo (number) (procedure type) procedure(s) per year. This (These) procedure(s) involve exposure to ionizing radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The average amount of radiation that the average person would receive from this (these) procedure(s) is less than (number)% of that received from natural sources of radiation by a Minnesota resident in one year (3 mSv). This exposure involves minimal risk and is necessary to obtain the research information desired."

Example 2. Total dose > 3 mSv

" As part of this study you will undergo (number) (procedure type) procedure(s) per year. This (These) procedure(s) involve exposure to ionizing radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The average amount of radiation that the average person would receive from this (these) procedure(s) is (number) times that received from natural sources of radiation by a Minnesota resident in one year (3 mSv). This exposure involves minimal risk and is necessary to obtain the research information desired.”

Liberal estimates of the effective doses for certain procedures are listed in the table found in Section 2. If, after calculating the effective dose for procedures in your study you find it exceeds 1 mSv (33% of background), you should contact a medical physicist to obtain a more precise estimate (612-626-6638). A medical physicist should also be contacted if the procedure being performed is not found in the list, or if a particular subgroup of the general population could alter the dose estimate (such as obese subjects).

**7. Applicant Signature**

***The information submitted in this application is complete and accurate.***

Applicant's signature: Date:

For UMMC use only

The designated staff of the Department of Therapeutic Radiology/Radiation Oncology has reviewed this protocol for external beam and/or brachytherapy. It has been deemed acceptable and approval is recommended.

The designated staff of the Division of Nuclear Medicine, Department of Radiology has reviewed this protocol for radiopharmaceutical therapy. It has been deemed acceptable and approval is recommended.

Division or

Department Chair: Physics Director:

***signature******signature***

Date: Date:

***For Subcommittee use only***

The HUS has reviewed this application. Date:

Conditions:

The Human Use Subcommittee has approved this application.

Chairperson signature: Date: