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|  | RS06 - Application for Use of Radiation in Research Involving Human Subjects |

**Instructions**: This application must be completed for each research study involving the use of radiation-emitting equipment or radioactive materials involving human subjects. The Radiation Safety Committee must review and approve any research study involving the use of radiation in research involving human subjects. Please contact the Radiation Safety Officer (RSO) at 588-1713 if you have any questions.

1. **Research Study Information**

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| **PROTOCOL TITLE:** |
| **PRINCIPAL INVESTIGATOR:**  |
| **HSC/PROTOCOL NUMBER**:  |
| **PRIMARY CONTACT:**  **EMAIL:**  |
| **AMENDMENT/MOD to an existing study?** [ ]   **Yes** **[ ]  No EXISTING STUDY #:**  |
| **SPONSOR:**  |
| **EXTERNAL IRB REVIEWED (or applied for)?** [ ]  **Yes** **[ ]  No EXTERNAL IRB:**  |

**2. Standard of Care Certification**

If the subjects were not part of this study, would they be receiving the same procedures listed in the tables below?

[ ]   **Yes** [ ]   **No**

If **YES**, would they receive the same number of procedures as are listed in the tables below if they were not in this study?

[ ]   **Yes** [ ]   **No**

**3. Subjects to be Studied**

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| --- |
|  **TOTAL NUMBER OF SUBJECTS**:  |
|  **Are any Subjects less than 18 years of age?** [ ]   **Yes**  [ ]   **No** **Please provide the reason/justification for using subjects under 18 years of age:**  |
|  **Will healthy subjects be used?** [ ]   **Yes**  [ ]   **No** **Please provide the reason/justification for using healthy subjects:**  |

**4. Procedures to which the research participants will be exposed**

**Radiation-emitting Equipment**

[ ]  Fluoroscopy [ ]  X-ray [ ]  CT Scan [ ]  DEXA Scan [ ]  Mammogram [ ]  Other

**Radioactive Materials**

[ ]  PET/CT [ ]  Nuclear medicine scans (such as MUGA, gastric emptying, or others)

[ ]  **Radiation Therapy (Explain):**

**5. Where will these procedures be administered?**

[ ]  CTSU (Fairway) [ ]  KU Hospital [ ]  KUCC Clinics [ ]  KU Med West

[ ]  KU Hospital, Westwood Cancer Center [ ]  Other Location: Identify (be specific)

**6. Describe which procedures are strictly for Research purposes and which are considered Standard of Care (SOC) for these participants.** For each exposure to radiation listed above, complete an entry in the following table.

***MAXIMUM number of SOC and RESEARCH procedures IN ONE YEAR.***

The last page of this form contains an example table showing TYPE and MAXIMUM NUMBER of procedures for both SOC and Research IN ONE YEAR.

Note: Cells will expand to fit your entry.

|  |  |  |
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| **PROCEDURE** | **MAXIMUM NUMBER of Procedures** **IN ONE YEAR** **Standard of Care** (i.e, they are part of the participant’s routine medical care) | **MAXIMUM NUMBER of Procedures** **IN ONE YEAR****Research** (i.e., they would NOT have been given if the participant were not in this study) |
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If more procedures are involved, please attach additional sheets containing the above information.

**7. Radiation Oncology If Not, go to Section 8.**

Will Radiation Oncology be done at KU Hospital, [ ]  **Yes** [ ]  **No**

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| **Site(s) to be Treated** | **Dose** | **Dose/Fraction** | **Frequency of Fraction** | **Number of Fractions** | **With/Without Chemotherapy** |
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**8. Principal Investigator's Certification**

As Principal Investigator for this research study, I understand and accept the following obligations. It is my responsibility to:

a. Obtain approval of the University of Kansas Medical Center Human Subjects Committee before proceeding with human studies.

b. Immediately report any adverse reactions associated with the use of radiation in the research study to the University of Kansas Medical Center Radiation Safety Committee, the University of Kansas Health System Radiation Safety Committee and the University of Kansas Medical Center Human Subject Committee.

c. Ensure that all research personnel working with radiation receive radiation safety orientation and annual radiation safety training commensurate with their duties.

d. Immediately report any changes to the study protocols or consent forms which would impact the administration of radiation to subjects to the University of Kansas Medical Center Radiation Safety Committee, the University of Kansas Health System Radiation Safety Committee, and the University of Kansas Medical Center Human Subject Committee.

I understand that failure to comply with applicable federal and state regulations regarding use of radiation and with the University of Kansas Medical Center’s and University of Kansas Health System’s requirements for using radiation-producing equipment and/or radioactive materials can result in termination of Radiation Safety Committee approval.

Principal Investigator’s Name:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_

Principal Investigator Signature

**EXAMPLE TABLE -**

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| **PROCEDURE** | **MAXIMUM NUMBER of Procedures** **IN ONE YEAR** **Standard of Care** (i.e, they are part of the participants routine medical care) | **MAXIMUM NUMBER of Procedures** **IN ONE YEAR****Research** (i.e., they would NOT have been given if the participant were not in this study) |
| **CT - Chest** | **2** | **1** |
| **CT - Ab/Pel** |  | **2** |
| **FDG PET** |  | **1** |
| **X-ray Chest** |  | **3** |
| **MUGA** | **1** |  |
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