**MEDSTAR GEORGETOWN UNVIVERSITY HOSPITAL**

**CHECKLIST TO DETERMINE WHICH APPLICATION IS REQUIRED BY THE**

**RADIATION SAFETY COMMITTEE FOR RESEARCH INVOLVING HUMAN SUBJECTS**

**Radiation use with RADIOACTIVE MATERIALS (pages 2-4)**

1. If, radioactive material use involves routine diagnostic or therapeutic procedures considered Standard of Care for the patient’s/subject's medical condition;

 **Then, complete Section I of the Application for Human Subject Use of Radioactive Materials.**

1. If radioactive material use involves:
2. Any existing diagnostic or therapeutic procedure greater than Standard of Care for patients with the patient’s/subject's medical condition; **or**
3. New diagnostic or therapeutic procedures for patients with the patient’s/subject's medical condition;

**Then, complete all sections of the Application for Human Subject Use of Radioactive Materials.**

**Radiation use with DEVICES PRODUCING Ionizing Radiation (pages 5-6)**

1. If ionizing radiation use involves routine diagnostic or therapeutic procedures considered Standard of Care for the patient’s/subject's medical condition (includes, but may not be limited to, Radiographic and Fluoroscopic procedures, DEXA scans, CT scans, and External Beam Radiotherapy).

**Then, complete Section I of the Application for Human Subject Use of Devices Producing Ionizing Radiation.**

1. If ionizing radiation use involves:
2. Any type of procedure on healthy subjects; **or**
3. Any existing diagnostic or therapeutic procedure greater than Standard of Care for the patient’s/subject's medical condition; **or**
4. Any new diagnostic or therapeutic procedure being performed for patients with the patient’s/subject's medical condition.

**Then, complete all sections of the Application for Human Subject Use of Devices Producing Ionizing Radiation.**

Questions should be directed to:

Dr. David A. Smith

Director, Radiation Safety

202-444-4637

david.a.smith@gunet.georgetown.edu

APPLICATION FOR HUMAN SUBJECT USE

OF *RADIOACTIVE MATERIALS*

# Please Print or Type Information

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| **I. General Information** |
| Principal Investigator: | Phone Number:Email: |
| PI Office Address: | Department: |
| Authorized User of Radioactive Materials:Listed as Co-Investigator? \_\_\_\_\_\_\_\_\_\_\_ | Department:Phone Number: |
| Name of Protocol and IRB Number: |
| Purpose of Protocol (attach copy of protocol): |
| Submitted to the Institutional Review Board (IRB)? \_\_\_\_\_\_ Yes \_\_\_\_\_ No\_\_\_\_\_\_ Approved \_\_\_\_\_ Pending |
| Is the proposed use of radioactive material an established clinical procedure for diagnostic or therapeutic purposes? \_\_\_\_\_ Yes\* \_\_\_\_\_ No\*\***\*If yes, submit without completing Sections II through VI.****\*\*If no, complete Sections II through VI.** |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of PI Date**

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| II. PATIENT INFORMATION |
| Total number of patients in study: | Age range of patients: |
| Will pregnant women be included in this study: \_\_\_\_\_ Yes \_\_\_\_\_ No |
| Will women who are breast-feeding be included in this study: \_\_\_\_\_ Yes \_\_\_\_\_ No |
| Will consent be obtained: \_\_\_\_\_ Yes \_\_\_\_\_ No |
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| **III. RADIOPHARMACEUTICAL INFORMATION** |
| Radionuclide: | Chemical Form: |
| Radiopharmaceutical: | Radiopharmaceutical Supplier: |
| Route of isotope administration: |
| Maximum activity administered per patient: | Maximum activity on hand at one time: |
| Number of times study will be repeated: |
| Is this study covered by a new drug application? \_\_\_\_\_ Yes \_\_\_\_\_ NoIf yes, provide the Investigational New Drug (IND) number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **IV. RADIATION DOSIMETRY FOR RADIOPHARMACEUTICALS (cite reference for dose estimate/information)** |
| Expected fate of radioactive materials in body: |
| Biological half-life of radiopharmaceutical: | Half-life of radionuclide: |
| Total Effective Dose Equivalent: \_\_\_\_\_\_\_\_\_\_ rem | Absorbed dose to target organ: \_\_\_\_\_\_\_\_\_\_\_\_ rad |
| **V. BRACYTHERAPY INFORMATION** |
| Radionuclide: | Physical Form: \_\_\_\_\_ Seeds \_\_\_\_\_ Gamma-Med \_\_\_\_\_ Other sealed source |
| Maximum activity: \_\_\_\_\_ mCi | Number of seeds/sources used: |
| Permanent Implant: \_\_\_\_\_ Yes \_\_\_\_\_ NoTemporary Implant: \_\_\_\_\_ Yes \_\_\_\_\_ No | New sources or current inventory? \_\_\_\_\_\_\_\_\_\_\_\_Manufacturer and Model (if new): \_\_\_\_\_\_\_\_\_\_\_\_ |
| Number of times study will be repeated on the same subject: |
| Is this study covered by an Investigational New Drug Application? \_\_\_\_\_ Yes \_\_\_\_\_ NoIf yes, provide the IND number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **VI. TRAINING INFORMATION** |
| List physician(s) who will be supervising use of radioactive material: |
| Name(s) | Training in Radiation Safety |
| Formal Training\*\* | Date of last MGUHradiation safety training\* |
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| \* If last MGUH radiation safety training was more than one year ago, training must be completed prior to initiation of study. Contact the Radiation Safety Department for training information.\*\*If currently authorized radiation oncologist or nuclear medicine physician, only the name needs to be submitted. Otherwise, submit a complete description of residency and specialty boards. |

I agree to abide by the policies and procedures of the Medstar Georgetown University Hospital Radiation Safety Department and to comply with all state and federal regulations regarding the use of radioactive materials.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_

 Signature of Authorized User Date

APPLICATION FOR HUMAN SUBJECT USE

OF *DEVICES PRODUCING IONIZING RADIATION*

# Please Print or Type Information

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| **I. General Information** |
| Principal Investigator: | Phone Number:Email: |
| PI Office Address: | Department: |
| Physician Supervising Radiation Use: | Phone Number: |
| Department: | Physician listed as co-investigator? |
| Office Address: | Estimated Start Date of Protocol: |
| Name of Protocol and IRB Number: |
| Purpose of Protocol (attach copy of protocol): |
| Submitted to the Institutional Review Board (IRB)? \_\_\_\_\_\_ Yes \_\_\_\_\_ No\_\_\_\_\_\_ Approved \_\_\_\_\_ Pending |
| Is the proposed use of radiation producing devices an established clinical procedure for diagnostic or therapeutic purposes? \_\_\_\_\_ Yes\* \_\_\_\_\_ No\*\* |

**\*If yes, submit without completing Sections II through V.**

**\*\*If no, complete Sections II through V.**

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| II. PATIENT INFORMATION |
| Total number of patients in study: | Age range of patients: |
| Will pregnant women be included in this study: \_\_\_\_\_ Yes \_\_\_\_\_ No |
| Will consent be obtained: \_\_\_\_\_ Yes \_\_\_\_\_ No |
| **III. DIAGNOSTIC RADIATION PRODUCING EQUIPMENT** |
| Radiation-Producing Equipment and Technique Factors: Radiography: Technique Factors: kVp: \_\_\_\_\_\_\_\_\_ mAs: \_\_\_\_\_\_\_\_\_\_ Source to Skin Distance: \_\_\_\_\_\_\_\_\_\_\_\_ Number of Images: \_\_\_\_\_\_\_\_ View and Projection: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Typical Entrance Skin Dose (cGy) or Effective Dose Equivalent (mSv): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Fluoroscopy: Procedure: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approximate Fluoro Runtime:\_\_\_\_\_\_\_\_\_\_\_\_\_ Approximate Cine/DSA Runtime: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approximate Total Dose Area Product (mGy-cm2): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Computed Tomography: Technique Factors: kVp:\_\_\_\_\_\_\_\_\_\_ Rotation Time: \_\_\_\_\_\_\_ msec mA/effective mA:\_\_\_\_\_\_\_\_\_  Pitch:\_\_\_\_\_\_\_\_\_\_ Beam Width:\_\_\_\_\_\_\_\_\_ mm Scan Length:\_\_\_\_\_\_\_\_\_\_ mm Approximate CTDIvol or CTDIw (mGy) per acquisition: \_\_\_\_\_\_\_\_\_  Approximate Dose Length Product (mGy-cm) per acquisition: \_\_\_\_\_\_\_\_\_Mammography: \_\_\_\_\_\_\_\_\_\_\_kVp \_\_\_\_\_\_\_\_\_mAs \_\_\_\_\_\_\_\_\_\_\_# of images |
| Equipment Location: |
| Number of times study will be repeated on the same subject and the time interval between studies: |
| **IV. THERAPEUTIC RADIATION PRODUCING EQUIPMENT** |
| Radiation producing device used: \_\_\_\_\_\_\_\_\_Accelerator \_\_\_\_\_\_\_\_\_Cyber Knife |
| What is novel about the clinical procedures?  |
| Number of times study will be repeated on the same subject: |
| **V. TRAINING INFORMATION** |
| List physician(s) who will be supervising ionizing radiation producing device(s): |
| Name(s) | Training in Radiation Safety |
| Formal Training\*\* | Date of last MGUHradiation safety training\* |
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| \* If last MGUH radiation safety training was more than one year ago, training must be completed prior to initiation of study. Contact the Radiation Safety Department for training information.\*\* If currently authorized radiation oncologist or radiologist, only the name needs to be submitted. Otherwise, submit a complete description of residency and specialty boards. |

I agree to abide by the policies and procedures of the Medstar Georgetown University Hospital Radiation Safety Department and to comply with all state and federal regulations regarding the use of radiation producing equipment.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_

 Signature of Authorized User Date