**Stony Brook University Application for Approval to Conduct Radioactive Drug Metabolism Research in Human Subjects with <Insert tracer name>**

[ ]  *Confirm submission of the study protocol to the IRB. Include the IRB protocol with the RDRC submission and provide IRBNet reference for the IRB submission* TEXT

**A. Title of the research project:** TEXT

**B. Brief description of the purpose of the research project:**

TEXT

**C. Principal Investigator Information**

Name: TEXT

SBU Employee #: TEXT

Title: TEXT

Department: TEXT

Phone #: TEXT

E-mail address TEXT

**D. Additional Personnel involved in the Research.** You are required to include the individuals listed below for all RDRC submissions. Please add additional study personnel and role on the study. Use an additional sheet if needed.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name****(Last, First)** | **Department** | **SBU** **Phone #** | **E-mail Address** | **Role on project** |
|  |  |  |  |   |
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|  |  |  |  |   |
|  |  |  |  |  |
|  |  |  |  |  |
| Qu, Wenchao | Psychiatry | 631-638-0045 | Wenchao.Qu@stonybrook.edu | Chemist |
| Franceschi, Dinko | Radiology | 631-444-7279 | Dinko.Franceschi@stonybrookmedicine.edu | Authorized User |

\*The nuclear medical technologists at Stony Brook University are all licensed by NYS and are the only personnel besides the authorized user, Dr. Franceschi to inject radioactive materials

 **E. Information Regarding the Radioactive Drug**

**1. State name of radioactive drug and give chemical structure:**

<Insert tracer name and chemical structure>

**2. Details of the physical characteristics:**

* 1. Physical half-life: TEXT

b. Total decay energy: TEXT

c. Type(s) of decay and decay fraction (s): TEXT

d. Energy, and relative abundance of major emissions: TEXT

Positron: TEXT

Gamma ray: TEXT

X-rays: TEXT

Auger electrons: TEXT

Electrons: TEXT

**3. Production source**

a. Source of isotope:

[ ]  Cyclotron (NCM, Bronx, NY)

[ ]  Cyclotron (MART)

b. Source of radioactive drug

[ ]  Acknowledge the following information

Stony Brook University FERM or MART cGMP facilities

**4. Preparation:**

Commercial products must be supported with either an NDC number or a certificate of analysis which states that materials are intended for human use. For all other materials:

a. Provide details of synthesis/preparation.

<Insert tracer name> will be synthesized according to <Insert details>

* 1. Provide detail regarding how batch records and quality control records are maintained, including their location:

[ ]  Acknowledge the following information

See attached SOP10-1001 (Document Origination & Change Control), and SOP10-1006 (Drug Product Quality Control/Quality Assurance).

**5. Composition:**

Final drug product minimum specifications:

a. Chemical purity: TEXT

b. Radiochemical purity: TEXT

* 1. pH: TEXT
	2. Dosage: TEXT

Or [ ]  provide a range of activity to be injected: TEXT

* 1. Sterility: TEXT
	2. Bacterial endotoxin levels: TEXT
	3. Radionuclide identification: TEXT
	4. Radionuclidic purity: TEXT
	5. Residual organic solvents: TEXT
	6. Visual inspection: TEXT
	7. Residual chemicals: TEXT
	8. Excipients (if any): TEXT

See attached Appendix I (Chemistry, Manufacturing and Control document) for quality control testing methods.

**6. Specific activity of administered material:**

a. Provide information on radiopharmaceutical specific activity (specification and testing methods):

 TEXT

b. State maximum total mass injected of each radiotracer:

TEXT

c. Describe any pharmacological or toxic actions of the parent compound or vehicle:

* + 1. State no-observed-effect-level (NOEL) mass dose (supply reference):

TEXT

* + 1. State no-observed-adverse-effect-level (NOAEL) mass dose (supply reference):

TEXT

**7. Radioassay:**

List instruments or devices used to measure the radioactivity prior to administration to the subject (e.g. dose calibrator) as well as the calibration/validation procedures:

TEXT

**8. Study Drug Administration**

1. Give route of administration: Intravenous (i.v.)
2. Give volume to be administered and vehicle: TEXT

 **F. Radiological Health Aspects**

1. **Hazards to other subjects and to personnel from external or internal radiation** (e.g., mr/hr at 1 meter at the time of radioisotope injection):

EXAMPLE: We estimate that, for one [18F]FEPPA PET/MRI scan the radiation exposure from a subject injected with 5 mCi of [18F]FEPPA will be comparable to that from a subject injected with 5 mCi of [18F]FDG. Unshielded, 1 mCi of [18F] is 0.6 mR/hr at 1 meter. While the syringes have shields, there may be unanticipated exposure.

1. **Steps to minimize the hazards identified in F.1 above**:

EXAMPLE: The nuclear medicine technologists are specifically trained to inject and work around patients injected with [18F]FDG; it will be a similar procedure for [18F]FEPPA. Only Nuclear Medicine personnel will handle the filled patient syringe and inject the patient at the ACP. Only a NYS licensed nuclear medicine technologist will handle the filled patient syringe and inject the patient at the MART.

All non-nuclear medicine personnel, involved at both the ACP and MART study sites have received SBU radiation training and are familiar with the ALARA principles.

The general rules for ALARA includes:

* Minimizing exposure time near a source or patient;
* Maintaining distance from source or patients;
* Placing shielding between the personnel and the source;
* Protecting against radioactive contamination.

These personnel will wear radiation badges, until the RSO deems them unnecessary.

1. **Personnel monitoring procedures, if necessary**:

[ ]  Acknowledge the following information:

The study physician will be on call during the scan.

All non-nuclear medicine staff working with the patient(s) will be issued with film badges if the RSO considers they need such monitoring.

After working with the subject, all personnel will check their hands, lab coats and feet for radioactive contamination with a calibrated Ludlum Model 3 meter equipped with a Model 44-9 detector. Any contamination will be dealt with according to the SBU EHS guidelines.

1. **Special procedures for handling waste products, excreta, and biological samples**:

[ ]  Acknowledge the following information:

As with other PET tracers, this tracer will be excreted through general dissipation and from urine (through the kidneys) from the body, generally within 24 hours. The cumulative radiation exposure is considered very small. However, we will ask about the subject’s previous radiation exposure during the initial evaluation to ensure that their yearly exposure is kept below the defined limits.

All non-biological waste generated will be disposed of through “Decay in Storage (DIS)”. As per “General Radiation Protection SOP: Procedure for Disposal by Decay-in-Storage”, contaminated materials will be retained for at least 10 half-lives. Liquid and solid wastes will be stored separately.

At the ACP:

Waste will be stored in radioactive waste receptacles in Nuclear Medicine’s Decay-in-Storage area. All waste receptacles will be clearly labeled “Radioactive Materials”, and with the isotope, total activity, unique storage number, date at which 10 half-lives will have transpired and initials of individual submitting it to storage all noted. Containers for contaminated wastes in Nuclear Medicine are clearly labeled “Radioactive Materials” and are handled only by Nuclear Medicine Personnel. Regular waste containers in Nuclear Medicine are surveyed daily to ensure no accidental contamination. To further ensure safety, regular wastes, brought to a designated location by housekeeping personnel, are routinely surveyed by Nuclear Medicine personnel before removal from the Nuclear Medicine area.

Radioactive waste is kept in the leaded containers and stored in the hot lab for Decay-in-Storage. Each week Medical Physics/Nuclear Medicine personnel will survey these containers with a thin-window GM meter. The container’s shielding is removed, and all surfaces are monitored. If the survey results are equal to background radiation, this waste will be trashed as regular medical waste. Any such receptacle with contents found to indicate residual radioactivity (i.e., any surface readings are distinguishable from background), will be returned to DIS area. For residual activity evidenced beyond the noted 10 half-lives, the Nuclear Medicine staff will contact the Radiation Safety Officer. For receptacles surveyed with no residual radioactivity, radiation labels will be defaced, and provided that there are no traces of contamination of infectious/hazardous wastes, these receptacles will be discharged as ordinary trash to the hospital waste stream (after a visual inspection for radiation labels). For receptacles with contents containing infectious/hazardous waste, upon verification of no residual radioactivity and removal of radiation labels, contents will be disposed of according to hospital procedure (e.g., red bag). Upon disposal of either ordinary or infectious/hazardous waste, Nuclear Medicine staff will record the date the container was sealed, the disposal date, type of waste, survey instrument used, and the initials of the individuals performing surveys and disposing of the waste. The placement of waste into the hot lab decay closet or other storage areas, as well as subsequent release into the usual hospital waste stream will be documented on a log sheet.

At the MART:

Waste will be stored in radioactive waste receptacles in the MART Decay-in-Storage area inside the Radioactive Materials closet. The longest half-life used at the MART will be F-18 with a half-life of 110 min; the Decay-in-Storage required 10 half-life decay period will be no greater than 18.3 hours. Containers for contaminated wastes at the MART are clearly labeled “Radioactive Materials” and are handled only by the MART nuclear medicine technologist. Regular waste containers at the MART are surveyed at the end of each scan day occur to ensure no accidental contamination. To further ensure safety, regular wastes will only be released for disposal by the MART nuclear medicine technologist or radiation safety staff.

Radioactive waste is stored in the Radioactive Materials closet for Decay-in-Storage. After at least 10 half-lives, the MART nuclear medicine technologist survey these containers with a thin-window GM meter. All surfaces are monitored. If the survey results are equal to background radiation, this waste will be trashed as regular medical waste. Any such receptacle with contents found to indicate residual radioactivity (i.e., any surface readings are distinguishable from background), will be returned to DIS area. For residual activity evidenced beyond the noted 10 half-lives, the MART nuclear technologist will contact the Radiation Safety Officer. For receptacles surveyed with no residual radioactivity, radiation labels will be defaced, and provided that there are no traces of contamination of infectious/hazardous wastes, these receptacles will be discharged as ordinary trash to the MART waste stream (after a visual inspection for radiation labels). For receptacles with contents containing infectious/hazardous waste, upon verification of no residual radioactivity and removal of radiation labels, contents will be disposed of according to MART procedures (e.g., red bag). Upon disposal of either ordinary or infectious/hazardous waste, the MART nuclear medicine technologist will record the date the container was sealed, the disposal date, type of waste, survey instrument used, and the initials of the individuals performing surveys and disposing of the waste. The placement of waste into the MART Radioactive Materials closet, as well as subsequent release into the usual MART waste stream will be documented on a log sheet.

1. **Supply a plan for isotope accountability**:

[ ]  Acknowledge the following information:

a) we will follow sign-in and sign-out procedures for the PET/MR suite or MART PET;

b) the Nuclear Medicine Tech will draw the subject’s radiopharmaceutical dose and measure the initial dose in the syringe as well as the activity remaining in the syringe after injection

c) the Nuclear Medicine Tech will record the patient’s name, the name of the study and the isotope used.

d) the Nuclear Medicine Tech will record the time and amount of radionuclide that goes into the waste stream (i.e. empty syringe).

**G. Radiation Dosage**

**1.** **Biological half-life or effective half-life of study drug** (*be sure to state whether the physical half-life of the radioisotope is shorter than the biological half-life, and by how much):*

 TEXT

**2**. **Dosimetry:**

1. Source of human dosimetry data: TEXT

b. Supply a dosimetry table for the maximum amount of radioactivity to be injected.

Insert here

c. List minimum and maximum inject activity to be administered: TEXT

d. Indicate total number of subjects proposed for this activity. Provide statistical justification for this number: TEXT.

e. Provide age, sex, and approximate weight of study population: TEXT

f. Will subjects under the age of 18 years old be enrolled in this study?

 [ ]  No [ ]  Yes

g. Indicate number of doses per subject per year: TEXT

h. Indicate number of doses per subject per protocol: TEXT

**3. Other Study Drugs:**

 a. Will there be any non-radioactive agent administered?

 [ ]  No

 [ ] Yes →Will the agent alter the distribution of the radioactivity?

 [ ]  No

 [ ]  Yes → Briefly describe what effect the non-radioactive

 agent will have upon that distribution: TEXT

1. Critical or ‘target’ organs: TEXT
2. Gonadal exposure: TEXT

**H. Maintenance of radionuclide administration and subject response documentation:**

**1. [ ]  Acknowledge the following information:**

The radiopharmaceutical will be provided as a vialed dose that will contain less mass than the limit specified for the tracer. The dose can be drawn and used at any time before the expiration time.

**2. Provide detail regarding how records of radionuclide administration and subject responses are maintained,** including their location: TEXT

**I. External Irradiation of Subject:**

[ ]  Acknowledge the following information:

**1. Provide radiation source**: Not applicable

**2. Provide whole-body dose to the subject**: Not applicable

**3. Identify organ or area where the radiation is concentrated and give dose**: Not applicable

**4. Describe how radiation dose to the subject is verified**: Not applicable

**5. Describe how the radiation source is calibrated**: Not applicable

**6. Describe monitoring of possible leakage from the external radiation source**: Not applicable

Or [ ]  provide data:

a. Provide radiation source: TEXT

b. Provide whole-body dose to the subject: TEXT

c. Identify organ or area where the radiation is concentrated and give dose: TEXT

d. Describe how radiation dose to the subject is verified: TEXT

e. Describe how the radiation source is calibrated: TEXT

f. Describe monitoring of possible leakage from the external radiation source: TEXT

**J. Miscellaneous:**

**1. Storage location of radioactive drug:**

TEXT

**2. Location(s) of the study: Select one location. If the study uses more than one location, justify how the scans will be evaluated based on different equipment.**

[ ]  PET/MRI in ACP (Ambulatory Care Pavilion)

[ ]  PET/CT in ACP (Ambulatory Care Pavilion)

[ ]  PET in MART (Medical and Research Translation)

**Justification if using more than one location:**

**3. Expected duration of the study**:

TEXT

 **4. [ ]  Acknowledge the following information**

 The study team will perform assessments prior to the subject leaving the facility and

 within 24-48 hours after the injection of radioactive material for the purpose of

 reporting Adverse Event.

**K. Principal Investigator Certification**

**By signing this application below, the Principal Investigator certifies the following:**

**1. The activity for which RDRC approval is being requested will be conducted in compliance with SBU’s RDRC policy and Standard Operating Procedure (SOP), as well as FDA 21 CFR 361.1.**

**2. The activity will be conducted in compliance with SBU RAM license terms and conditions.**

**3. The activity will not commence until RDRC and IRB approvals are obtained.**

**4. All adverse reactions associated with the use of the radioactive drug will be reported within 5 working days to the RDRC and IRB.**

**5. All research personnel working with radioactive materials have received radiation safety orientation and annual radiation safety training commensurate with their duties.**

**6. No changes will be implemented to this activity without prior approval of the RDRC and IRB, unless a deviation from protocol is required for the immediate safety of a subject (in which case, immediate report of the deviation will be made to the RDRC and IRB).**

**7. Provide the RDRC committee with an annual list of subjects recruited as well as the dates and amounts of radioactive drug administered.**

Principal Investigator Signature Date