Workflow for Use of Radiopharmaceuticals in Research Protocols
Icahn School of Medicine and the Mount Sinai Health System
October 5, 2021 (FINAL)

1. OVERVIEW

There is a defined pathway for protocols employing radiopharmaceuticals for research purposes at any Icahn School of Medicine site.

2. DEFINITIONS

AUTHORIZED USER (AU): *An Authorized User (AU) is a physician (MD, DO) approved by the Radiation Safety Committee and operating under a Radioactive Materials License (for example Human Use Radioactive Materials License # 75-2909-04 at Mount Sinai Medical Center, or parallel construct at another Mount Sinai Health System site). The AU is permitted to order, inject and dispense (or supervise thereof) particular diagnostic and/or therapeutic radiopharmaceuticals, pursuant to Article 175.103 of the New York City Healthy Code. AUs are also responsible for ensuring compliance and overseeing safe storage and administration of radiopharmaceuticals. AUs are further approved to interpret imaging acquired using the specified radiopharmaceutical(s). The full scope of AU responsibilities is defined by the Radiation Safety Committee that confers this credential.*

LICENSED INDEPENDENT PRACTITIONER (LIP): *an individual, as permitted by law and regulation, and also by the organization, to provide care and services without direction or supervision within the scope of the individual's license and consistent with the privileges granted by the organization. For the purposes of this document, an LIP is used to indicate a provider who is not otherwise credentialed to serve as an AU. Ordinarily the LIP is a physician (MD/DO), physician assistant (PA) or nurse practitioner (NP).*

3. MINIMAL PROVIDER INVOLVEMENT

All protocols employing radiopharmaceuticals or radionuclides must include at least one LIP on the formal submission. It is strongly encouraged that this individual be an AU, however in Class 2 scenarios defined below a non-AU LIP serve this role.

4. RADIOPHARMACEUTICAL USAGE CLASSIFICATIONS

Usage of radiopharmaceuticals in a way that differs from standard of care:

- **Class 1A** Use of a *non-FDA-approved* radiopharmaceutical, or
- **Class 1B** Use of an *FDA-approved* radiopharmaceutical that is not also offered as clinical standard of care at the performing site, or
- **Class 1C** Use of an *FDA-approved* radiopharmaceutical in a route or method differing significantly from clinical standard of care or for off-label use, or

Uses of radiopharmaceuticals consistent with a clinical pathway follow an abbreviated workflow:

- **Class 2** Radiopharmaceutical usage in a method consistent with standard of care *at the performing site*, even if at increased frequency or modestly differing dose. Note that in this category it is still strongly encouraged that an ***Authorized User (AU)*** be named in the formal protocol submission even though this is not required. If no AU is specified, another ***licensed physician*** must instead be named on the protocol to serve as the requesting provider, but as in the clinical context an AU must sign-off each request.

5. WORKFLOW

Workflows differ slightly depending on the radiopharmaceutical usage scenarios:

		RADIOPHARMACEUTICAL (RP) RESEARCH CLASS	
		CLASS 1A – 1C	**CLASS 2**
1	**CONSENT**	The *Radiation Safety Committee* requires and enforces disclosure of any research radiation on the informed consent form if use exceeds what is necessary as standard of care. If standardized exposure metrics are not available Radiation Safety can help determine the effective dose.	SAME
2	**PROVIDER ROLE**	PI will identify an **AU,** who must specifically accept this role for each relevant protocol. Investigators should submit evidence of acceptance (letter or email is permissible) at submission to the IRB/PPHS. An investigator must not assume acceptance of this role simply because they have worked with this provider previously.	PI will identify an **AU (preferred) or LIP**, who must specifically accept this role for each relevant protocol. Investigators should submit evidence of acceptance (letter or email is permissible) at submission to the IRB/PPHS. An investigator must not assume acceptance of this role simply because they have worked with this provider previously.
3	**PROVIDER DESIGNATION**	An **AU** must be designated on the IRB/PPHS submission. It is recommended that this individual be identified early in the planning stages of a protocol for optimal and timely contribution to the design process.	An **AU or LIP** must be designated on the IRB/PPHS submission. It is recommended that this individual be identified early in the planning stages of a protocol for optimal and timely contribution to the design process.
4	**REQUEST PROCESS**	The *request* and *order* are provided by the **AU** named on the IRB/PPHS submission as specified below.	Note that while an initial scheduling request may come from a provider or non-physician researcher, it is a regulatory requirement that the formal order to procure and inject must come from an **AU** (i.e., an LIP request cannot independently authorize). Therefore, when an **LIP** is the named provider on IRB/PPHS submission, this person or another LIP delegate may *request* a radiopharmaceutical exam but they may not officially *order* this agent. The actual order for administration of a radiopharmaceutical comes from an **AU** that uses the agent clinically as well. This parallels the clinical workflow.

5	RADIOPHARMACEUTICAL ORDERING AND ENDORSEMENT	The **AU** places the formal order for all radiopharmaceutical administrations. While the mechanism may vary to accommodate operational flexibility, at minimum each instance of patient/subject injection must have a trackable order that is signed (electronically or physically) by the **AU,** which may involve a delegate so long as that individual has similar level of authority for ordering that agent as well. This official order is necessary for procurement of the radiopharmaceutical as well as administration into subject/patient and management thereafter. This record should be kept and archived meeting the minimum recording requirements expected for similar clinical use.	SAME
6	RP SAFETY & CUSTODY	The a) AU, b) minimal patient/subject identifiers {name and DOB} and c) radiopharmaceutical/dose must be specified on the isotope order, injection record and vessel. This level of safety is necessary even if the subject will otherwise be deidentified in PACS, RIS or other clinically-facing systems.	SAME
7	CASE REPORT FORM/ FLOWSHEET	The patient visit/encounter under which the radiopharmaceutical is administered must be tracked either consistent with clinical documentation or with an CRF/flowsheet that captures similar relevant attributes. This will ensure that information that would ordinarily be acquired for clinical use would also be acquired and recorded for research purposes while complying with GCP.	SAME
8	PRE-ADMINISTRATION VERIFICATION	As with any procedure associated with more than minimal risk, the personnel involved with radiopharmaceutical management must confirm the appropriate identifiers before the agent is injected. Patient demographics, radiopharmaceutical and dose must be confirmed on the radiopharmaceutical vessel before administration. In the Mount Sinai Health System, minimum identifiers include name and date of birth. Any discrepancy between identifiers contained in the medical record and patient verbalization must be reconciled before radiopharmaceutical administration. This may delay injection or management but this is a necessary step for record integrity. Likewise, any radiopharmaceutical order that differs from the agent specified in the IRB-approved protocol needs to be corrected for administration.	SAME

9	INTERPRETATION & INCIDENTAL REPORTING	For **approved** agents (Class 1B/1C), unless specified in the protocol, interpretation of imaging that is performed consistent with standard of care may be achieved by any **AU**-credentialed to interpret these exams clinically. For **non-approved** agents (Class 1A), the **AU**-designated on the study will provide final interpretation. As needed, the Director of Nuclear Medicine may permit another **AU** to interpret to ensure timely review and ensure subject safety.	For these approved agents (Class 2), unless specified in the protocol, interpretation of imaging that is performed consistent with standard of care may be achieved by any **AU**-credentialed to interpret these exams clinically.

6. DOCUMENTATION

As indicated above, the request for each radiopharmaceutical administration must be archived, although the vehicle is left flexible so long as the request is retrievable on demand. Sample radiopharmaceutical request form is provided in Appendix 1.

Documentation related to injection and imaging must be consistent with GCP. Appendices 2 and 3 include sample forms for investigators to work from. Minimal documented elements include the following:

1. Patient's name, Date of birth and MRN
2. Exam
3. Radiopharmaceutical name and lot number
4. Radiopharmaceutical Dose (activity administered), Volume administered, Date and time administered to patient, Initials of Individual administering radiopharmaceutical
5. Individual starting IV and location
6. Route of administration, site of IV injection, initials of individual documenting information
7. Completion of Pre-Procedure Check (PPC) items with documentation of initials, date & time
8. Vital signs when necessary, with initials of individual performing vitals.

7. RESEARCH ADMINISTRATION (ALL PROTOCOLS)

1. **HARMONIZATION.** Legacy protocols must be harmonized with these standards:
    a. Existing/approved protocols that already specify an AU as part of the formal IRB submission are expected to follow these processes as soon as feasible.
    b. Existing protocols which do not specify an AU currently, but require one under this workflow, will be expected to include this designation as a modification at the next review.
    c. Protocols which have not yet been submitted for IRB approval must follow these standards for approval.

2. **ACCESS.** These Standard Operating Procedures are to be kept in a location that is conspicuous and available for review or clarification. For example, this should be posted on the BMEII website with other procedural and reference documents. It is also encouraged that systems that rely on this workflow provide an electronic link for access.

APPENDIX 1. SAMPLE RADIOPHARMACEUTICAL PROCUREMENT FORM

Dose Request Form

All ordered submitted to:

To be filled out by the clinical/imaging facility:

Study Title:

Site: Icahn School of Medicine at Mount Sinai

Site #:

Principal Investigator:

Investigational Product:

Ordering Physician (AU):

Signature of the ordering physician:

Order Date:

Phone number:

Ship to:

ORDER DETAILS:

Radiopharmaceutical:

Planned Injection Date:

Planned Injection Time:

Activity Requested at injection (mCi/MBq):

APPENDIX 2. SAMPLE CASE REPORT/TRACKING FORM 1

STUDY #:
[Vendor Name and IND]
[Protocol Name]
Subject Number:

Assessment	**Baseline**
Scanner Manufacturer and Model	Siemens Biograph Vision
Data Quality Control (QC) performed and passed prior to scanning: Yes/No	
Date of Scan	
Was PET/CT scan performed?	
Reason not done (if applicable)	
Height (cm)	
Weight (kg)	
BP/T/HR/O2	
Total Volume Received	
Measured activity before injection	
Time of measured activity	
REQUIRED: CONFIRM NAME AND DATE OF BIRTH BEFORE INJECTING/ADMINISTERING Name and DOB confirmed, Sign here:	
Administration date and time	
Site of Injection	
Was injection successful?	
If No, please comment	
Residual Activity post injection	
Residual Activity Time Measured	
How much tracer injected (total dose)	
Residual Volume	
Volume injected	
Scan Start Time	
Time per PET bed position	
Scan stop time	
Any deviations from the PET/CT Protocol?	
If yes, please comment	
Scan performed by	

APPENDIX 3. SAMPLE CASE REPORT/TRACKING FORM 2

ROOM____

Mount Sinai Hospital

Oncology PET Worksheet (To be completed by a Nurse/Technologist)

Patient Name _____ MRN _____ Age _____ Sex: M / F

Date _____ Referring MD _____

Indication _____

QUESTIONS FOR CONTRAST

1) Kidney disease? ☐YES ☐NO
If yes, Lab Date _____ Check Date_____
Creatinine ____mg/dL, GFR____ mL/min/1.73m2)
2) Multiple Myeloma? ☐YES ☐NO
3) Pheochromocytoma? ☐YES ☐NO
4) Asthma? ☐YES ☐NO
5) Allergies to foods, medications or IV contrast?
☐YES ☐NO _____
6) Diabetes? ☐YES ☐NO
Oral hypoglycemic medications: ☐YES ☐NO
Glucophage/Metformin, Glucovance? Other :
_____
IF YES, BUN/CREATININE MUST BE CHECKED BY REFERRING MD BEFORE RESUMPTION

IV CONTRAST ☐
Agent? Isovue 300 (_____) Volume_____ml
Needle gauge _____ Injected by _____
ORAL CONTRAST given? ☐YES ☐NO
_____

PATIENT HISTORY

NPO:_____
_____
Diabetes: _____
_____
Chemo:_____
_____
Radiation: _____
_____
Biopsy: _____
_____
Surgery: _____
_____

RADIOPHARMACEUTICAL:

Enter radiotracer:
_____
Dose _____ mCi **Injected by** _____
Assay time_____ **Inj. time**_____
Inj. site _____
Residual Activity
Post-inj _____ mCi **Assay time** _____
Weight _____ lb(____kg) **Height** ___ft___in(____cm)
Glucose _____ **Meas. time** _____

IMAGING

PET: _____
_____
CT: _____
_____
MRI: _____
_____

PREGNANCY SCREENING ☐

1) Last menses? _____
2) Possibility of pregnancy? ☐YES ☐NO
3) Pregnancy test performed? ☐YES ☐NO (attach results)
4) Currently breastfeeding? ☐YES ☐NO
5) Caring for small children/ infants? ☐YES ☐NO
Verified by _____ **Date** _____ **Time**_____

FINAL CHECK

To ensure patient undergoes correct exam, each team member initials a box to confirm following 6 items.
1) Patient Identity (name & DOB)
2) Exam type, including contrast / radionuclide
3) Exam side & site
4) Exam is consistent with expectations of patient (if aware & oriented)
5) Identifiers match data on screening console
6) Scan protocol matches physician & institution protocol
These verifications should be performed as close to the start of the procedure as practical, with the patient in scanning position when appropriate.

☐____ ☐____ ☐____ ☐__ ☐__ ☐____