Radiopharmaceutical PET Tracer Request Form

Use this form for all requests to produce PET Drugs in the University of Wisconsin Radiopharmaceutical Production Facility (RPF).

Please provide the following information to best enable us to efficiently process your request for manufacturing PET drugs in the RPF. This request should be completed prior to submitting a grant application or protocol submission to the IRB. If you have questions regarding the information being requested, please contact: RadiologyRPForm@uwhealth.org or phone (608) 265-2435. After completion, email form to RadiologyRPForm@uwhealth.org.

*Required

Clear Form

1. Date of request (MM/DD/YYYY):* MM/DD/YY

2. Name of person requesting service:*

3. Email address:*

Radiopharmaceutical Information

4. Identity of the radioactive drug (generic name):*

5. Identity of the radioactive drug (chemical name):*

6. Radionuclide label and proposed clinical indication:

7. Is the clinical indication, dose, and route of administration the same as indicated on the label? Select only one.

- ◯ Yes
- ◯ No
- ◯ Don't know

8. List (via hyperlinks) publications or relevant references or documents. In particular, list references to published literature of chemistry and manufacturing procedures:

9. Is the radiopharmaceutical commercially available? Select only one.

- ◯ Yes
- ◯ No
- ◯ Don't know

10. Is use of the radiopharmaceutical FDA approved? Select only one.

- ◯ Yes, under a New Drug Approval (NDA)
- ◯ Yes, under an Abbreviated New Drug Approval (ANDA)
- ◯ Yes, under an Investigational New Drug (IND) Application
- ◯ No
- ◯ Don't know

11. Can the radiopharmaceutical be used in clinical research under a RDRC approval mechanism? Select only one.

- ◯ Yes
- ◯ No
- ◯ Don't know

Clinical Information

12. Route of administration: Select only one.

- ◯ Administration route via intravenous infusion (IV)
- ◯ Other:
- ◯ Don't know

13. Maximum activity administered:

14. Estimated radiation doses to human subjects: total effective dose equivalent

15. Critical organ and dose:

16. Is this PET drug intended to support a single center study or a multicenter/collaborative research study? Select only one.

- ◯ Single Center Study
- ◯ Multicenter / Collaborative Study

17. If a multicenter/collaborative research study, then is there a specific requirement to produce the PET drug in accordance with an established manufacturing method? Select only one.

- ◯ Yes
- ◯ No
- ◯ Don't know

18. How many subjects are anticipated and during what period of time?

19. What is the pharmacological dosage of the active ingredient?

20. Who is the designated Clinical Investigator for a clinical study or Physician for medical care?

Funding / Regulatory Information

21. Grant Application Deadline:* MM/DD/YY

22. Anticipated funding date: MM/DD/YY

23. Anticipated submission date to IRB: MM/DD/YY

24. Who is the designated Authorized User (for radioactive radiopharmaceutical)?

25. Estimated number of PET drug synthesis runs (i.e. doses) for clinical use over a one year period?

26. Are funds available for radiopharmaceutical start-up? Select only one.

- ◯ Yes
- ◯ No
- ◯ Don't know

27. Please provide the amount of funding available for radiopharmaceutical production to support clinical research:

Other Information

28. Priority* 1 = very high priority, 5 = very low priority 5

29. Response from RPF required by date: MM/DD/YY

30. More details: