Health Canada Santé Canada

Appendix 1 – Application for Authorization of Positron-emitting Radiopharmaceuticals (PERs) for Use in a Basic Clinical Research Study

PART 1 – General Information

Brand name, if any, of positron-emitting radiopharmaceutical(s)				
Chemical or generic name of the active ingredients in the study drug				
A) Sponsor				
Name of sponsor (e.g. Institution)				
Street / Suite	City / Town	Prov. / State	Country	Postal/ZIP Code
Postal address (if different)	City / Town	Prov. / State	Country	Postal/ZIP Code
Name of study contact (e.g. Investigator or Consultant)		Title		
Company Name				
Street / Suite	City / Town	Prov. / State	Country	Postal/ZIP Code
Telephone No.	Fax No.	E-mail Address		
B) Manufacturer or in the case of an application for importation, the manufacturer's representative in Canada who is responsible for the sale of the study drug				
Name of manufacturer				
Street / Suite	City / Town	Province	Country Canada	Postal Code
Postal address (if different)	City / Town	Province	Country Canada	Postal Code
Name of contact		Title		
Telephone No.	Fax No.	E-mail Address		
C) Related Submissions*				
Type	Control No.	File No.	Date Cleared (yyyy/mm/dd)	
Brand Name		Manufacturer/Sponsor Name		
*** Attach separate sheets if necessary (same format). Number of pages attached:** _____				

Canada

PART 2 – Application and Information Requirements	
Title of the basic clinical research study and the protocol code or identification	
Purposes and concise description of study - Please attach a 1-2 page summary. - Ensure that an explanation is provided as to how the criteria for basic clinical research (as outlined herein) have been met.	☐ Summary attached
Number of study subjects	
Qualitative list of the non-active ingredients of the study drug	
Maximum mass to be administered	
Radioactive dose range of the study drug, expressed in MBq or mCi	
Effective dose or effective dose equivalent of the study drug, expressed in mSv/MBq or rem/mCi	

	PART 3 – Attestation (NOTE: if any item is left unchecked, a CTA should be filed)
☐	1. The purpose of the study is to a) obtain data on the pharmacokinetics or metabolism of the study drug; b) normal human biochemistry or physiology; or c) changes caused to human biochemistry or physiology by aging, disease or medical interventions.
☐	2. The study is NOT primarily intended to a) discover, identify or verify the pharmacodynamic effects of the study drug; b) identify adverse reactions; c) fulfil an immediate therapeutic or diagnostic purpose; or d) ascertain the safety or efficacy of the study drug.
☐	3. There is sufficient data from testing the study drug in animals and humans to demonstrate its safety in humans.
☐	4. The amount of active ingredients or combination of active ingredients in the study drug has been shown not to cause any clinically detectable pharmacodynamic effect in humans.
☐	5. The total radiation dose incurred annually by a study subject, including from multiple administrations of the study drug, from significant contaminants or from impurities and from the use of other procedures for the purposes of the study, will be not more than 50 mSv.
☐	6. All concurrent medications (other than the PER) used in this study have been granted market authorization by Health Canada.
☐	7. Subjects are over 18 years old and have legal capacity at the time of the study.
☐ ☐	8. Confirm that female subjects are not pregnant (as confirmed by a pregnancy test or signed declaration) and/or are to suspend breast feeding for 24 hours after the administration of the study drug. There are no females in this study.
☐ ☐	9. The total number of subjects in this study is equal to or less than 30 individuals. ***If the study includes more than 30 individuals, a scientific rationale has been provided to the Minister.

☐	10. All criteria for a basic clinical research study as set out in subsection C.03.307 (1) of the *Food and Drug Regulations* have been met.
☐	11. The starting date for each study site has been provided. Please note that if the date is not known at this time, the sponsor must notify the Minister in writing of the day on which the sale or importation of the study drug is intended to start in respect of each study site, not later than 15 days before that day.
☐	12. A research ethics board has approved the study proposed within this submission, and the approval letter is enclosed. (Please see attached REB attestation form)
	13. A list of any previous applications for studies related to the current study has been provided. ◯ yes ◯ n/a
☐	14. The study will be conducted in accordance with all applicable *Regulations*.
☐	15. All information contained or referred to in the application is complete and accurate and is not false or misleading.
☐	16. All requirements for clinical information, as outlined in this template and within section C.03.307 of the *Food and Drug Regulations* have been met.
☐	17. All requirements for quality information and data, as outlined in this template and within section C.03.311 of the *Food and Drug Regulations* have been met.
☐	18. Subjects in the study will be monitored according to pre-determined procedures, and any serious adverse reaction attributable to the use of the PER should be reported to Health Canada within the prescribed time frames.

Sponsor's Senior Medical Officer or Scientific Officer or Qualified Investigator in Canada:	Telephone Number:
Signature:	Date (yyyy/mm/dd):
Sponsor's Senior Executive Officer (if different than above):	Telephone Number:
Signature:	Date (yyyy/mm/dd):