Health Canada Santé Canada

Appendix 2 – Study Site Information and Research Ethics Board Attestation

An attestation must be completed by the Research Ethics Board that reviewed and approved the basic research study protocol and informed consent form for the study at the site specified below. The completed attestation must be retained by the study sponsor for a period of 5 years after the day on which the study ends.

PART 1 – Basic Research Study Protocol Information

Type of change (if applicable):

- ☐ Change in Sponsor Information (complete Part 2)
- ☐ Change in Site Address (complete Part 3A)
- ☐ Change/Addition of a Study Start Date (complete Part 3A)
- ☐ Change in Qualified Investigator (Name of Previous Investigator:_____) (complete Part 3B)
- ☐ Change in Research Ethics Board (complete Part 3C)
- ☐ Addition of a New Study Site (complete all of Part 3)
- ☐ Other (please specify):_____

Basic Research Study Protocol Title	
Basic Research Study Protocol Number (if applicable)	Health Canada Control Number (if assigned)

PART 2 – Drug Product / Sponsor Information

A) Drug Product Information

Brand Name				
Proper or Common Name				

B) Sponsor of the Basic Research Study

Name of sponsor (e.g. Institution)				
Street / Suite	City / Town	Prov. / State	Country	Postal/ZIP Code
Name of contact	Title			
Telephone No.	Fax No.	E-mail Address		

PART 3 – Basic Research Study Site Information*

A) Basic Research Study Site

Name of Site (Full Name - No Abbreviations)			
Street / Suite / PO Box	City / Town	Province	Postal Code

Canada

Start Date of the Basic Research Study (yyyy/mm/dd) : _____			
B) Qualified Investigator			
Name	Title		Language Preferred ◯ English ◯ French
Street / Suite / PO Box	City / Town	Province	Postal Code
E-mail Address		Telephone No.	Fax No.
C) Research Ethics Board Approval			
Name of Research Ethics Board		Date of Approval (yyyy/mm/dd)	
Street / Suite / PO Box	City / Town	Province	Postal Code
Name of Research Ethics Board Chair	Telephone No.	Fax No.	Language Preferred ◯ English ◯ French
Title		E-mail Address	
*** Attach separate sheets if necessary (same format) for each Basic Research Study Site.** **Number of pages attached:** _____			

In respect of the identified basic research study, as a representative of this Research Ethics Board, I certify that:

1. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in C.03.306 of the *Food and Drug Regulations*;

2. This Research Ethics Board carries out its functions in a manner consistent with Good Clinical Practices; and

3. This Research Ethics Board has reviewed and approved the basic research study protocol and informed consent form for the study which is to be conducted by the qualified investigator named above at the specified basic research study site. This approval and the views of this Research Ethics Board have been documented in writing.

Name, Title and Signature of Research Ethics Board Representative	
Name:	Title:
Signature: _____	Date (yyyy/mm/dd):