

RESEARCH ETHICS BOARD ATTESTATION

An attestation must be completed by the Research Ethics Board that reviewed and approved the clinical trial protocol and informed consent form for this clinical trial at the site specified below. The completed attestation must be retained by the clinical trial sponsor for a period of 25 years.

Please note that the Research Ethics Board Form should not be submitted to Health Canada unless requested.

PART 1 - Clinical Trial Protocol Information				
Please check one of the following: Clinical Trial Application (CTA) <input type="checkbox"/> Clinical Trial Application Amendment (CTA-A) <input type="checkbox"/>				
1. Clinical Trial Protocol Title			2. Clinical Trial Protocol Number (If Applicable)	
PART 2 - Drug Product / Sponsor Information				
A) Drug Product Information				
3. Brand Name				
4. Proper or Common Name				
B) Sponsor of Clinical Trial				
5. Company Name (Full Name - No Abbreviations)				
6. Street / Suite / PO Box	7. City / Town	8. Prov. / State	9. Country	10. Postal/ZIP Code
C) Contact for THIS Clinical Trial				
11. Contact Name			12. E-mail	
13. Company Name (Full Name - No Abbreviations)				
14. Street / Suite / PO Box	15. City / Town	16. Prov. / State	17. Country	
18. Telephone No.	19. Fax No.		20. Postal/ZIP Code	



PART 3 - Clinical Trial Site Information			
A) Clinical Trial Site			
21. Name of Site (Full Name - No Abbreviations)			
22. Street / Suite / PO Box	23. City / Town	24. Province	25. Postal Code
B) Qualified Investigator			
26. Name	27. Title	28. Language Preferred <input type="checkbox"/> English <input type="checkbox"/> French	
29. Street / Suite / PO Box	30. City / Town	31. Province	32. Postal Code
33. E-mail		34. Tel. No.	35. Fax No.
* Attach separate sheets (same format) for each Clinical Trial Site. Number of pages attached: _____			
C) Research Ethics Board Approval			
36. Name of Research Ethics Board		37. Date of Approval	
38. Street / Suite / PO Box	39. City / Town	40. Province	41. Postal Code
42. Name of Research Ethics Board Chair	43. Telephone No.	44. Fax No.	45. Language Preferred <input type="checkbox"/> English <input type="checkbox"/> French
46. Title		47. E-mail	

In respect of the identified clinical trial, I certify, as representative of this Research Ethics Board that:

1. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Part C Division 5 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 clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named above at the specified clinical trial site. This approval and the views of this Research Ethics Board have been documented in writing.

48. Name, Title and Signature of Research Ethics Board Representative		49. Date			
Name:	Title:	YYYY	M	D	
Signature:					