



QUALIFIED INVESTIGATOR UNDERTAKING

An undertaking must be completed by the qualified investigator responsible for the conduct of the clinical trial at the site specified below. The completed undertaking must be retained by the clinical trial sponsor for a period of 25 years.

Please note that the Qualified Investigator Undertaking 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 - Qualified Investigator 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.

In respect of the identified clinical trial, I certify, as the qualified investigator for this site that:

1. I am a physician or dentist and a member in good standing of a professional medical or dental association as defined in Part C Division 5 of the *Food and Drug Regulations*;
2. I will supervise the medical care and medical decisions respecting this clinical trial at this site;
3. I will conduct this clinical trial in accordance with Good Clinical Practices; and
4. I will immediately on discontinuance of the clinical trial by the sponsor, in its entirety or at a clinical trial site, inform both the clinical trial subjects and the Research Ethics Board for this site of the discontinuance, provide them with the reasons for the discontinuance, and advise them in writing of any potential risks to the health of clinical trial subjects or other persons.

36. Signature of Qualified Investigator	37. Date					
	YYYY		M		D	