# 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 15 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) ⭘ Clinical Trial Application Amendment (CTA-A) ⭘ |
| 1. Clinical Trial Protocol Title | 2. Clinical Trial Protocol Number |
| 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 English 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* or a person who is a member in good standing of a professional association of persons entitled under the laws of a province to provide health care under their license in that province as defined in the *Clinical Trials for Medical Devices and Drugs Relating to COVID-19 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-MM-DD)  |
|  | YYYY | MM | DD |
|  |  |  |  |  |  |  |  |