**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 Attestation should not be submitted to Health Canada unless requested.**

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| **PART 1 - Clinical Trial Protocol Information**  Please check one of the following:  **Clinical Trial Application (CTA) ⭘**  **Clinical Trial Application Amendment (CTA-A) ⭘** | | | | | |
| Amendment Number | | | Amendment Date (YYYY-MM-DD) | | |
| 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 | |

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| **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. |
| **\* 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  English French |
| 46. Title | | 47. E-mail | |



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

1. 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* or with the definition in the *Interim Order No.2 Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19*;
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 | | | | MM | | DD | |
| Signature: | |  |  |  |  |  |  |  |  |