Clinical Trial Site Information Form

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Click here to view the instructions

1. Clinical Trial Lead (required) ◯ Pharmaceutical ◯ Biologic

2. Reason for Filing (required) ◯ **New Site** ◯ Change to Existing Site

3. Changes (required for 'Changes to Existing Site') ☐ Clinical Trial Site ☐ Commencement Date ☐ Research Ethics Board ☐ Qualified Investigator

☐ Safety Amendment (when invoking C.05.008(4) of the *Regulations* or Part 2, 24(2) of the *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Related to COVID-19*)

4. Protocol Number (field auto-converts text to CAPS) (required)

5. Clinical Trial Parent Control Number (required)

6. Clinical Trial Amendment Control Number(s), if applicable

Clinical Trial Site

7. Name of Site previously provided to Health Canada (full name, no abbreviations)

8. Name of Site (full name, no abbreviations)

9. Street Number | 10. Street Name | 11. Suite/Unit | 12. P.O. Box

13. City/Town | 14. Province/Territory | 15. Postal Code

16. Commencement Date of the Clinical Trial Protocol (YYYY-MM-DD)

Qualified Investigator

17. First Name | 18. Last Name | 19. Qualification(s)

20. Street Number | 21. Street Name | 22. Suite/Unit | 23. P.O. Box

24. City/Town | 25. Province/Territory | 26. Postal Code

27. Email Address | 28. Phone | 29. Ext. | 30. Fax | 31. Language

Research Ethics Board Approval

32. Name of Research Ethics Board, including affiliations (if applicable) (full name, no abbreviations)

Note: You only need to include the contact information for a research ethics board once per trial, as long as the same contact information has already been provided to Health Canada in the context of this clinical trial, and continues to be up to date.

33. Street Number | 34. Street Name | 35. Suite/Unit | 36. P.O. Box

37. City/Town | 38. Province/Territory/State | 39. Country | 40. Postal Code/ZIP

41. Title | 42. First Name | 43. Last Name

44. Email Address | 45. Phone | 46. Ext. | 47. Fax | 48. Language

49. Date of Research Ethics Board Approval (YYYY-MM-DD)

It is required that this date be BEFORE the commencement date of the clinical trial

50. Safety Implementation Rationale (required for Safety Amendments) Clear Rationale

Save and rename before submitting

Ver.20.05.14