Health Canada Santé Canada

# Clinical Trial Site Information Form

**Protected B** When Completed

**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) (required)

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

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

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

## Qualified Investigator

Title | 17. First Name (required) | 18. Last Name (required) | 19. Medical Designation(s) (required)

Dr.

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

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

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

## Research Ethics Board Approval

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

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

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

41. Title | 42. First Name (required) | 43. Last Name (required)

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

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

**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**



Canada