Health Canada Santé Canada

Protected B When Completed

Application Form for an Amendment to a Medical Device Clinical Trial under the *Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations*

* denotes a mandatory field

Part 1 – Revision to clinical trial information		
1. Please indicate the Clinical Trial Application Number that is to be revised. *		
2. Please check off all the modifications that have been made to the last authorization. *		
	Types of Amendments (Check ALL that apply)	**Briefly describe the change (more details and substantiating documents should be provided within the submission).**
Changes to device details	☐ A change to the classification of a device	
	☐ A change in the manufacturer's name or address	
	☐ A change in the regulatory contact's name or address	
	☐ A change in the importer's name or address	
	☐ A change to device name (s)	
	☐ A change to the intended use of the device	
	☐ A change to the design or performance specifications (including software changes)	
	☐ A change in device materials	
	☐ A change to sterilization	
	☐ A change to the labelling	
	☐ A change in manufacturing process, facility, equipment or quality control procedures	
	☐ Any change which could affect the safety and effectiveness of the device	
	☐ Addition, deletion, or change in device components or associated model/catalogue numbers	
Change to study details	☐ A change to protocol details	
	☐ A change to Informed Consent Form (ICF)	
	☐ A change to the number of study subjects in Canada	
	☐ A change to the duration of the study	
	☐ A change to the number of device units requested	

Canada

Change to institutional information	☐ Addition or deletion of institution(s)	
	☐ **Class III & IV only** Change to the name of lead qualified investigator	
	☐ **Class III & IV only** Updated institutional approval information (REB)	
Other	☐ Other changes not described by any option above	

Part 2 – Contact Information

A) Applicant mailing address * ☐ No Changes

3. Applicant name (Full legal name – No abbreviations)			
4. Street address/suite/post office box			
5. City	6. Prov./State	7. Country	8. Postal/Zip code
9. Contact name	10. Title		
11. Telephone number	12. Fax number	13. Language preferred O English O French	
14. Email			

B) Manufacturer Mailing Address ☐ No Changes

15. Manufacturer name (Full legal name – No abbreviations)			
16. Street address/suite/post office box			
17. City	18. Prov./State	19. Country	20. Postal/Zip code
21. Contact name	22. Title		
23. Telephone number	24. Fax number	25. Language preferred O English O French	
26. Email			

C) Importer mailing address ☐ No changes			
27. Importer name (Full legal name – No abbreviations)			
28. Street address/suite/post office box			
29. City	30. Prov./State	31. Country	32. Postal/Zip code
33. Contact name	34. Title		
35. Telephone number	36. Fax number	37. Language preferred ○ English ○ French	
38. Email			

Part 3 – Changes to device Information

39. Device name - as it appears on the label. This is the device name for which the authorization will be issued.

☐ No changes

40. Intended use of device. Please provide the change in the intended use statement indicating the disease(s) or condition(s) the device is intended to diagnose, treat, prevent or mitigate.

☐ No changes

Part 4 – Changes to institution information		
41. Clinical trial site(s) name and address	**42. Qualified investigator**	**43. REB name and contact information (Class III and IV only)**
O Add O Delete O Modify		
O Add O Delete O Modify		
O Add O Delete O Modify		

Part 5 – Changes to device details ■ No changes

Please provide the following information for each device, component, part or accessory to be changed from the previous authorization by completing **Sections 44-47**. Please note: **Only device details which have been modified** from the previous authorization should be included in the table below.

Note: Only list one device per row. If additional rows are required, please use a PDF Editor or the Word Document version of this form.

Additions (New devices to be added to the Clinical Trial Authorization)

44. Name of device, components, parts and/or accessories as per product label	45. Model or catalogue number	46. Total number of units requested (for Canadian sites only	47. Global medical device nomenclature (GMDN)	48.Preferred Name Code (PNC)

Removal (Devices being removed from the Clinical Trial Authorization)

44. Name of device, components, parts and/or accessories as per product label	45. Model or catalogue number	46. Total number of units requested (for Canadian sites only	47. Global medical device nomenclature (GMDN)	48.Preferred Name Code (PNC)

Changes (changes to devices from what was previously authorized)

Note: This section should only be used for changes to device model or catalogue numbers. If there is a change to the device name (i,e, field #44), use the addition and removal sections above.

44. Name of device, components, parts and/or accessories as per product label	45. Model or catalogue number	46. Total number of units requested (for Canadian sites only	47. Global medical device nomenclature (GMDN)	48.Preferred Name Code (PNC)

Part 6 – Changes to protocol identification	▣ No changes
49. Protocol title:	
50. Protocol version and date:	
51. Total number of patients in the study (Canadian sites only):	
52. Total duration of study:	
53. Duration of the study enrolment phase:	
54. Study objectives:	

Part 7 – Supporting information/evidence to be submitted with an application for an amendment to a medical device clinical trial under the *Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations*

55. Please check all items that are included in the submission to support the requested amendment to the Clinical Trial Authorization

Required for ALL Applications
(Class II, III, and IV)

- ☐ Device identifier & description of features of the device (design philosophy and performance specifications)
- ☐ Directions for use
- ☐ Device labels
- ☐ Institution name(s) and contact information
- ☐ Study protocol document (date/version)
- ☐ Informed consent form (ICF) (date/version)
- ☐ Attestation for post-market oversight

Required for Class III and Class IV device applications
Optional for Class II devices)

- ☐ Device description & intended use
- ☐ Marketing history
- ☐ Quality, safety and effectiveness information (e.g. bench testing, animal studies, clinical studies, risk assessment)
- ☐ Name of lead qualified investigator and qualifications (academic and/or clinical curriculum vitaes (CV) and evidence of membership in good standing with a health care professional's regulatory body)
- ☐ Signed agreement from lead qualified investigator
- ☐ Standards and declaration of conformity (DoC)
- ☐ Research ethics board (REB) name and contact information

Part 8 – Attestations and Signatures*

I, the applicant named in **Section 9** of this application, hereby attest that I have direct knowledge of the items checked above and declare that these identified statements are true and that the information provided in this application and in any attached documentation is accurate and complete.

56. Name:	57. Title:
58. Signature:	59. Date (YYYY-MM-DD):