Health Canada Santé Canada

Application form for revision to medical device clinical trials under the interim order (COVID-19)

* 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 revisions
Changes to device details	☐ A change to the classification of a device
	☐ A change in the manufacturer'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 labeling
	☐ 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
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)

Canada

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 label. This is the device name for which the authorization will be issued.

☐ No changes

40. Intended use of device (required for Class III and IV only). Please provide the change in the intended use statement to indicate 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 sites name and address	**42. Qualified investigator (Class III and IV only)**	**43. REB name and contact information (Class III and IV only)**
○ **Add** ○ **Delete** ○ **Modify**		
○ **Add** ○ **Delete** ○ **Modify**		
○ **Add** ○ **Delete** ○ **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.

	44. Name of device, components, parts and/or accessories as per product label	45. Model or catalogue number	46. Total number of units requested	47. Global medical device nomenclature (GMDN)	Health Canada use only Device identification number
Addition					
	44. Name of device, components, parts and/or accessories as per product label	45. Model or catalogue number	46. Total number of units requested	47. Global medical device nomenclature (GMDN)	Health Canada use only Device identification number
Deletion					

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

Part 7 – Supporting information/evidence to be submitted with an application for a revision to a medical device clinical trial under the interim order (COVID-19)
54. Please check all items that are included in the submission to support the requested revision to medical device clinical trial under the interim order (COVID-19)
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 labeling
☐ Institution name(s) and contact information
☐ Study protocol document (date/version)
☐ Informed consent form (ICF) (date/version)
☐ Attestation for post-market oversight
☐ Recommended for Class II: Standards and declaration of conformity (DoC)
Required for Class III and Class IV only **(May include for Class II devices if necessary)**
☐ Device description & intended use
☐ Marketing history
☐ Quality, safety and effectiveness information (e.g. 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)
☐ Verification and validation: device design (e.g. mechanical, electrical); performance; shelf life; sterilization; bioburden, pyrogenicity; software; packaging stability; and, biocompatibility.
☐ Research ethics board (REB)/Ethics committee (EC)/Investigational research board (IRB) 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.	
55. Name: *	56. Title:
57. Signature:	58. Date (YYYY-MM-DD):