# 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

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| 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 |  |

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| **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  ⭘ English ⭘ 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  ⭘ English ⭘ 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)** | | | |
| ⭘ **Add** ⭘ **Delete** ⭘ **Modify** | | | | | | | | | | | | | | |
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| ⭘ **Add** ⭘ **Delete** ⭘ **Modify** | | | | | | | | | | | | | | |
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| ⭘ **Add** ⭘ **Delete** ⭘ **Modify** | | | | | | | | | | | | | | |
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| 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)** |
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| **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)** |
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| **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)** |
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| 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): | | | | |