National Research Ethics Committee

Substantial Amendment Application Form

Version 1.0

This application form should be completed and submitted by the Principal Investigator (the person who takes primary responsibility for the conduct of the clinical investigation). Please complete all sections of this form. It should be filled out in language comprehensible to a lay person. If you are uncertain whether the proposed change to your study constitutes a Substantial Amendment, please see guidance on <https://www.nrecoffice.ie/guide-to-substantial-amendments/>.

A. Investigation Information

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| --- | --- | --- | --- |
| A.1 Please provide details of your study. | | | |
| Title of Research Study | Click or tap here to enter text. | | |
| NREC Application Code | Click or tap here to enter text. | | |
| Date of Submission | Click or tap to enter a date. | | |
| Name(s) of Principal Investigator | Click or tap here to enter text. | Email | Click or tap here to enter text. |
|  |  | Telephone | Click or tap here to enter text. |
|  |  | Address | Click or tap here to enter text. |
| Name(s) of Sponsor/Legal Representative (Must be in EU) | Click or tap here to enter text. | Email | Click or tap here to enter text. |
|  |  | Telephone | Click or tap here to enter text. |
|  |  | Address | Click or tap here to enter text. |
| EU-CT or UDI Identifier (select identifier applicable) | Click or tap here to enter text. | | |
| Name of Original Ethics Committee | Click or tap here to enter text. | | |
| Date of Original Ethics Approval | Click or tap to enter a date. | | |
| Original REC Letter Reference Number  (Please attach copy of original REC/NREC-MD letter with amendment form) | Click or tap here to enter text. | | |

B. Nature of Proposed Substantial Amendment

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| --- | --- |
| Please indicate the nature of the Substantial Amendment, and provide details along with a justification in Section C. | |
| 1. Amendment to the Clinical Investigation / Trial Protocol (If YES, please attach a copy and highlight the changes) | Yes No |
| 1. Change of Sponsor(s) or Sponsor(s) Legal Representative | Yes No |
| 1. Appointment/Departure of a Principal Investigator (If YES, please include brief CV) | Yes No |
| 1. Inclusion of a Study Site (If YES, please attach Site Suitability From) | Yes No |
| 1. Change to Insurance or Indemnity Arrangements (If YES, please include relevant documentation) | Yes No |
| 1. Amendment to Patient/Next-of-Kin Information Leaflet   (If YES, please attach a copy and highlight the changes) | Yes No |
| 1. Amendment to Consent Form/Assent Form (If YES, please attach a copy and highlight the changes) | Yes No |
| 1. Amendment to Other Documents included in the Original Application   (If YES, please attach a copy and highlight the changes) | Yes No |
| 1. Amendment characterised by Urgent Safety Measures already implemented | Yes No |
| 1. Notification of a Temporary Suspension in Clinical Investigation | Yes No |
| 1. Notification to request Restart of Clinical Investigation | Yes No |
| 1. Other Amendment that affects the Safety/Physical/Mental Integrity of Participants or to the Risk/Benefit Assessment for the Study | Yes No |
| 1. Substantial Amendment not listed above | Yes No |

C. Details and Justification for Proposed Substantial Amendment

Please complete Section C as it relates to the proposed Substantial Amendment.

Where it requires a change(s) to study documentation, the proposed change(s) should be highlighted as Tracked Changes in the relevant document(s) and submitted along with this form to the National Research Ethics Committee. Please provide section references and page numbers for proposed changes to documentation in the table below.

|  |  |
| --- | --- |
| Details and justification for the proposed Substantial Amendment. | Document Reference -  Section/Page |
| Click or tap here to enter text. | Click or tap here to enter text. |

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| **Declaration of the Principal Investigator**  ***This declaration must be signed and sent to the NREC together with the requisite fee before the application will be considered as valid. Digital signatures will be accepted.***   * I certify that the information in this form is accurate to the best of my knowledge and I take full responsibility for it. * I undertake to abide by the ethical principles outlined in the Declaration of Helsinki, and my obligations as set out in the relevant Good Clinical Practice Guidelines, *(International Conference on Harmonisation’s Good Clinical Practice Guidelines (ICH GCP), International Organisation for Standardisation 14155 (ISO 14155))* and the relevant European Regulations, *(European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 (S.I. No 190 of 2004), Clinical Trials Regulation (EU) 536/2014, Medical Devices Regulation (EU) 2017/745*). * If the amendment is approved, I undertake to adhere to the study protocol and to comply with any conditions set out in the letter of approval sent by the relevant NREC. * I am aware of my responsibility to be up to date and comply with the requirements of the law relating to security and confidentiality of patient or other personal data.   **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name**: Click or tap here to enter text.  **Date:** Click or tap to enter a date. (dd/mm/yyyy) |