National Research Ethics Committee

Applications for PMCF Investigations with Additional Invasive/Burdensome Procedure(s)

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.

A. Investigation Information

|  |  |  |  |
| --- | --- | --- | --- |
| A.1 Please provide details of your study. | | | |
| Title of Research Study | Click or tap here to enter text. | | |
| NREC Application Code (if applicable) | 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. |
| UDI Identifier | Click or tap here to enter text. | | |
| Date of Original Submission | Click or tap to enter a date. | | |
| 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 PMCF application form) | Click or tap here to enter text. | | |

B. Nature, Details and Justification of Proposed Additional Invasive / Burdensome Procedure(s)

Please complete Section B as it relates to the proposed additional invasive/burdensome procedure(s).

|  |  |
| --- | --- |
| Please provide details of the additional invasive / burdensome procedure(s). | |
| Click or tap here to enter text. | |
| Please provide a justification for the additional invasive / burdensome procedure(s). | |
| Click or tap here to enter text. | |
| Where it requires a change(s) to study documentation, the proposed additional procedure(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 box below. | Document Reference -  Section/Page |
| Click or tap here to enter text. | Click or tap here to enter text. |

|  |
| --- |
| **Declaration of the Principal Investigator**  ***This declaration must be signed and sent to the NREC-MD 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 additional invasive/burdensome procedure(s) to the PMCF investigation is(/are) 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 NREC-MD. * 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) |