National Research Ethics Committee

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

Version 2.0

Instructions

* This application form is designed for clinical investigations of medical devices and performance studies of *in vitro* diagnostic medical devices only.
* Unless indicated otherwise, the term “medical device” is used in this form to refer both to medical devices as defined by the Medical Devices Regulation (EU) 2017/745 and *in vitro* diagnostic medical devices as defined by the *In Vitro* Diagnostic Medical Device Regulation (EU) 2017/746.
* This application form should be completed and submitted by the National 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**

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| --- | --- | --- | --- |
| 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/PMPF 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).

|  |  |
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| 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. |