National Research Ethics Committee for Clinical Investigations of Medical Devices (NREC-MD)

Document Submission Checklist for clinical investigations of medical devices submitted under EU 745/2017

Version 2

Instructions

* This application form is designed for clinical investigations of medical devices only.
* Please enclose a completed version of this checklist with your application and documentation for ethical review by the NREC-MD. Please note this list is not exhaustive and additional documents may be requested by the Committee for the purposes of their evaluation.
* For each of the requirements, please ensure the content and structure of information presented is in line with relevant regulatory requirements and associated standards.

| Mandatory items | Enclosed  | Document name / justification if not included |
| --- | --- | --- |
| **Cover Letter** * On headed paper

Please include: * Statement outlining the relevant Article within the Medical Device Regulation (EU) 2017/745 to which the investigation refers.
* Statement confirming whether the medical device incorporates a medicinal product, contains tissues or cells of animal/ human origin.
* Statement of compliance with recognised ethical principles for medical research involving humans and the principles of good clinical practice in the field of clinical investigations of devices and with applicable regulatory requirements.
* A table outlining which documents are for ethical review and which are for reference only.
* Contact details of Sponsor or legal representative who is established in the EEA.
* For studies carried out under Article 74 (1), please outline the additional, invasive or burdensome procedures carried out as a part of the clinical investigation.
* For studies carried out under Article 74 (2), please provide a justification.
* Any points for noting eg rationale for no Data Monitoring Committee etc.
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| **NREC-MD Application Form** * Current effective version of the form
* Signed and dated by the national PI
* All relevant sections are comprehensively completed in accessible language
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Summary CV for National Principal Investigator and each Site Principal Investigator** Please include:* Reference to GCP training/ attach a copy of GCP certificate
* Reference to experience in clinical investigations as applicable.
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Site Suitability Form** * Include for each site
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Participant Information Leaflet (PIL)** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Informed Consent Form (ICF)** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Recruitment material for participants**Include any letters, posters, newspaper adverts, website, etc. For video or audio recordings, please also provide the printed script. | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Evidence of Insurance/Indemnity policy cover** * For more information please review guidance of the [State Claims Agency](https://stateclaims.ie/uploads/banner/SIG-10-03-Indemnity-and-Insurance-Arrangements-for-Clinical-Trials-Health-Research-Interactive.pdf) such as study specific policy, products liability, employers’ liability/ public liability, other.
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Itemised study budget** | [ ] Yes [ ] No | Click or tap here to enter text. |
| [**Declaration of interest for Principal Investigators**](https://www.nrecoffice.ie/wp-content/uploads/NREC-MD_Declaration_of_Interest_V1.docx) | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Draft clinical investigation agreement** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **[Statement of Compliance’ for](https://www.nrecoffice.ie/wp-content/uploads/Guidance_Statement-of-Compliance.pdf)****[data protection compliance/](https://www.nrecoffice.ie/wp-content/uploads/Guidance_Statement-of-Compliance.pdf) Data Protection Impact Assessment** * Include evidence of DPO input/feedback
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Details of Data Monitoring Committee** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **CE certificate/ Declaration of conformity to safety and performance requirements** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Letter from Sponsor confirming outsourcing of duties/functions**(e.g. to CRO) | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Case Report Form** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Clinical Investigation Plan/ Protocol*** Include all points listed in MDR Annex XV – Chapter 2, points 3-3.19. Where points are not included, please list and include justification in the cover letter.
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Investigator Brochure*** Include all points listed in MDR Annex XV – Chapter 2, points 2-2.8
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Bank Advice Note**  | [ ] Yes [ ] No | Click or tap here to enter text. |
| **All documents are in a format accessible for screen readers**[[1]](#footnote-2) | [ ] Yes [ ] No |  |
| **All application documents are numbered and file names include version number and date** | [ ] Yes [ ] No |  |

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| Additional Documentation – Mandatory if Applicable to the study | Enclosed  | Document name / justification if not included |
| **Legally Designated Representative Information Leaflet and Assent Form** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Letter to participant healthcare provider** (e.g., GP or hospital consultant) | [ ] Yes [ ] No | Click or tap here to enter text. |
| **All other materials** (written, audio-visual, etc) **that will be used during the course of the study** (e.g. questionnaire, interview schedule) | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Sample Diary Card/ Participant Card** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Participant Implant card** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Other** | [ ] Yes [ ] No | Click or tap here to enter text. |

1. Any documentation submitted for NREC review must be presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents as these documents are composed of images, rather than searchable text, and cannot be optimised for use with assistive software. If it’s not possible to submit an accessible document due to a scanned wet ink signature, an unsigned accessible version must also be included as part of the submission. Submissions that are not in an accessible format may be deemed invalid or may delay the assessment process. [↑](#footnote-ref-2)