National Research Ethics Committee for Clinical Investigations of Medical Devices and Performance Studies of *In Vitro* Diagnostic Medical Devices (NREC-MD)

Document Submission Checklist

Version 5

Instructions

* This application form is designed for clinical investigations of medical devices and performance studies of *in vitro* diagnostic 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.

| General (each item is mandatory) | Enclosed  | Document Name (or justification if not included)  |
| --- | --- | --- |
| **Cover Letter (On headed paper)**Please ensure the Cover Letter includes: * Statement outlining the relevant Article within the Medical Device Regulation (EU) 2017/745 or *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 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 performance studies of in vitro diagnostic devices and with applicable regulatory requirements.
* Contact details of Sponsor or legal representative who is established in the EEA.
* Justification, in the event that a Data Monitoring Committee is considered not applicable to the study.
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| **NREC-MD Application Form** Required:* Current effective version of the form
* Signed and dated by the PI
* Details of Sponsor (or legal representative in the EEA) and manufacturer (or authorised representative in the EEA)
* All sites in Republic of Ireland included
* Signature of medical physics expert (MPE), or as applicable
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Summary CV for National Principal Investigator and each site Principal Investigator** Within/accompanying the CV include:* Reference to GCP training, or GCP cert(s)
* Reference to experience in clinical investigations/performance studies 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** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Informed Consent Form** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Copies of Advertisement Material for Participants**Include any 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. |
| **Proof of Insurance/Indemnity** Please ensure proof of Insurance/ Indemnity is valid, including completed Clinical Trial Indemnity Form (as applicable). For more information please review guidance of the State Claims Agency. | [ ] Yes [ ] No | Click or tap here to enter text. |
| * Study specific e.g. Clinical Trial Insurance policy
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| * Products Liability (as applicable)
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| * Employers’ Liability, Public Liability,
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| * Other organisational insurances such as professional indemnity, cyber/data protection. Please specify.
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Itemised study budget** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Clinical Investigation Agreement/ Performance Study Agreement** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Data Protection Impact Assessment** * Include evidence of DPO input/feedback
* Include justification if a DPIA is not applicable
* If a DPIA is not applicable, please submit the NREC Statement of Compliance, available on the NREC-MD website.
 | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Details of Data Monitoring Committee** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Signed Statement of Conformity to Safety and Performance Requirements** * Include precautions for protection of subjects
* Provide a current CE certificate/Declaration of Conformity as applicable.
 | [ ] 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. |
| **NREC-MD PMCF/PMPF form (where applicable)**See details on the NREC-MD website ([linked here](https://www.nrecoffice.ie/post-market-clinical-follow-up-studies/)) | [ ] Yes [ ] No | Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| Clinical Investigation Plan(Mandatory for MDR) | Enclosed  | Document name (or justification if not included)  |
| **Clinical Investigation Plan**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. |

|  |  |  |
| --- | --- | --- |
| Performance Study Plan(Mandatory for IVDR) | Enclosed  | Document name (or justification if not included)  |
| **Performance Study Plan**Include all points listed in IVDR as referred to in Annex XIII Sections 2 and 3 and Annex XIV Point 3. 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 (IB)/ Instructions for Use (IFU) | Enclosed  | Document name (or justification if not included) |
| **Investigator Brochure**Include all points listed in the below, as applicable. Where points are not included, please list and include justification in the cover letter.* MDR Annex XV – Chapter 2, points 2-2.8
* IVDR Annex XIV 2-2.8.
 | [ ] Yes [ ] No | Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| Additional Documentation(Required if Available) | Enclosed  | Document name (or justification if not included)  |
| **Letter of Invitation for Participant** | [ ] 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 participant facing materials (written, electronic or otherwise) that will be provided to the participants** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **All 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. |
| **Legally Designated Representative Information Leaflet and Assent Form** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Diary Card/Participant Card****•** Include sample if available | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Participant Implant card** | [ ] Yes [ ] No | Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| Fee Payment | Enclosed  | Document name (or justification if not included)  |
| **National Office Payment Processing Form (not mandatory)** | [ ] Yes [ ] No | Click or tap here to enter text. |
| **Bank Advice Note (mandatory)** | [ ] Yes [ ] No |  |