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

Document Submission Checklist – applications for performance studies submitted under EU 2017/746

Version 2

Instructions

* This application form is designed for 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.

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| **Mandatory documents** | **Enclosed** | **Document name / justification if not included** |
| **Cover Letter**   * On headed paper   Please include:   * Statement outlining the relevant Article within the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 to which the study refers. * Statement confirming whether the *In Vitro* Diagnostic 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 performance studies of in vitro diagnostic 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 70 (1), please outline the additional, invasive or burdensome procedures carried out as a part of the clinical investigation. * For studies carried out under Article 70 (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 Principal Investigator * All relevant sections are comprehensively completed in accessible language | Yes No | Click or tap here to enter text. |
| **Summary CV for national Principal Investigator (PI) and each site PI, including a PI leading on the CPS if different from national PI**  Please include:   * Reference to GCP training/ attach a copy of GCP certificate * Reference to experience in performance studies as applicable. | Yes No | Click or tap here to enter text. |
| **Site Suitability Form**   * One per each site in Ireland * One for the laboratory leading the analyses. Please highlight any relevant certification/ authorisation of the laboratory | Yes No | Click or tap here to enter text. |
| **Participant Information Leaflet (PIL)**   * Specific to the performance study. * For combined studies, a standalone PIL for the performance study is necessary | Yes No | Click or tap here to enter text. |
| **Informed Consent Form (ICF)**   * For combined studies, a standalone ICF for the performance must be provided | 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**   * List all items relevant to the performance study | 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 performance study 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. |
| **Performance Study Plan/ Protocol**   * Include all points listed in IVDR 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**   * Include all points listed in IVDR Annex XIV 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. |
| **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)