**Documentation checklist**

For performance studies of in vitro diagnostic medical devices as defined by the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746

Version 4

**Instructions**

* This checklist lists documents that are mandatory for your application.
* The title of the documents listed in the checklist must be identical to the file title
* Where a mandatory document is not provided, a clear and detailed justification must be outlined below and in the cover letter.
* This checklist must be included in your application.

| General instructions | Declaration | Comment |
| --- | --- | --- |
| All documents are in a format accessible for screen readers[[1]](#footnote-2) | Yes  No | Click or tap here to enter text. |
| All application documents file names include version number or date. | Yes  No | Click or tap here to enter text. |
| Documents are numbered in the order they appear in the checklist below | Yes  No | Click or tap here to enter text. |

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| --- | --- | --- |
| Mandatory documents | Enclosed | Document name / justification if not included |
| 1. **NREC-MD Application Form** | Yes  No | Click or tap here to enter text. |
| * Current effective version of the form | Yes  No | Click or tap here to enter text. |
| * All relevant sections are comprehensively completed in accessible language | Yes  No | Click or tap here to enter text. |
| 1. **Summary CV for each site principal investigator** | Yes  No | Click or tap here to enter text. |
| * Reference to GCP training/ copy of GCP certificate | Yes  No | Click or tap here to enter text. |
| * Reference to experience in clinical investigations as applicable. | Yes  No | Click or tap here to enter text. |
| 1. **Site suitability form for each study site in Ireland** | Yes  No | Click or tap here to enter text. |
| 1. **Declaration of interest for each site principal investigator** | Yes  No | Click or tap here to enter text. |
| 1. **Performance study plan/ protocol**  * As per IVDR Annex XIII Sections 2 and 3 and Annex XIV Point 3. | Yes  No | Click or tap here to enter text. |
| 1. **Participant information leaflet (PIL)**  * For combined studies, a standalone PIL for the performance study is necessary | Yes  No | Click or tap here to enter text. |
| 1. **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. |
| 1. **Case report forms** | Yes  No | Click or tap here to enter text. |
| 1. **Statement of compliance’ for data protection compliance** | Yes  No | Click or tap here to enter text. |
| 1. **Evidence of insurance/indemnity policy cover**  * As per 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). | Yes  No | Click or tap here to enter text. |
| 1. **Itemised study budget** | Yes  No | Click or tap here to enter text. |
| 1. **Draft clinical investigation agreement** | Yes  No | Click or tap here to enter text. |
| 1. **CE certificate for CE marked devices**   Or | Yes  No | Click or tap here to enter text. |
| **Declaration of conformity to safety and performance requirements for non-CE marked devices** | Yes  No | Click or tap here to enter text. |
| 1. **Investigator brochure or instructions for use**  * As per IVDR Annex XIV, 2-2.8. | Yes  No | Click or tap here to enter text. |
| 1. **Details of data monitoring committee** | Yes  No | Click or tap here to enter text. |
| 1. **Proof of payment** | Yes  No | Click or tap here to enter text. |

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| --- | --- | --- |
| Additional Documentation – Mandatory if Applicable to the study | Enclosed | Document name / justification if not included |
| 1. **ecruitment material for participants**  * Include any letters, posters, newspaper adverts, website, etc. For video or audio recordings, please provide the transcript | Yes  No | Click or tap here to enter text. |
| 1. **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. |
| 1. **Letter to participant healthcare provider** (e.g. GP or hospital consultant) | Yes  No | Click or tap here to enter text. |
| 1. **Legally designated representative information leaflet and assent form** | Yes  No | Click or tap here to enter text. |
| 1. **Participant implant card** | Yes  No | Click or tap here to enter text. |
| 1. **Other (please specify use)** | 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)