**Site suitability form for clinical investigations of medical devices as defined in the Medical Devices Regulation (EU) 2017/745 and performance studies of in vitro diagnostic medical device as defined by the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746**

Version 5.0

* All sections of the application form must be completed. If a section does not apply, select ‘No’ or ‘N/A’, or enter ‘N/A’ in the text box, as appropriate.
* Ensure all answers are in plain English comprehensible to a lay person.
* A separate form should be completed for each site.
* This form should be signed by the CEO, Head of Clinic / Institution, Director of Research, Clinical Director, or delegate at each site in Ireland.
* Completed form must be submitted in machine readable Word or PDF format.

# **Overview of sections of the form**

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# **Study and site information**

|  |  |
| --- | --- |
| A1 | Study CIV-ID / PS-ID |
|  | Click or tap here to enter text. |
| A2 | Study title |
|  | Click or tap here to enter text. |
| A3 | Name of site |
|  | Click or tap here to enter text. |
| A4 | Planned number of participants at the site |
|  | Click or tap here to enter text. |

# **Details of site investigator**

|  |  |  |
| --- | --- | --- |
| B1 | Name | Click or tap here to enter text. |
|  | Title | Click or tap here to enter text. |
|  | Institution | Click or tap here to enter text. |
|  | Email address | Click or tap here to enter text. |
|  | Telephone | Click or tap here to enter text. |
| B2 | Has the site investigator undergone GCP training as per ISO 14155:2011 / ISO 20916:2019? | Click or tap here to enter text. |

# 

# **Staff experience / qualifications**

|  |  |
| --- | --- |
| C1 | Outline the qualifications and experience of investigators and staff relevant to the current study. |
|  | Click or tap here to enter text. |
| C2 | Outline any additional human resources arrangements and expertise at the site. |
|  | Click or tap here to enter text. |

# **Suitability of the site**

|  |  |
| --- | --- |
| D1 | Outline the suitability of the site as relevant to the nature and use of the medical device / in vitro diagnostic medical device.  (Include the number of relevant procedures performed at the site annually, as applicable) |
|  | Click or tap here to enter text. |
| D2 | Outline the suitability of the facilities at the site. |
|  | Click or tap here to enter text. |
| D3 | Outline the suitability of the equipment at the site. |
|  | Click or tap here to enter text. |
| D4 | For performance studies: provide details of any laboratory accreditation / certification. |
|  | Click or tap here to enter text. |

# **Study procedures**

|  |  |
| --- | --- |
| E1 | Outline the study procedures that will take place at the site. |
|  | Click or tap here to enter text. |

# **Ionising radiation**

|  |  |
| --- | --- |
| F1 | Does this study involve exposure to ionising radiation. |
|  | Yes  No |
| F2 | Outline the qualifications of the person overseeing the ionising radiation aspects at the trial site |
|  | Click or tap here to enter text. |
| F3 | Is the exposure at this site above what is required for standard of care? |
|  | Yes  No |

# **Study procedures**

|  |  |  |  |
| --- | --- | --- | --- |
| G1 | Declaration of Chief Executive Officer, Head of Clinic / Institution, Director of Research, Clinical Director, or delegate at site. | | |
|  | This declaration confirms the suitability of facilities, equipment and human resources at a given site to support the ethics review assessment of this study. It does not confirm that the study may take place at the site, nor does it preclude the requirement for the local review and approvals that may be necessary at a site level. | | Yes  No |
| I confirm that the site has the facilities and equipment to be able to conduct the study and has suitable arrangements in place to ensure that all investigators and other individuals involved in conducting the study have the suitable qualifications, expertise and training in relation to their role in the clinical investigation/ performance study, in compliance with EU Regulation 2017/745 / 2017/746, and all conditions identified, which might influence the impartiality of any investigators, were addressed. | | Yes  No |
| Name | Click or tap here to enter text. | |
| Title | Click or tap here to enter text. | |
| Role | Click or tap here to enter text. | |
| Date | Click or tap here to enter text. | |