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

Site Suitability Form

Version 4.0

**Instructions**

* This form should be completed for clinical investigations of medical devices and performance evaluations of *in vitro* ­diagnostic medical devices only.
* For the purpose of this form, the term *study* is used to refer to both for clinical investigations of medical devices and performance evaluations of *in vitro* ­diagnostic medical devices.
* 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.
* This form must be signed and submitted to the National Office before an application will be considered valid.

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| 1. Study and site identification |
| **Study CIV-ID/ PS-ID:** |  Click or tap here to enter text. |
| **Title of clinical investigation / performance study:** | Click or tap here to enter text. |
| **Name of site:** | Click or tap here to enter text. |
| **Planned number of participants at the site:** | Click or tap here to enter text. |

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| 2. Details of site investigator  |
| **Name:**  | Click or tap here to enter text. |
| **Title:** | Click or tap here to enter text. |
| **Institution:**  | Click or tap here to enter text. |
| **Tel:**  | Click or tap here to enter text. |
| **E-mail (Work):**  | Click or tap here to enter text. |
| **Has the site investigator undergone GCP Training, as per ISO 14155:2011/ ISO 20916:2019** | Yes ☐ No ☐Please comment/ provide details of training:Click or tap here to enter text. |

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| 3. Outline the qualifications and experience of investigators and staff relevant to the current study. If the study involves exposure to ionising radiation, please outline the qualifications of the person overseeing these aspects at the trial site. |
| Click or tap here to enter text. |

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| 4. Outline the study procedures which will take place at the site. |
| Click or tap here to enter text. |

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| 5. Is the exposure to ionising radiation at this site above what is required for standard of care? |
| Yes [ ]  No [ ]  |
| **If yes, please provide justification below for the increased exposure.** |
| Click or tap here to enter text. |

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| 6. 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. |

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| 7. Outline the suitability of the facilities at the site. |
| Click or tap here to enter text. |

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| 8. Outline the suitability of the equipment at the site. |
| Click or tap here to enter text. |

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| 9. For performance studies: provide details of any laboratory accreditation/ certification. |
| Click or tap here to enter text. |

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| 10. Outline any additional human resources arrangements and expertise at the site. |
| Click or tap here to enter text. |

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| 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.
* 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.
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| **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Print Name**: Click or tap here to enter text.**Role:** Click or tap here to enter text.On behalf of the site/organisation **Date:** Click or tap here to enter text. (dd/mm/yyyy)  |