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 3.0

**Instructions**

* This form should be completed for clinical investigations of medical devices and performance evaluations of *in vitro* ­diagnostic medical devices only.
* This form should be completed and signed by the Lead Principal Investigator at each site in the Republic of Ireland.
* A separate document should be completed and submitted for each site.
* This template must be signed and submitted to the National Office before an application will be considered valid.

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| 1. Trial/Investigation and Site Identification | |
| **Study CIV-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. |
| **Address of site:** | Click or tap here to enter text. |
| **Target recruitment at site:** | Click or tap here to enter text. |

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| 2. Who is the Principal Investigator for the research study at this site? | |
| **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. |

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| 3. Outline the qualifications and experience of investigators and staff relevant to the current study. |
| 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. Outline the suitability of the site adapted to the nature and use of the medical device / *in vitro* diagnostic medical device. (Include the number of procedures performed at the site annually, as applicable). |
| Click or tap here to enter text. |

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| 6. Outline the suitability of the facilities at the proposed site. |
| Click or tap here to enter text. |

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

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| Declaration of Principal Investigator at Site |
| * I am satisfied as to my suitability as Principal Investigator for the conduct of the research at this site and in respect of the supporting staff available to undertake the research at the site. * I am satisfied that the facilities and equipment at this site are of such quality and adequacy as to conduct the research at this site. * I certify that the information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it. |
| **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name**: Click or tap here to enter text.  **Date:** Click or tap here to enter text. (DD/MMM/YYYY) |