National Research Ethics Committee for Clinical Trials (NREC-CT)

Site Suitability Template V 2.0

**Instructions**

* This form has been adapted from the EMA Site Suitability Template, which was developed and endorsed by the EU Clinical Trials Expert Group.
* This form should be signed by the CEO, Head of Clinic / Institution, Director of Research, Clinical Director, or delegate at each site in Ireland.
* A separate document should be completed and submitted for each site.
* This template must be signed before an application will be considered valid.

*Updated 31 July 2023*

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| 1. Trial / Investigation and Site Identification | |
| Clinical trial number | Click or tap here to enter text. |
| Title of clinical trial / investigation: | Click or tap here to enter text. |
| Submission date: | Click or tap to enter a date. |
| Name of site: | Click or tap here to enter text. |
| Planned number of trial participants at the 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: | 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 clinical trial or investigation. If the trial 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 trial or investigation 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 adapted to the nature and use of the investigational medicinal product or medical device. |
| Click or tap here to enter text. |

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

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

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| 9. Outline the additional Human Resources arrangement 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 clinical trial. It does not confirm that a trial 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 clinical trial and has suitable arrangements in place to ensure that all investigators and other individuals involved in conducting the trial have the suitable qualifications, expertise and training in relation to their role in the clinical trial, in compliance with EU Regulation 536/2014, and all conditions identified, which might influence the impartiality of any investigators, were addressed. |
| **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 to enter a date. (dd/mm/yyyy) |