National Research Ethics Committee for Clinical Trials

Appendix form: Clinical trials of investigational medicinal production in combination with a medical device

Version 1.0

**Instructions**

* This Appendix must be submitted along with the main application form for ethics review to [clinicaltrials@nrec.ie](mailto:clinicaltrials@nrec.ie) .
* All sections of the Appendix form should be completed. If a section does not apply, select “No” or “N/A”, or enter “N/A” in the text box, as appropriate.
* Digital signatures are accepted and encouraged.
* Please provide a copy of this Application and Appendix to your Research Office or equivalent body in your research institution
* All communications to the NRECs should be directed to the National Office via [clinicalrials@nrec.ie](mailto:clinicalrials@nrec.ie)

1.0 General

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| --- | --- |
| 1.1 (a) What is the name of the medical device? | |
| Answer: | Click or tap here to enter text. |

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| 1.1 (b) What is the generic name or nomenclature of the device? | |
| Answer: | Click or tap here to enter text. |

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| 1.1 (c) What is the proposed device classification? | |
| Answer: | Click or tap here to enter text. |

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| 1.1 (d) What is the device development stage? | |
| Answer: | Click or tap here to enter text. |

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| 1.1 (e) Please provide a general description of the medical device. | |
| Answer: | Click or tap here to enter text. |

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| 1.1 (f) Does this device incorporate a medicinal substance, including a human blood or plasma derivative? | | |
| Yes  No | |  |
| If yes, please describe: | | |
| Answer: | Click or tap here to enter text. | |

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| --- | --- | --- |
| 1.1 (g) Is this device manufactured utilizing non-viable tissues or cells of human or animal origin, or their derivatives? | | |
| Yes  No | |  |
| If yes, please describe: | | |
| Answer: | Click or tap here to enter text. | |

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| --- | --- |
| 1.2 (a) Does the medical device have a CE mark? | |
| Yes  No |  |

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| 1.2 (b) Please name the notified body/bodies who affixed the CE mark (NANDO code). | |
| Answer: | Click or tap here to enter text. |

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| 1.2 (c) CE mark number: | |
| Answer: | Click or tap here to enter text. |

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| --- | --- |
| 1.2 (d) If the device has a CE mark, is it proposed to use the device within its stated intended use for CE marking? | |
| Yes  No |  |

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| --- | --- |
| 1.2 (e) If no, please describe: | |
| Answer: | Click or tap here to enter text. |

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| 1.2 (f) Device identifier (UDI-DI): | |
| Answer: | Click or tap here to enter text. |

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| 1.2 (g) If the device does not have a CE mark, or is being used outside its intended use, is this study being undertaken for the purposes of obtaining a CE mark? | |
| Yes  No |  |

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| --- | --- | --- |
| 1.2 (h) Will a comparator device be used during this clinical investigation? | | |
| Yes  No | |  |
| If yes, please provide details of the comparator device, including its classification and any information necessary for the identification of the comparator device. | | |
| Answer: | Click or tap here to enter text. | |

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| **Declaration of the Principal Investigator**  ***This declaration must be signed and sent to the NREC-CT together with the requisite fee before the application will be considered as valid. Digital signatures will be accepted.***   * I certify that the information in this form is accurate to the best of my knowledge and I take full responsibility for it. * I undertake to abide by the ethical principles outlined in the Declaration of Helsinki, and my obligations as set out in the relevant Good Clinical Practice Guidelines, *(International Conference on Harmonisation’s Good Clinical Practice Guidelines (ICH GCP), International Organisation for Standardisation 14155 (ISO 14155)),* andthe relevant European Regulations, *Medical Devices Regulation (EU) 2017/745*). * If the investigation is approved, I undertake to adhere to the study protocol and to comply with any conditions set out in the letter of approval sent by the NREC-CT. * I am aware of my responsibility to be up to date and comply with the requirements of the law relating to security and confidentiality of patient or other personal data.   **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name**: Click or tap here to enter text.  **Date:** Click or tap to enter a date. (dd/mm/yyyy) |