National Research Ethics Committee – Medical Devices

Appendix to Application form for the Ethical Review of Clinical Investigations of Medical Devices

Version 1.0

**Instructions**

* This Application Form is divided into Sections.
* Please ensure all answers are completed in Plain English.
* \*Sections A, B, C, D, E, F, J, K and L are **Mandatory.**
* Sections G, H, and I are **Optional.**
* Digital signatures are encouraged.
* Information on this form will remain confidential, however, the NREC-MD may seek an external expert to provide advice on any aspect of the application which lies beyond the expertise of the members.
* **IMPORTANT NOTE:** This application appendix is designed for clinical investigations of medical devices. Please respond to each question carefully. Please contact the National Office (devices@nrec.ie) in the event of queries which may arise in the completion of this form.

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DESCRIPTION

This document should accompany all applications submitted to NREC-MD which do not use the NREC-MD Application Form (Version 1.0).

This form is divided into Sections. Please ensure all Sections marked Mandatory\* are fully completed before submission. Please contact the National Office (devices@nrec.ie) in the event of queries which may arise in the completion of this form.

SECTION A GENERAL INFORMATION (MANDATORY\*)

|  |
| --- |
| A1 (a) Is this an application to conduct a clinical investigation of a medical device? |
| [ ]  Yes [ ]  No |  |
| A1 (b) Will you be seeking advanced ethics review or parallel review? Advanced ethics review refers to ethical review performed in advance of submission to/notification of the Health Products Regulatory Authority (HPRA). Parallel review refers to ethical review performed at the same time as clinical review conducted by the HPRA. |
| [ ]  Yes [ ]  No |  |

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| A2 Lay title of the research study (if different):  |
| Answer: | Click or tap here to enter text. |

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| A3 (a) Please name the sponsor of this study. |
| Sponsor Name: | Click or tap here to enter text. |
| Address: | Click or tap here to enter text. |
| Telephone: | Click or tap here to enter text. |
| E-mail: | Click or tap here to enter text. |
| Contact Person: |
| Title: | Click or tap here to enter text. |
| Name: | Click or tap here to enter text. |
| Qualifications: | Click or tap here to enter text. |
| Position: | Click or tap here to enter text. |
| Department: | Click or tap here to enter text. |
| Address: | Click or tap here to enter text. |
| Telephone: | Click or tap here to enter text. |
| E-mail: | Click or tap here to enter text. |

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| A3 (b) If the sponsor referred to in A2 (a) above is not established in the European Union, please provide contact details of a legal representative who is established in the union (c.f. Art 62(2) MDR 2017/745). |
| Title: | Click or tap here to enter text. |
| Legal Representative Name: | Click or tap here to enter text. |
| Qualifications: | Click or tap here to enter text. |
| Position: | Click or tap here to enter text. |
| Department: | Click or tap here to enter text. |
| Organisation: | Click or tap here to enter text. |
| Address: | Click or tap here to enter text. |
| Telephone: | Click or tap here to enter text. |
| E-mail: | Click or tap here to enter text. |

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| A4 (a) Please name the manufacturer of this study. |
| Manufacturer Name: | Click or tap here to enter text. |
| Address: | Click or tap here to enter text. |
| Telephone: | Click or tap here to enter text. |
| E-mail: | Click or tap here to enter text. |
| Contact person or legal representative: |
| Title: | Click or tap here to enter text. |
| Name: | Click or tap here to enter text. |
| Qualifications: | Click or tap here to enter text. |
| Position: | Click or tap here to enter text. |
| Department: | Click or tap here to enter text. |
| Address: | Click or tap here to enter text. |
| Telephone: | Click or tap here to enter text. |
| E-mail: | Click or tap here to enter text. |
| Heading | Heading | Heading | Heading | Heading | Heading | Heading | Heading | Heading | Heading |

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| A4 (b) If the manufacturer is not based in a European Union state, please provide the contact details of an authorised representative. |
| Title: | Click or tap here to enter text. |
| Name of Authorised Representative: | Click or tap here to enter text. |
| Qualifications: | Click or tap here to enter text. |
| Position: | Click or tap here to enter text. |
| Department: | Click or tap here to enter text. |
| Organisation: | Click or tap here to enter text. |
| Address: | Click or tap here to enter text. |
| Telephone: | Click or tap here to enter text. |
| E-mail: | Click or tap here to enter text. |

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| A5 (a) Is this application a resubmission for this device? If no, please proceed to A6.  |
| Date of previous application: | Click or tap to enter a date. |
| REC for previous submission: | Click or tap here to enter text. |
| Please include details of the previous REC opinion. Click or tap here to enter text. |

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| A5 (b) Please describe all changes from the previous application, together with a rationale for those changes. In particular, please describe whether any changes have been made to address conclusions of previous competent authority or ethics committee reviews. |
| Answer: | Click or tap here to enter text. |

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| A6 Is this application submitted in parallel with an application for a clinical trial in accordance with regulation (EU) No 536/2014? |
| [ ]  Yes [ ]  No |
| Official registration number of the clinical trial (if applicable): |
| Answer: | Click or tap here to enter text. |

SECTION B MEDICAL DEVICES (MANDATORY\*)

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| B1 Will the medical devices division of the HPRA be reviewing this study? |
| [ ]  Yes [ ]  No |  |

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| B2 (a) What is the name of the medical device? |
| Answer: | Click or tap here to enter text. |

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| B2 (b) What is the generic name or nomenclature of the device?  |
| Answer: | Click or tap here to enter text. |

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| B2 (c) What is the proposed device classification?  |
| Answer: | Click or tap here to enter text. |

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| B2 (d) What is the device development stage?  |
| Answer: | Click or tap here to enter text. |

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| B2 (e) Please provide a general description of the medical device.  |
| Answer: | Click or tap here to enter text. |

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| B2 (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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| B2 (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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| B3 (a) Does the medical device have a CE mark?  |
| [ ]  Yes [ ]  No |  |

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| B3 (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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| B3 (c) CE mark number: |
| Answer: | Click or tap here to enter text. |

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| B3 (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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| B3 (e) If no, please describe:  |
| Answer: | Click or tap here to enter text. |

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| B3 (f) Device identifier (UDI-DI):  |
| Answer: | Click or tap here to enter text. |

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| B3 (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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| B3 (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. |

SECTION D STUDY PARTICIPANTS (MANDATORY\*)

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| D1 Will informed consent for participation to take part in the research be obtained?  |
| [ ]  Yes [ ]  No |  |

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| D2.1 Please confirm if persons from any of the following groups will participate in this study. This is a quick checklist to assist research ethics committee members and to identify whether study participants include persons from vulnerable groups and to establish what special arrangements, if any, have been made to deal with issues of consent. it is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity. Please refer to the HSE’s National Consent Policy, particularly Part 3, Section 5.Committees are particularly interested to know if persons in any of these groups are being targeted for inclusion, as per the inclusion criteria. |
| Healthy volunteers | [ ]  Yes [ ]  No |
| Patients-unconscious patients-current psychiatric in-patients-patients in an emergency medical setting | [ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No |
| Relatives / carers of patients | [ ]  Yes [ ]  No |
| Persons in dependent or unequal relationships-students -employees / staff members -persons in residential care-persons highly dependent on medical care | [ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No |
| Intellectually disabled persons | [ ]  Yes [ ]  No |
| Persons with a life-limiting condition  | [ ]  Yes [ ]  No |
| Persons with an acquired brain injury  | [ ]  Yes [ ]  No |
| Persons suffering from dementia  | [ ]  Yes [ ]  No |
| Persons with mental illness  | [ ]  Yes [ ]  No |
| Prisoners | [ ]  Yes [ ]  No |

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| D2.2 If yes to any of the above, please comment on the vulnerability of the research participants, outline the special arrangements in recognition of this vulnerability (if any), and outline how the study is expected to benefit research participants. |
| Answer: | Click or tap here to enter text. |

Adult Participants (Aged 18 or Over) – Decision-making capacity

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| D3 Does this research relate directly to a medical condition which the adults lacking decision-making capacity have been diagnosed with? Please describe. |
| Answer: | Click or tap here to enter text. |

Participants under the age of 18

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| D4 Does this research relate directly to a medical condition which the children have been diagnosed with? Please describe. |
| Answer: | Click or tap here to enter text. |

Participants - Women of child-bearing potential and women who are pregnant or breastfeeding

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| D5.1 Please comment on whether women of child-bearing potential, breastfeeding mothers, or pregnant women will be included or excluded in this research study. |
| Answer: | Click or tap here to enter text. |

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| D5.2 If included, is the research expected to provide direct benefit to women of child-bearing potential, breastfeeding mothers, pregnant women or her embryo, foetus or child after birth? If there is no prospect of direct benefit, are the risks no more than minimal? Please describe. |
| Answer: | Click or tap here to enter text. |

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| D5.3 Where research is undertaken on pregnant or breastfeeding women, is particular care being taken to avoid any adverse impact on the health of the embryo, foetus, or the child? Please describe. |
| Answer: | Click or tap here to enter text. |

SECTION E RESEARCH PROCEDURES (MANDATORY\*)

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| E1 Please comment on how individual results will be managed. Please provide details of any data collection tools and include an example of a case report form (if applicable) as part of the documentation to be submitted. |
| Answer: | Click or tap here to enter text. |

SECTION F DATA PROTECTION (MANDATORY\*)

A data protection impact assessment for each clinical investigation is necessary and should be included as part of the application documentation.

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| F1.1 Please specify the controls in place to limit access to the personal data undergoing processing in order to prevent unauthorised consultation, access, dissemination, alteration, disclosure, erasure, or loss of information and/or personal data. |
| Answer: | Click or tap here to enter text. |

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| F1.2 Please describe the measures that will be implemented in the case of a data security breach in order to mitigate the possible adverse effects. |
| Answer: | Click or tap here to enter text. |

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| F2.1 (a) Will identification of potential participants involve access to identifiable information?  |
| [ ]  Yes [ ]  No |  |

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| F2.1 (b) If yes, please describe what measures will be in place to confirm that access to this information will be lawful. |
| Answer: | Click or tap here to enter text. |

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| F2.1 (c) Who will access this identifiable information? |
| Answer: | Click or tap here to enter text. |

SECTION G HUMAN BIOLOGICAL MATERIAL (OPTIONAL)

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| G1 (i) If yes, please set out the steps that will be taken and the information that will be provided to study participants prior to genetic testing and processing of genetic data in relation to any potential implications for the health of study participants, which may become known as a result of the genetic testing and the processing of genetic data. please consider whether a consent declaration is required under Section 10. |
| Answer: | Click or tap here to enter text. |

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| G1 (ii) If no, you must explain fully why it is not intended to obtain consent for the genetic testing.Where genetic testing for research purposes gives rise to the processing of personal data explicit consent is required as a safeguard (please indicate whether it is intended to seek a consent declaration under Section 10 of this form).(It is important that this information should be prominently placed in any information leaflets or consent forms. It is extremely important that research participants be told of the result of the genetic testing, which may include a diagnosis or if they are a ‘control’ in this research study. Participants may not understand the term ‘control’ and may need this to be explained to them. It is very important that the implications of any testing be stated clearly in any information leaflets, in particular, if there are implications for next of kin, offspring or future offspring). |
| Answer: | Click or tap here to enter text. |

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| G2 Please set out the strategy and arrangements that will be in place to address any significant results or information arising from the genetic testing or processing of genetic data with the study participant. Please consider whether consent may be required from the next-of-kin or person with parental responsibility of for this disclosure. If so, please ensure that this is captured in the information leaflet(s) and the consent/assent form.  |
| Answer: | Click or tap here to enter text. |

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| G3 What strategy / arrangements will be in place regarding third party disclosure, in particular, to family members or others. Please consider whether consent may be required from the participant for this disclosure. If so, please ensure that this is captured in the patient leaflet and consent form. |
| Answer: | Click or tap here to enter text. |

SECTION H COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS (MANDATORY\*)

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| --- |
| H1 (a) is funding in place to conduct this study?  |
| [ ]  Yes [ ]  No |  |

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| H1 (b) if no, has funding been sought to conduct this study? From where? Please describe. |
| Answer: | Click or tap here to enter text. |

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| H1 (c) If yes, please state the source of funding (industry, grant, person or other), the name of the funder, the amount of funding and duration of funding. |
| Source of funding (industry, grant, other) | Click or tap here to enter text. |
| Name of funder | Click or tap here to enter text. |
| Amount of funding | Click or tap here to enter text. |
| Duration of funding | Click or tap here to enter text. |

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| H2.1 Do any conflicts of interest exist, including in relation to funding or potential funding?  |
| [ ]  Yes [ ]  No |  |

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| H2.2 (a) Will any payments (monetary or otherwise) be made to investigators or the investigation site (s)?  |
| [ ]  Yes [ ]  No |  |

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| H3 A clinical investigation agreement for each investigation site should be submitted as part of documentation. If unavailable, please specify the reason(s) why. |
| Answer: | Click or tap here to enter text. |

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| H4.1 (a) Will any compensation / expenses (monetary or otherwise) be made to participants? Please note, compensation refers to payments made as a token for participation in research, whereas expenses refer to payments made to cover any cost(s) incurred when participating in the study.  |
| [ ]  Yes [ ]  No |  |

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| H4.2 (b) If yes, please provide details of compensation / expenses (including amount). |
| Answer: | Click or tap here to enter text. |

SECTION I ADDITIONAL ETHICAL ISSUES (MANDATORY\*)

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| I1 (a) Does this project raise any additional ethical issues?  |
| [ ]  Yes [ ]  No |  |

If answer is No, please skip the remaining question in Section I.

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| I1 (b) If yes, please identify any particular additional ethical issues that this project raises and discuss how you have addressed them.  |
| Answer: | Click or tap here to enter text. |

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED AND WILL BE RETURNED TO THE SENDER.

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| **Declaration of the Principal Investigator*****This declaration must be signed and sent to the NREC-MD 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-MD.
* 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)  |