**Substantial modification application form for clinical investigations of medical devices as defined in the Medical Devices Regulation (EU) 2017/745 and performance studies of in vitro diagnostic medical device as defined by the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746**

Version 4.0

* All sections of the application form must be completed. If a section does not apply, select ‘No’ or ‘N/A’, or enter ‘N/A’ in the text box, as appropriate.
* Ensure all answers are in plain English comprehensible to a lay person.
* Completed form must be submitted in machine readable Word or PDF format.

# **Overview of sections of the application**

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# **Study information**

|  |  |
| --- | --- |
| A1 | NREC-MD application code |
|  | Click or tap here to enter text. |
| A2 | Study title |
|  | Click or tap here to enter text. |
| A3 | CIV-ID/ PS-ID if available |
|  | Click or tap here to enter text. |

# **Sponsor / legal representative details**

|  |  |  |
| --- | --- | --- |
| B1 | Sponsor name | Click or tap here to enter text. |
|  | Contact person name | Click or tap here to enter text. |
|  | Address | Click or tap here to enter text. |
|  | Email address | Click or tap here to enter text. |
|  | Telephone | Click or tap here to enter text. |
| B2 | Legal representative name | Click or tap here to enter text. |
|  | Contact person name | Click or tap here to enter text. |
|  | Address | Click or tap here to enter text. |
|  | Email address | Click or tap here to enter text. |
|  | Telephone | Click or tap here to enter text. |

# **Lead contact for application**

|  |  |  |
| --- | --- | --- |
| C1 | Title and name | Click or tap here to enter text. |
|  | Organisation | Click or tap here to enter text. |
|  | Address | Click or tap here to enter text. |
|  | Email address | Click or tap here to enter text. |
|  | Telephone | Click or tap here to enter text. |

# **Sites and investigators**

This section relates to sites and investigators involved in the proposed clinical investigation.

|  |  |
| --- | --- |
| D1 | Sites in the Republic of Ireland and lead site investigators |
|  | Site name | Site address | Site lead investigator name | Site lead investigator email | Site lead phone number |
|  | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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# **Details and justification for the proposed substantial modification**

|  |  |
| --- | --- |
| E1 | Nature of proposed substantial modification |
|  a. | Appointment/departure of a Principal of Lead Site Investigator Please include CV and completed Declaration of interest | [ ]  Yes[ ]  No |
| b. | Inclusion of a study sitePlease provide Site Suitability Form | [ ]  Yes[ ]  No |
| c. | Modification to participant and/or proxy information leaflet/ consent form and/or assent form Please provide redline and clean version of updated documents | [ ]  Yes[ ]  No |
| d. | Change to insurance or indemnity arrangements, other than an extension of an already approved/existing policyPlease include updated documentation | [ ]  Yes[ ]  No |
| e. | Modification triggered by urgent safety measures  | [ ]  Yes[ ]  No |
|  f. | Notification of a temporary suspension of the study | [ ]  Yes[ ]  No |
| g. | Notification to request restart of the study | [ ]  Yes[ ]  No |
| h. | Modification to the study protocolPlease provide redline and clean version of updated documents | [ ]  Yes[ ]  No |
| i. | Modification to the investigator’s brochurePlease provide redline and clean version of updated documents | [ ]  Yes[ ]  No |
| j. | Substantial modification not listed above | [ ]  Yes[ ]  No |
| E2 | Please provide details of the substantial modification proposed and a rationale for this change |
|  | Click or tap here to enter text. |
| E3 | Is the substantial modification likely to have an impact on any of the following: |
|  a. | Rights of participants | [ ]  Yes[ ]  No |
| b. | Safety of participants | [ ]  Yes[ ]  No |
| c. | Health of participants | [ ]  Yes[ ]  No |
| d. | Risk / benefit ratio of the study | [ ]  Yes[ ]  No |
| e. | Other. Please specify. Click or tap here to enter text. | [ ]  Yes[ ]  No |
| E3 | If yes to any of the above, please provide details. |
|  | Click or tap here to enter text. |
| E4 | Will this substantial modification likely have an impact on generated study / clinical data |
|  | [ ]  Yes[ ]  No |
| E5 | If yes, please provide details. |
|  | Click or tap here to enter text. |