National Research Ethics Committee

Annual Progress Report V3

**INSTRUCTIONS**

* The Principal Investigator must submit an ‘Annual Progress Report’ to the National Office for Research Ethics Committees on the anniversary date of final ethics approval and for every year thereafter for the duration of the study.
* For medical device studies approved under the Directives 93/42/EEC or 90/385/EEC (SI 252/1994; SI 253/1994), Principal Investigator must submit an ‘Annual Progress Report’ on the anniversary date of final ethics approval from the relevant local Research Ethics Committee and for every year thereafter for the duration of the study. In the case of multisite studies with multiple ethics approvals with various dates, Principal Investigator must submit the first annual report to the National Office on the anniversary of the approval that is due to be submitted next in calendar order.
* All sections of the application 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 report to your Research Office or equivalent body in your research institution
* All communications to the NRECs and questions on the process should be directed to the National Office: nationaloffice@nrec.ie
1. **General information**

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| **1.1. Clinical investigation identification** |
| Unique Device Identification (UDI) | Click or tap here to enter text. |
| Title of clinical investigation | Click or tap here to enter text. |
| NREC Application Number[[1]](#footnote-2) | Click or tap here to enter text. |
| Date of final ethics approval | Click or tap here to enter text. |
| Study sites (for each site please include names of site lead investigator) | Click or tap here to enter text. |

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| **B. Applicant identification** |
| Principal Investigator name | Click or tap here to enter text. |
| Title | Click or tap here to enter text. |
| Position | Click or tap here to enter text. |
| Institution | Click or tap here to enter text. |
| Email | Click or tap here to enter text. |
| Mobile | Click or tap here to enter text. |
| Sponsor details (or Legal Representative if Sponsor is not established in the European Union) | Click or tap here to enter text. |

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| **C. Complete this section only if your study is a clinical investigation of a medical device that received ethics approval under the Directive 93/42/EEC or 90/385/EEC (SI 252/1994 or SI 253/1994).** |
| Name of REC that approved the study | Click or tap here to enter text. |
| Application ID assigned by local REC | Click or tap here to enter text. |
| Final approval date | Click or tap here to enter text. |

**2.0 Commencement and termination dates**

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| **2.1 Has the study commenced?** |  |
| [ ] Yes[ ] No |  |
| If yes, what was the actual start date? | Click or tap here to enter text. |
| If no, what are the reasons for the study not commencing? | Click or tap here to enter text. |
| What is the expected start date? | Click or tap here to enter text. |

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| **2.2 Has the study finished?** |
| [ ]  Yes [ ]  No |  |
| If No, what is the expected completion date? | Click or tap to enter a date. |
| If you expect the study to overrun the planned completion date, what are the reasons for this?  | Click or tap here to enter text. |
| If you do not expect the study to be completed, please provide an explanation. | Click or tap here to enter text. |

**3.0 Research registration**

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| **3.1 Is your study registered on a publicly accessible database?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide the name of the publicly accessible database and the registration number | Click or tap here to enter text. |
| If No, what are your reasons for not registering your study? | Click or tap here to enter text. |

**4.0 Study modifications**

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| **4.1 Have any substantial amendments been made to the study during the preceding 12 months?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please give NREC Amendment Code for each substantial amendment made | Click or tap here to enter text. |

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| **4.2 Have any amendments or modifications been made to the study that have not required ethical approval during the preceding 12 months?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide details | Click or tap here to enter text. |

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| **4.3 Have there been any breaches to the study protocol that the NREC have not been notified of?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please enclose a report of any serious breaches not already notified to the NREC. | [ ]  Yes [ ]  No |

**5.0 Participant recruitment**

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| **5.1 Recruitment information** |  |
| Proposed total number of participants in the study (specific to Ireland) | Click or tap here to enter text. |
| Number of participants recruited to date (specific to Ireland) | Click or tap here to enter text. |
| Number of participant withdrawals from study due to |  |
| a) Number lost to withdrawal of consent  | Click or tap here to enter text. |
| b) Number lost to follow-up  | Click or tap here to enter text. |
| c) Number lost to death  | Click or tap here to enter text. |
| d) Number lost to other causes (please state what the causes were) | Click or tap here to enter text. |

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| **5.2 Has there been any serious difficulty recruiting participants or accessing samples?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide details | Click or tap here to enter text. |

**6.0 Safety of participants**

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| **6.1 Have there been any related and unexpected serious adverse events (SAEs) in this study?** |
| [ ]  Yes [ ]  No |  |
| If Yes, have the NREC been notified | [ ]  Yes [ ]  No |
| If No, please submit details with this report and give reasons for late notification. | Click or tap here to enter text. |

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| **6.2 Have any additional concerns arisen about the safety of participants in this study?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide additional information  | Click or tap here to enter text. |
| Outline any measures undertaken / proposed to maintain patient safety. | Click or tap here to enter text. |
| **If your study is not related to a CTIMP, please skip to section 7.0** |
| **6.3 Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this trial in Ireland?** |
| [ ]  Yes [ ]  No |  |
| If Yes, have the NREC been notified | [ ]  Yes [ ]  No |
| If the NREC have not been notified, please submit details with this report and give reasons for late notification. | Click or tap here to enter text. |

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| **6.4 Has the Development Safety Update Report (DSUR) been submitted?**(Sponsors are required to submit a DSUR within one year of the Development International Birth Date (DIBD – the date of first authorisation of a clinical trial in any country worldwide) and provide annual DSUR submissions until all open clinical studies have ended (the final clinical study is completed and its study report has been submitted). |
| [ ]  Yes [ ]  No [ ]  Not due |  |

**7.0 Dissemination and engagement**

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| **7.1 Have any engagement or dissemination activities related to the study been undertaken over the past 12 months?**(This can include publications, conference attendance, presentations, outreach activities, data sharing etc.) |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide details | Click or tap here to enter text. |

**8.0 Additional ethical matters**

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| **8.1 Are there any other developments in the study that you wish to report to the NREC? This may include additional ethical considerations not captured in this report.** |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide additional information | Click or tap here to enter text. |

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| **Declaration of Principal Investigator** |
| * **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.**
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| **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Print Name**: Click or tap here to enter text.**Date:** Click or tap here to enter text. (dd/mm/yyyy)  |

1. If this study received ethics approval under the Directive 93/42/EEC or 90/385/EEC (SI 252/1994 or SI 253/1994) and does not have an NREC Application number, please insert NA. [↑](#footnote-ref-2)