National Research Ethics Committee

End of Study Report V3

**INSTRUCTIONS**

* The Principal Investigator must submit an ‘End of Study Report’ to the National Office for Research Ethics Committees within twelve months of the finish date
* 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

**1.0 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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| **1.2 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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| **1.3 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. |

**2.0 Research registration**

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| **2.1 Was 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. |

**3.0 Commencement and completion dates**

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| **3.1 When did the study commence?** |
| What was the proposed start date? | Click or tap to enter a date. |
| What was the actual start date? | Click or tap to enter a date. |
| If study commencement was delayed, please describe. | Click or tap here to enter text. |

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| **3.2 When was the study completed?****(If yes, you will need to complete and submit “Declaration of end of study”)** |
| What was the proposed completion date? | Click or tap to enter a date. |
| What was the actual completion date? | Click or tap to enter a date. |
| If study completion was delayed on account of delays incurred during the study, please describe.  | Click or tap here to enter text. |
| Has the study ended prematurely? If Yes, please answer 3.3. If No, please proceed to 4.0. | [ ]  Yes [x]  No |

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| **3.3 Was the study ended prematurely?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please explain why the study ended prematurely and what impact this had on the study. | Click or tap here to enter text. |

**4.0 Study modifications**

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| **4.1 Have any substantial amendments been made during this study?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please give the NREC number for each substantial amendment made (if applicable) and briefly describe the substantial amendment(s). | Click or tap here to enter text. |

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| **4.2 Have any amendments or modifications been made that have not required ethical approval during this study?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide details and rationale for each amendment/modification. | Click or tap here to enter text. |

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| **4.3 Have there been instances where the study protocol was not followed (study breach)?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please outline how many breaches occurred during the study. | Click or tap here to enter text. |
| Briefly describe those breaches already notified to the NREC.  | Click or tap here to enter text. |
| 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 (specific to Ireland) | Click or tap here to enter text. |
| Number of participant withdrawals from study due toa) 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) | Click or tap here to enter text. |

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| **5.2 Was there serious difficulty recruiting participants or accessing samples during this study?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please provide details | Click or tap here to enter text. |
| If Yes, was there any impact on the study? | 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) and / or device deficiencies during this study?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please outline how many SAEs / device deficiencies occurred during the study. | Click or tap here to enter text. |
| If Yes, have the NREC been notified. | [ ]  Yes [ ]  No |
| Briefly describe those SAEs / device deficiencies already notified to the NREC. | Click or tap here to enter text. |
| 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 Were any additional concerns raised about the safety of participants during this study?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please outline these concerns and provide details of how they were addressed. | Click or tap here to enter text. |

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| **If your study is not related to a CTIMP, please skip to Section 7.0** |
| **6.3 Were there any Suspected Unexpected Serious Adverse Reactions (SUSARs) during this trial in Ireland?** |
| [ ]  Yes [ ]  No |  |
| If Yes, please outline how many SAEs occurred during the study. | Click or tap here to enter text. |
| If Yes, have the NREC been notified. | [ ]  Yes [ ]  No |
| Briefly describe those SAEs already notified to the NREC. | Click or tap here to enter text. |
| 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 engagement or dissemination activities have been undertaken during the study?**(This can include publications, conference attendance, presentations, outreach activities, data sharing etc.) |
| [ ]  Yes [ ]  No |  |
| **Please provide details below for all items relevant to the study.** |
| Book Chapters | Click or tap here to enter text. |
| Conferences | Click or tap here to enter text. |
| Data Sharing | Click or tap here to enter text. |
| Journal Articles | Click or tap here to enter text. |
| Media/Press | Click or tap here to enter text. |
| Other Publications | Click or tap here to enter text. |
| Outreach Activities | Click or tap here to enter text. |
| Patient and Public Involvement Activities | Click or tap here to enter text. |
| Presentations | Click or tap here to enter text. |
| Workshops | Click or tap here to enter text. |
| Any other items not listed above | Click or tap here to enter text. |

**8.0 Additional ethical matters**

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| **8.1 Were 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 and complete section 1.3. [↑](#footnote-ref-2)