National Research Ethics Committee

End of Study Report V4

**INSTRUCTIONS**

* The Sponsor 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
* All communications to the NRECs and questions on the process should be directed to: devices@nrec.ie

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| **Study Information** |
| NREC Application ID | Click or tap here to enter text. |
|  Name of the publicly accessible database on which the study was registered | Click or tap here to enter text. |
| Study registration number | Click or tap here to enter text. |
| Study date completion (international) | Click or tap here to enter text. |
| Study date completion (Ireland) | Click or tap here to enter text. |

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| **Summary study information** |
| Proposed number of participants for the study | Click or tap here to enter text. |
| Actual number of participants for the study | Click or tap here to enter text. |
| Proposed number of participants from Ireland | Click or tap here to enter text. |
| Actual number of participants from Ireland | Click or tap here to enter text. |
| Was the study completed as planned or terminated prematurely? | [ ]  As Planned [ ]  Terminated Prematurely |
| If terminated prematurely, outline the reasons for this: | Click or tap here to enter text. |
| Did participants experience any: | Click or tap here to enter text. |
| * Serious adverse events
 | [ ] Yes [ ] No |
| * Device deficiencies
 | [ ] Yes [ ] No |
| * Suspected unexpected serious adverse reactions
 | [ ] Yes [ ] No |
| * Data breaches
 | [ ] Yes [ ] No |
| * Protocol deviations
 | [ ] Yes [ ] No |
| * Other concerns about the safety of participants, their data or samples during this study
 | [ ] Yes [ ] No |
| If yes to any of the above, please provide detail: | Click or tap here to enter text. |
| Please outline any engagement or dissemination activities that have been undertaken during the study | Click or tap here to enter text. |
| Please outline any other ethical matters/ considerations pertaining to the study that you wish to report to the NREC | Click or tap here to enter text. |

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| **Clinical investigation report/ Clinical performance study report** |
| I confirm that I have attached a copy of the Clinical Investigation Report (as per ISO 14155:2020)/ Clinical Performance Study Report (as per ISO 20916:2019) to this form*(Please note that this report is provided for information purposes only and will not be formally reviewed)* | [ ] Yes [ ] No  |

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| **Declaration**  |
| * 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.
 | [ ] Yes [ ] No  |
| * I confirm that I am authorised by the study sponsor to submit this application.
 | [ ] Yes [ ] No  |
| **Print Name:** Click or tap here to enter text.**Signature** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Role in the study:** Click or tap here to enter text.**Date** Click or tap here to enter text. (dd/mm/yyyy)  |