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](mailto:nationaloffice@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) | |