National Research Ethics Committee for Medical Devices (NREC-MD)

Declaration of the End of a Clinical Clinical Investigation

**This form should be completed by the Sponsor. It should be submitted to the NREC within 90-days of the conclusion (last person - last visit) of the investigation.**

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| A. 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 Number: | Click or tap here to enter text. |
| Name of site(s): | Click or tap here to enter text. |
| Submission date: | Click or tap to enter a date. |

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| B. APPLICANT IDENTIFICATION |
| 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. INVESTIGATION DURATION |
| Start date (first person first visit) | Click or tap to enter a date. |
| End date (last person last visit) | Click or tap to enter a date. |
| Duration (years / months) | Years:Click or tap here to enter text. Months: Click or tap here to enter text. |

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| D. CIRCUMSTANCES FOR ENDING CLINICAL INVESTIGATION |
| D.1 Has this clinical investigation ended prematurely? | [ ] Yes [ ] No |
| If Yes, please specify the reasons for ending the investigation prematurely. | Click or tap here to enter text. |
| D.2 Is this a temporary halt to the investigation? | [ ] Yes [ ] No |
| If Yes, please specify the reasons for temporarily halting the clinical investigation and, if possible, identify when you expect the clinical investigation to re-start. | Click or tap here to enter text. |
| D.3 Are there any potential implications for research participants as a result of terminating/halting the clinical investigation prematurely? | [ ] Yes [ ] No |
| If Yes, please describe the steps taken to address them. | Click or tap here to enter text. |

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| E. FINAL REPORT ON THE RESEARCH |
| E.1 Is a summary of the final report on the research enclosed with this form? | [ ] Yes [ ] No |
| **If No, please submit a copy to the NREC-MD within twelve months of the end of the clinical investigation.** |

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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. |
| **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Print Name**: Click or tap here to enter text.**Date:** Click or tap to enter a date. (dd/mm/yyyy)  |