**How to complete this form:**

* Site to complete Sections 1 through 12, including Investigator signature
* Return the form to Philips Respironics
* Scan & Email this report, including any supporting documentation, within 24 hrs. of any serious adverse events (SAE), any Investigational medical device deficiencies that might have led to a SAE if a) suitable action had not been taken or b) intervention had not been made or c) if circumstances had been less fortunate and any new findings/updates in relation to already reported events
* Use a new, blank Serious Adverse Event or Unanticipated Adverse Device Effect Report form for each status update / follow up report
* Sponsor to complete Sections A through D, including signatures

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1.** **Check one:**  ❑ Initial Report ❑ Follow-up Report | | | | | | Date of Report: | | | --  (MM) (DD) (YYYY) |
| **2. REPORT INFORMATION** | | | | | | | | | |
|  | Date Report Submitted to Sponsor: | | --  (MM) (DD) (YYYY) | | |
|  | Was this reported to your IRB?  If Yes, Date Report Submitted to IRB (if not central): | | Yes No  --  (MM) (DD) (YYYY) | | |
|  |  | | | | | | | | |
| **3. SUBJECT INFORMATION** | | | | | | | | | |
|  | Date of birth: | --  (MM) (DD) (YYYY) | | | | | Gender: | | ❑ Male ❑ Female |
| **4. SERIOUS ADVERSE EVENT INFORMATION** | | | | | | | | | |
| Clinical Diagnosis: | | | |  | | | | | |
| Onset date and time: | | | | | --  (MM) (DD) (YYYY) | | | :  (24-HOUR CLOCK) | |
| **5. IN YOUR OPINION, IS THIS EVENT:** | | | | | | | | | |
| Investigational Device Related?❑ Yes ❑ No ❑ Unknown  Study Related?❑ Yes ❑ No ❑ Unknown | | | | | | | | | |
|  | | | | | | | | | |

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| **6. Serious Adverse Event Description** |
| ❑ Please check if additional sheet is attached |

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| **7. SERIOUSNESS CRITERIA (*check all that apply*)** | | | | | | |
|  | ❑ | | Death | Date of death: --  (MM) (DD) (YYYY) | | |
|  | ❑ | | Persistent or significant disability / incapacity | | | |
|  | ❑ | | Congenital anomaly / birth defect | | | |
|  | ❑ | | Medically significant/important event | | | |
|  | ❑ | | Life-threatening | | | |
|  | ❑ | | Required hospitalization / prolonged hospitalization (Complete dates below) | | | |
|  | | Date of hospitalization: --  (MM) (DD) (YYYY) | | |  | Date of discharge: --  (MM) (DD) (YYYY) |

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| --- | --- | --- | --- |
| **8. MEDICAL HISTORY / CO-EXISTING DISEASES**  ❑ Please check if additional sheet is attached | | | |
|  | | | |
| **9. RELEVANT LABS AND OTHER TEST RESULTS**  ❑ Please check if additional sheet is attached  **10. SERIOUS ADVERSE EVENT STATUS:** | | | |
| ❑ | Resolved Date Resolved: | --  (MM) (DD) (YYYY) |  |
| ❑ | Continuing | --  (MM) (DD) (YYYY) |  |
| ❑ | Fatal Date of death: | --  (MM) (DD) (YYYY) |  |
| ❑ | Unknown | --  (MM) (DD) (YYYY) |  |

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| --- | --- | --- | --- | --- |
| **11. REPORTER’S SIGNATURE** | |  |  | |
| Reporter’s Printed Name & Title | |  | Reporter’s Signature | |
| Date signed: | --  (MM) (DD) (YYYY) | | |  |
| **12. INVESTIGATOR’S SIGNATURE** | |  |  | |
| Principal Investigator’s Printed Name & Title | |  | Principal Investigator’s Signature | |
| Date signed: | --  (MM) (DD) (YYYY) | | |  |

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| **\*\*SPONSOR USE ONLY\*\*** |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **ACTION TAKEN DUE TO THIS EVENT (check one)** | | | | | | | |
| ❑ **No Action Necessary** | | | | | | | |
| Justification**:** | | | | --  (MM) (DD) (YYYY) | | | |
| ❑ **Modify Protocol and/or Consent** | | | | | | | |
|  | | |  | | | | |
| * **Temporarily Stopped / Suspended**   ❑ **Study** ❑ **Study Participant** | | | | | | | |
|  | | |  | | | | |
| * **Termination**   ❑ **Study** ❑ **Study Participant** | | | | | | | |
| 1. **Sponsor determination:**   **This Event Is:** | | | | | | | |
| Investigational Device Related❑ Yes ❑ No ❑ Unknown | | | | | | | |
| Study Related❑ Yes ❑ No ❑ Unknown  Related to a released device, used per intended use ❑ Yes ❑ No  **If yes, reporting should follow QSP 8.4-836** | | | | | | | |
| Does this Event Represent a Trend? ❑ Yes ❑ No ❑ Unknown | | | | | | | |
| 1. **DATE ACTION TAKEN** | | | | | | | |
| Report Submitted to: | | --  (MM) (DD) (YYYY) | ❑ Site Investigator notified  ❑ All Investigators/ Sites notified  ❑ Site IRB notified  ❑ All IRB’s notified  ❑ Related communication attached | | | |
| Report Submitted to FDA: | --  (MM) (DD) (YYYY) | | | | ❑ N/A |  |
| **NOTE: If report is to be submitted to the FDA, it must be reviewed and notification submitted to FDA by Manager of Regulatory Affairs, or next higher level**  **Review By (Regulatory Manager, or next level higher):** ❑ N/A  Printed Name / Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: --  (MM) (DD) (YYYY)  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | |
| 1. **SIGNATURES** | | | | | | | |
| **Evaluation Prepared By (ex. CRA, Manager etc.):**  Printed Name / Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: --  (MM) (DD) (YYYY)  Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Review By (Manager of Clinical Research, or next level higher):**  Printed Name / Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: --  (MM) (DD) (YYYY)  Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |