Form for Reporting Study Adverse Events 

|  |  |
| --- | --- |
| **Study name and REC ref number** |  |
| **Volunteer ID number** |  |
| **Principal Investigator** |  |
| **Study Researcher** |  |

**NB: This form must be completed on the day of the adverse event and sent to all research nurses and the unit managers at time of event. This will enable logging of the adverse event and follow up with the volunteer by a nurse.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Description of AE** | **Category of AE \*** | **Date of start** | **Date of end** | **Grading \*\*** | **Date/ time reported** | **Measures taken including nurse advice/study withdrawal** |
|  |  |  |  | Seriousness:  Intensity:    Frequency:  Relation to study product: |  |  |
| **Form sent to nurses and unit managers**: YES / NO completed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| **To be completed by a nurse**  Followed up by (name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Outcome:** | | | | | | |

Grading\*\* **Seriousness:** if resulted in death; is life-threatening; requires hospitalisation; disability or incapacity;

congenital anomality=**1**; No=**2**

**Intensity**: Mild= **1;** Moderate=**2**; Severe=3

**Frequency:** rare=**1**; frequent=**2**; often=**3**; non applicable=**4**

**Relation to study product**: unrelated=**1**; unlikely=**2**; probable=**3**, definitely related=**4**

Category of AE\*: **1**.Cannula related AE

**2.** Upper and lower respiratory

**3**. Allergy- skin reactions

**4**. Gastro – intestinal reactions

**5.** Other