Form for Adverse Events

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

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| **Description of AE** | **Category of AE \*** | **Date of start** | **Date of end** | **Grading \*\*** | **Date/ time reported** | **Measures taken including medical/ nurse advice/study withdrawal** |
|  |  |  |  | Intensity: Frequency: Relation to study product: |  |  |
| **Form sent to unit managers and nurses**: YES / NO completed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **To be completed by a nurse**Followed up by (name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Outcome:**  |
| Category of AE\*: **1**.Cannula related AE (pain, erythema or swelling) **2a**. Upper respiratory **2b**. Lower respiratory **3**. Allergy- skin reactions **4**. Gastro – intestinal reactions **5.** Other | Grading\*\*: **Intensity:** light=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 |
| **NB: This form must be completed on the day of the adverse event and sent to all research nurses and unit managers at time of event. This will enable logging of the adverse event and follow up with the volunteer by a nurse.** |