ADVERSE EVENT FORM

Definitions

An **Adverse Event (AE)** is defined as any untoward occurrence in a patient or research subject who is involved in a clinical research study and **which does not necessarily have a causal relationship** with study participation or procedures.

NRES defines a **Serious Adverse Event (SAE)** as an untoward occurrence that:

- Results in death;
- Is life-threatening*;
- Requires in-patient hospitalisation or prolongation of existing hospitalisation**
- Results in persistent or significant disability or incapacity, or;
- Consists of a congenital anomaly or birth defect;
- Other important medical events***.

NRES defines **related** and **unexpected** SAEs as follows:

- related – that is, it resulted from administration of any of the research procedures;
- unexpected – that is, the type of event is not listed in the protocol as an expected occurrence.

Severity is graded as follows:
Mild: does not interfere with routine activities
Moderate: interferes with routine activities
Severe: impossible to perform routine activities

Name of study	
Subject ID	
Subject DOB	
Subject Initials	
Study Site Number	
Name of Person reporting the AE	

Description of the AE (please continue on a separate sheet of paper if necessary)

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Is the AE Mild ☐ Moderate ☐ Severe ☐ ?

Date of Onset of AE (dd/mm/yy) ☐☐ ☐☐ ☐☐

Current status of subject (*resolved; resolved with sequelae (specifying with additional narrative); not resolved/ongoing; ongoing at final follow-up; fatal or unknown.)*

	Yes	No
Is this AE a SAE?		
Is the AE **related** to study participation?		
Is the AE **unexpected**?		

If the answer to all 3 of the last questions is YES an SAE form needs to be sent from the BIUKCC to the MREC. Please fax this form to the BIUKCC within one working day of notification of the SAE and telephone the coordinating centre on **0151 795 9606** to advise that an SAE report has been submitted.

FAX Number 0151 795 5528

Reason for AE being an SAE. **At least one of the following must be ticked.**

Resulted in Death	
Life Threatening	
Requires inpatient hospitalisation or prolongation of hospitalisation*	
Results in significant disability or incapacity	
Consists of a genital anomaly or birth defect	
Other important medical event**	

* *Hospitalisations for a pre-existing condition, including elective procedures that have not worsened, do not constitute an SAE.*

** *Other important medical events that may not result in death, be life-threatening, or require hospitalisation may be considered a serious adverse event/experience when, based upon appropriate medical judgment, they may jeopardise the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.*