SOP 206
Serious Adverse Event report – non CTIMP study

Study information		
Study title (short):		
REC or IRAS number:	**Chief Investigator:**	**Sponsor:**
Report type: Initial report ☐	Follow up report ☐	Follow up report #:
Protocol title and current version number:		
Participant information		
Participant DOB: *(dd/mm/yy)*	**Participant initials:**	**Participant Gender:** ☐ Male ☐ Female
Participant Randomisation or Study No:	**Study site name:**	
Evaluation of Event		
Event/Reaction: *(keywords; e.g. body site, symptoms, severity, treatment)*		
Principal (site) Investigator:	**Date of sending report:** *(dd/mm/yy)*	

Date of onset: *(dd/mm/yy)*	**Time of onset:** *(hh:mm)*	**Date person completing form became aware of SAE** *(dd/mm/yy)*

Criteria for definition as SAE:

☐ Congenital abnormality/birth defect
☐ Resulted in death
☐ Life threatening
☐ In patient hospitalisation/prolongation
☐ Persistent or significant disability
☐ Considered medically significant by the investigator

If there is more than one criterion, choose the more/most significant one.

Describe event: *(A summary of signs and symptoms, diagnosis, treatment of event, concurrent treatment, other relevant medical history, including re-challenge details if applicable. Please include the point in the study at which the event occurred.)*

In the opinion of the Investigator at the study site was the event related to a research procedure?	**Please specify which procedure if applicable**
☐ Definitely ☐ Likely ☐ Possibly ☐ Unlikely ☐ Not related	

Is the Chief/Principal Investigator blinded to the treatment arm?

☐ Yes ☐ No ☐ Not applicable

Is this Event foreseen in the study protocol as a study endpoint?

☐ Yes
☐ No
☐ Not applicable

Have urgent safety measures been implemented? ☐ Yes ☐ No ☐ Not applicable	**If yes, please detail below:**

Outcome of event

Initial SAE report should not be delayed to wait for outcome

What is the outcome of the SAE?	**Date event resolved:** *(dd/mm/yy)*	**Date patient died:** *(dd/mm/yy)*
☐ Recovered ☐ Recovered with sequelae ☐ AE Continuing ☐ Resulted in death ☐ Unknown		

Cause of death obtained from:

☐ Coroner's inquest
☐ Death certificate
☐ Working diagnosis

Contact and signatures

Please supply contact details where further information may be obtained: (e.g. CI, PI at site, research nurse, study manager, GP [if patient has given consent for GP to be contacted])

Person to contact:

Phone number:

Email address:

_____

Signature ***(person completing report)*** **Print name** **Date** *(dd/mm/yy)*

_____

PI Signature ***(if multicentre trial)*** **Print name** **Date** *(dd/mm/yy)*

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CI Signature ***(if not completing report)*** **Print name** **Date** *(dd/mm/yy)*

Please fax completed form to XXX XXX or scan and email to rdoffice@nnuh.nhs.uk or researchsponsor@uea.ac.uk