Joint Arrangements for Research

Serious Adverse Event report – NNUH or UEA sponsored Non CTIMP studies

What are you reporting?	
SAE / SAR ☐	SUSAR* ☐
Note: If you are reporting a SUSAR the randomisation code for that participant will have to be unblinded	
Report Type:	Initial ☐ Follow-up Report ☐ Follow-up Report #
Study information	
Study Title: (short)	
Sponsor:	**Chief Investigator Name:** **Email Address:**
R&D or RIN Reference Number / IRAS Number:	
Protocol title and version number:	
Site Number: *(for multi-site studies only)*	**Site Name:**
Principal Investigator	**Name:** **Email address:**
Date of site becoming aware of the event *(dd/mm/yy)*:	
Participant information	
Participant initials:	**Participant Gender:** ☐ Male ☐ Female
Participant Randomisation No:	

Evaluation of Event – please refer to definitions in the SOP (206) for guide on understanding of seriousness, relatedness and expectedness		
Event/Reaction: *(keywords; e.g. body site, symptoms, severity, treatment)*		
Date of onset: *(dd/mm/yy)*	**Date person completing form became aware of event:** *(dd/mm/yy)*	
Criteria for definition as SAE	☐ Congenital abnormality/birth defect ☐ Resulted in death ☐ Life threatening ☐ In patient hospitalisation/prolongation of hospitalisation ☐ Persistent or significant disability ☐ Is otherwise 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 investigators opinion was the event related to a research procedure / treatment / intervention?	☐ Definitely ☐ Likely ☐ Possibly ☐ Unlikely ☐ Not related	
Please specify which procedure / treatment / intervention (if applicable)		
Have urgent safety measures been implemented? ☐ Yes ☐ No ☐ Not applicable	**If yes, please detail below:**	
Outcome of event		
What is the outcome of the SAE?	**Date event resolved:** *(dd/mm/yy)*	**Date patient died:** *(dd/mm/yy)*

☐ Recovered ☐ Recovered with sequalae ☐ 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: **Person to contact:** **Phone number:** **Email address:**		

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

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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)*

If the study is sponsored by NNUH please send the completed form to rdsae@nnuh.nhs.uk

If the study is sponsored by UEA please send the completed form to researchsponsor@uea.ac.uk

If the study is sponsored by UEA and Hosted by NNUH, please send the form to researchsponsor@uea.ac.uk and rdsae@nnuh.nhs.uk.

For R&D Office use only

For SUSAR only:	Date reported to the REC:
For NNUH Sponsored study only REVIEW BY NNUH MEDICAL ADVISOR	Medical Advisor comments:
SIGNED:	
Name (print):	
Date:	