

Joint Arrangements for Research

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

What are you reporting?	
SAE / SAR <input type="checkbox"/>	SUSAR* <input type="checkbox"/>
<i>*Note: If you are reporting a SUSAR the randomisation code for that participant will have to be unblinded</i>	
Report Type:	Initial <input type="checkbox"/> Follow-up Report <input type="checkbox"/> 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: <i>(for multi-site studies only)</i>	Site Name:
Principal Investigator	Name: Email address:
Date of site becoming aware of the event (dd/mm/yy):	
Participant information	
Participant initials:	Participant Gender: <input type="checkbox"/> Male <input type="checkbox"/> 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: <i>(keywords; e.g. body site, symptoms, severity, treatment)</i>		
Date of onset: <i>(dd/mm/yy)</i>	Date person completing form became aware of event: <i>(dd/mm/yy)</i>	
Criteria for definition as SAE	<input type="checkbox"/> Congenital abnormality/birth defect <input type="checkbox"/> Resulted in death <input type="checkbox"/> Life threatening <input type="checkbox"/> In patient hospitalisation/prolongation of hospitalisation <input type="checkbox"/> Persistent or significant disability <input type="checkbox"/> Is otherwise considered medically significant by the Investigator <i>* If there is more than one criterion, choose the more/most significant one.</i>	
Describe event: <i>(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.)</i>		
In the investigators opinion was the event related to a research procedure / treatment / intervention?	<input type="checkbox"/> Definitely <input type="checkbox"/> Likely <input type="checkbox"/> Possibly <input type="checkbox"/> Unlikely <input type="checkbox"/> Not related	
Please specify which procedure / treatment / intervention (if applicable)		
Have urgent safety measures been implemented? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable	If yes, please detail below:	
Outcome of event		
What is the outcome of the SAE?	Date event resolved: <i>(dd/mm/yy)</i>	Date patient died: <i>(dd/mm/yy)</i>

<input type="checkbox"/> Recovered <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Continuing <input type="checkbox"/> Resulted in death <input type="checkbox"/> Unknown		
Cause of death obtained from:		<input type="checkbox"/> Coroner's inquest <input type="checkbox"/> Death certificate <input type="checkbox"/> Working diagnosis
Contact and signatures		
Please supply contact details where further information may be obtained: 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)

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:	