

## Joint Arrangements for Research

### Form for Protocol and Regulatory Non-Compliance Including Serious Breaches

To be used in conjunction with SOP 210 Managing Protocol and Regulatory Non-Compliance including Serious Breaches

Title of Trial/Acronym:		
Sponsor:	NNUH <input type="checkbox"/> University of East Anglia <input type="checkbox"/>	
Sponsor Reference (R&D/RIN number):		
Chief Investigator:		
Research Ethics Committee Reference:		
Eudract Reference (if applicable):		
NCTU NCR Report Reference (if applicable):		
Name of Institution / Site:		
Report type:	Initial <input type="checkbox"/> Follow-up <input type="checkbox"/> Final <input type="checkbox"/>	
Report dates: (DD/MM/YY)	Initial: Follow-up: Final:	
<b>Section 1: Description of Non-compliance</b> (include dates, participant identifiers, location of event(s) / organisations involved and names of staff involved in non-conformance, if known and appropriate)		
Identified by:		
Is this a serious breach of GCP or Protocol?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>Section 2: Reasons</b> (What are the root cause (s) / investigation results)		
Corrective actions: (Please list as many as required)	Lead Person & Target Date (DD/MM/YY)	Date Completed (DD/MM/YY)



Preventative actions: (Please list as many as required)	Lead Person & Target Date (DD/MM/YY)	Date Completed (DD/MM/YY)

**Please supply contact details where further information may be obtained:**

**Person to contact:**

**Phone number:**

**Email address:**

If the study is sponsored by NNUH please send the completed form to [office.rd@nnuh.nhs.uk](mailto:office.rd@nnuh.nhs.uk) .

If the study is sponsored by the University of East Anglia and Hosted by NNUH, please scan and email the form to [researchsponsor@uea.ac.uk](mailto:researchsponsor@uea.ac.uk) and [office.rd@nnuh.nhs.uk](mailto:office.rd@nnuh.nhs.uk) .

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Date form RECEIVED by R&D: <i>(dd/mm/yy)</i>	Reviewed by:
( )	Date reviewed: ( ) <i>(dd/mm/yy)</i>
	Date reported to the REC: ( )
	Date reported to MHRA: ( )