

### 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

<b>Title of Trial/Acronym:</b>		
<b>Sponsor:</b>	NNUH <input type="checkbox"/> University of East Anglia <input type="checkbox"/>	
<b>IRAS number:</b>		
<b>Sponsor Reference (R&amp;D/RIN number):</b>		
<b>Chief Investigator:</b>		
<b>Research Ethics Committee Reference:</b>		
<b>Eudract Reference (if applicable):</b>		
<b>NCTU NCR Report Reference (if applicable):</b>		
<b>Name of Institution / Site:</b>		
<b>Report type:</b>	Initial <input type="checkbox"/> Follow-up <input type="checkbox"/> Final <input type="checkbox"/>	
<b>Report dates:</b> (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)		
<b>Identified by:</b>		
<b>Is this a serious breach of GCP or Protocol?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>Section 2: Reasons</b> (What are the root cause (s) / investigation results)		
<b>Corrective actions:</b> (Please list as many as required)	<b>Lead Person &amp; Target Date</b> (DD/MM/YY)	<b>Date Completed</b> (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) .