**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

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| Title of Trial/Acronym: |       |
| Sponsor:  | NNUH [ ]  University of East Anglia [ ]  |
| 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 [ ] Follow-up [ ]  Final [ ]  |
| Report dates:(DD/MM/YY) | Initial:      Follow-up:      Final:        |
| **Section 1: Description of Non-compliance** (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 [ ]  No [ ]  |
| **Section 2: Reasons** (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) |
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| Preventative actions:(Please list as many as required)  | Lead Person & Target Date (DD/MM/YY) | Date Completed (DD/MM/YY) |
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| **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 .

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 and office.rd@nnuh.nhs.uk .

**For R&D Office use only**

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