**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](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) .

**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: (     ) |