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| **NON-COMPLIANCE REPORTING FORM**  Please complete this form in **word format**  Section A must be completed by the person reporting the non-compliance  After completion please submit to the Research & Innovation Department’s Quality Assurance Team via [R&IQATeam@nuh.nhs.uk](mailto:R&IQATeam@nuh.nhs.uk)  Please ensure all three pages are returned  For queries regarding completion of this form please contact R&IQATeam@nuh.nhs.uk |

**Section A**

**Study Details**

|  |  |
| --- | --- |
| **Sponsor organisation** | Nottingham University Hospitals NHS Trust |
| **R&I study code reference** | 22SR001 |
| **IRAS number** | 1004870 |
| **Study title** | MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage  (MACE-ICH): a feasibility trial |
| **Chief Investigator** | Dr Kailash Krishnan |

**Non-compliance details**

|  |  |
| --- | --- |
| 1. **Organisation where non-compliance occurred** |  |
| 1. **Does this non-compliance affect (a) specific participant(s)?**   If no, please proceed to question 5 | Yes No |
| 1. **How many participants are affected?** | NUMBER |
| 1. **Details of affected participant(s)** | Participant trial number(s):  Participant initials:  Participant trial number(s):  Participant initials:  If more participants are affected by this non-compliance, please include an appendix with the full list of participant details  Please do not included any personal identifiers |

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| 1. **Details of non-compliance** | Please add as much detail as possible (staff names, job titles, dates and description of events) |
| 1. **Details of corrective action (CA) taken** | Please state here all steps have taken to immediately correct the non-compliance |
| 1. **Details of preventative action (PA) taken** | Please state here any steps you have taken to prevent repetition of the non-compliance. |
| 1. **Date acknowledged** | DD/MMM/YYYY |
| 1. **Date Resolved** | DD/MMM/YYYY |

**Contact Details**

|  |  |
| --- | --- |
| **Name of person completing report** |  |
| **Contact details** | Email:  Tel: |
| **Job role** |  |
| **Date of report** | DD/MMM/YYYY |
| **Signature** |  |

**Section B - THIS SECTION IS TO BE COMPLETED BY THE Quality Assurance TEAM**

**Review details:**

|  |  |
| --- | --- |
| **Date report received** | DD/MMM/YYYY |
| **Date report reviewed** | DD/MMM/YYYY |
| **Is CAPA sufficient?**  (if no, detail extra actions needed below) | Yes No |
| **Is this a repeat non-compliance?** | Yes No  How many? XXX |
| **Further actions (if applicable)** |  |
| **Does this non-compliance constitute a serious breach?** | Yes No |
| **Is this reportable to REC?** | Yes No  Date reported: DD/MMM/YYYY |
| **Is this reportable to MHRA?** | Yes No  Date reported: DD/MMM/YYYY |
| **Date non-compliance resolved** | DD/MMM/YYYY |
| **Reviewer name** |  |
| **Job role** |  |
| **Signature** |  |