



Mannitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH)

File Note

MACE-ICH Trial Number: _____ N/A _____
(in the format: C999/999)

Details: NUH Sponsor SOPs

Sponsor SOPs relevant to the trial (listed below) can be accessed via the following link:

<https://www.nuh.nhs.uk/guidance-researchers>

| SOP Reference | Title |
|---------------|---|
| SOP-RES-010 | Site Initiation for NUH sponsored studies |
| SOP-RES-011 | Site Green Light |
| SOP-RES-014 | Maintaining Study Files |
| SOP-RES-015 | Informed Consent |
| SOP-RES-016 | Patient Health Records and Source Data |
| SOP-RES-017 | Non-Compliance and Serious Breach Reporting |
| SOP-RES-019 | Adverse Event Reporting |
| SOP-RES-020 | Annual Progress and Safety Reports |
| SOP-RES-021 | Out of hours medical cover |
| SOP-RES-022 | Urgent Safety Measures |
| SOP-RES-024 | Amendments to Active Research Studies |
| SOP-RES-026 | End of Study Notification, Site Close Out and Reporting for NUH Sponsored Studies |
| SOP-RES-028 | Archiving and Destruction of Records |

Actions: Training provided by the Coordinating Centre (via site investigator training and/or WPDs) will cover the above SOPs.

Impact on Patient Safety: None

Impact on Compliance: None

J. Craig

08/02/2024

Name (Signature)

Date

JEN CRAIG

Name (Print)