|  |  |  |
| --- | --- | --- |
| **Site Initiation Checklist**  Please complete this checklist before study start and send to [info@stepcare.org](mailto:info@stepcare.org). | | |
| **Activities to complete** | **Yes** | **N/A** |
| **TRIAL PROTOCOL**  The trial protocol and local routines have been explained to: |  |  |
| ICU consultants |  |  |
| ICU on-call physicians |  |  |
| ICU nurses |  |  |
| Blinded prognosticators (Neurologist or other external specialist) |  |  |
| Neurophysiology (EEG-protocol) |  |  |
| **TRIAL PROCEDURES**  The following have been explained to the involved personnel: |  |  |
| Screening and randomization procedure |  |  |
| Inclusion and exclusion criteria |  |  |
| Informed consent procedure |  |  |
| Procedure for reporting safety events |  |  |
| Procedure for reporting protocol deviations |  |  |
| **INTERVENTIONS**  The following have been discussed internally: |  |  |
| Sedation intervention |  |  |
| Temperature intervention |  |  |
| MAP-intervention |  |  |
| **LOGISTICS** |  |  |
| Cooling device and required disposables/attachments in ICU |  |  |
| Bladder temperature probes |  |  |
| Sedation level assessment |  |  |
| Delirium assessment |  |  |
| Study staff, equipment and materials required to conduct the study |  |  |
| **DATA COLLECTION**  Accounts for randomization and data entry will be set up after completion of this checklist. The eCRF can be tested at [stepcare.org/start.](https://stepcare.org/start) |  |  |
| Routines discussed for completion of the eCRF |  |  |
| Requirements for documentation in the medical record discussed |  |  |
| **FOLLOW UP** |  |  |
| Follow-up plan available, blinded assessor appointed |  |  |
| Translated forms available (contact [followup@stepcare.org](mailto:followup@stepcare.org)) |  |  |
| **SUBSTUDIES** – [stepcare.org/substudies](https://stepcare.org/substudies)  Planned participation in: |  |  |
| EARLY NEURO |  |  |
| Biomarkers |  |  |
| Extended follow-up |  |  |
| PROPEA (EEG) |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | **Yes** | **N/A** |
| **AGREEMENTS** | | |  |  |
| Clinical Trial Agreement signed | | |  |  |
| Data Transfer Agreement signed | | |  |  |
| **INVESTIGATOR SITE FILE (ISF)**  Contact [info@stepcare.org](mailto:info@stepcare.org) to receive the ISF.The following documents have been filed at the site: | | |  |  |
| The documents provided in the electronic ISF | | |  |  |
| Ethics committee approval | | |  |  |
| Patient information and consent form | | |  |  |
| Contact list (completed) | | |  |  |
| Delegation and signature list (completed) | | |  |  |
| CVs of personnel on signature list | | |  |  |
| Origin of source data (completed) | | |  |  |
| Insurance statement (if required) | | |  |  |
| Laboratory accreditation certificate | | |  |  |
| Other documents according to national regulations | | |  |  |
| **TRIAL MASTER FILE**  Please send the following documents to [info@stepcare.org](mailto:info@stepcare.org): | | | | |
| * Ethics committee approval and if applicable approvals from other local authorities * Completed delegation and signature list * CVs of principal investigator and key personnel * Laboratory accreditation certificate * The completed site initiation checklist | | | | |
| **CONTACT DETAILS** | | | | |
| Hospital name: | | | | |
| Planned start date: | | | | |
| Principal Investigator | Name: | Email: | | |
| Research Coordinator | Name: | Email: | | |
| Follow-up assessor | Name: | Email: | | |
| Neurophysiologist | Name: | Email: | | |

**Comments or questions:**

**I confirm that the information provided above is correct.**

**Signature of Site Principal Investigator:** ……………………………………………………………… **Date:**     

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| Reviewed by:  Signature of the Sponsor’s representative:……..…………………………………………………… Date: |