|  |
| --- |
| **Site Initiation Checklist**Please complete this checklist before study start and send to 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) | **[ ]**  | **[ ]**  |
| **SUBSTUDIES** – [stepcare.org/substudies](https://stepcare.org/substudies) Planned participation in:  |  |  |
| EARLY NEURO | **[ ]**  | **[ ]**  |
| Biomarkers  | **[ ]**  | **[ ]**  |
| Extended follow-up | **[ ]**  | **[ ]**  |
| PROPEA (EEG) | **[ ]**  | **[ ]**  |

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| --- | --- | --- |
|  | **Yes** | **N/A** |
| **AGREEMENTS**  |  |  |
| Clinical Trial Agreement signed | **[ ]**  | **[ ]**  |
| Data Transfer Agreement signed | **[ ]**  | **[ ]**  |
| **INVESTIGATOR SITE FILE (ISF)**Contact 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:  |
| * 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:       |