RESCUE-ASDH

CRF Completion Guidelines

Randomised Evaluation of Surgery with Craniectomy for patients Undergoing Evacuation of Acute Subdural Haematoma.

RESCUE-ASDH is a multi –centre, pragmatic parallel group randomised trial comparing craniectomy vs. craniotomy for acute subdural haematoma patients.

REC Number:	14/NW/1076
ISRCTN Number:	ISRCTN87370545
Chief Investigator:	Professor Peter Hutchinson
Trial Coordinator:	Dr Natalia Igosheva
Senior Data Manager:	Dr Sridevi Nagarajan
Data Manager:	Mrs Kamila Walker
Trial Sponsor:	University of Cambridge & Cambridge University Hospital NHS Foundation Trust

Please remember that CRFs (and any other study-related documentation) sent to Data Management team MUST NOT contain any patient-identifiable data.

1. General Principles for CRF Completion

- All CRF pages must be clear, legible and completed in black ball point ink.
- The correct version of the CRF form must be completed
- Once a patient is registered, a CRF pack should be labelled with the patient trial number.
- Data reported on the CRF must be extracted from, and be consistent with, documented source data. Any discrepancies should be fully explained
- Where selection boxes indicate a selection of Y or N or numerical options (i.e. 1, 2, 3), only ONE entry should be recorded per box.
- CRFs must be completed, dated and signed by an Investigator or designee as soon as the requested information is available
- CRFs must only be completed by authorised personnel who are sufficiently informed and trained to do so, and who have completed and signed the site's trial Delegation Log
- **Copies of completed and signed** CRF pages should be sent to the RESCUE- ASDH Data Manager within a time framed specified on each form
- Original completed CRFs with wet signature to be kept at the site
- Changes must not be made to original CRF pages once the copies have been returned to the RESCUE- ASDH Data Manager.
- Serious Adverse Events that are Related and Unexpected must be recorded on SAE Form and sent to the coordination centre within 24 hours of becoming aware of the event.
- The timely completion, legibility and accuracy of the CRFs remain the responsibility of the Principal Investigator of the site.

1.1. Header Boxes

The following data must be completed in the header of every completed CRF:

- Patient Initials: First, Middle and last initials only . If there are no middle initials, please fill them as follows : e.g. J-K
- Patient Date of Birth: Enter using the DD/MMM/YYYY format (e.g. 13 AUG 2013)
- Patient Trial Number: Each subject will receive a unique seven-digit trial number upon randomisation (e.g. R-NXX-1XX). Patients in the observational cohort will also be assigned number by Tenalea (e.g O-NXX-5XX)

1.2. Footer Boxes

The following data MUST be completed in the footer of every completed CRF:

- Completed By: Name of person completing the form
- Date Completed: Enter using the DD/MMM/YYYY format (e.g. 13 AUG 2013)

1.3. Patient Data

- CRFs (and any other study related documentation) sent to the RESCUE Data Manager at the CCTU **MUST NOT** contain any patient-identifiable information.
- Please use **ONLY** the patient's first and last initials, date of birth and Subject ID when communicating with the coordination team.
- The only CRF page with participant's identifiable information (PID- Baseline) needs to be emailed to Trial Coordinator at **natalia.igosheva@addenbrookes.nhs.uk**

1.4. Completion of Dates

- All dates are to be completed in the sequence day/month/year (DD/MMM/YYYY) with the month written using LETTERS not numbers.
- If the day or month is unknown complete the boxes with UK

1.5. Unavailable Data

- **All** applicable questions must be answered.
- Where data are not available **please do not leave the answer blank** as this will create unnecessary data queries.
- Please include one of the following abbreviations instead:

  - **NK** = Not known

  - **NA** = Not applicable

  - **ND** = Not done

1.6. Correcting Errors

- Errors and/or corrections should be crossed out with a single line (i.e. mistake), the correction inserted and the change initialled and dated by the investigator or designee.
- Typing correction fluid should NOT be used.
- If it is not clear why a change has been made, an explanation should be written next to the change

1.7. Sending CRFs to the CCTU

Please send **copies / scanned** CRF forms to: RESCUE_ASDH Data Manager by either email or fax

(CRF@RESCUEASDH.ORG) or fax (+44 1223 596471)

Cambridge Clinical Trials Unit
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Clinical School Level 3 - Box 111
Hills Road Cambridge CB2 0QQ

Ensure that originals of forms sent to the Data Manager are kept at your site

1.8 Data Quality

- Completed CRFs and questionnaires sent to CCTU will be checked for:
  - Compliance with protocol
  - Consistent/missing data
  - Timing of completion
- A data query will be raised if there are any missing data or data inconsistencies observed
- Data clarification requests will be sent to the site within **2 weeks** of CRF page receipt
- CRF queries should be answered and returned within **2 weeks** of receipt

2. RESCUE- ASDH Competition Guidelines by Stages.

*All of the following CRFs are required for the **randomised cohort**.*

*For the **observational cohort** only Baseline, Stage 1, and EQ-5D-5L at 12 months post surgery are required.*

2.1 BASELINE- all completed and signed Baseline CRFs MUST be returned within 2 weeks from NSU discharge.

Please fill:

- **Baseline assessments**: cause, type, mechanism and place of injury qualifying for the cranial surgery, if none of the listed options applies please fill in the "other" box. Please, tick all co-existing injuries and their severity if applicable.
- **Pre-hospital admission event**: was there any delay in transfer or getting the patient required treatment? Please tick all known observations and vital signs.
- **Clinical laboratory tests at admission**: please fill in the available results of the blood test done at admission. The units will be completed centrally by the Data Manager.
- **Medical History& Co-morbidities**: fill in the table if there are any pre-existing Medical conditions. Please tick YES next to condition present, if left blank it will be assumed that condition does not exists.
- **Medication History**: tick the medications that participant was taking prior to admission and indication if applicable.
- **Participant information (PID)**: please note that this form with patient identifiable information's should be **emailed ONLY** to the RESCUE-ASDH Coordinator - Natalia Igosheva **natalia.igosheva@addenbrookes.nhs.uk**
- **Socio-demographics:** tick all the boxes that apply.
- **Adverse events:** Only expected adverse events and surgical complications should be recorded in this form. Each event needs to be assessed for relatedness, severity and seriousness. Please enter dates of onset and resolution and the outcome of the event.

2.2 STAGE 1 - to be returned within 3 days of enrolment.

- **Eligibility review and Enrolment:** All the boxes on this form are MANDATORY.

  All the inclusion criteria should be ticked "YES" and all exclusion criteria should be ticked "NO". Eligibility must be assessed **PRIOR** to surgery by the operating surgen with the designated role. Only if participant is eligible they can be enrolled into the trial. Following enrolment in the study, suitability for randomisation is assessed by the operating surgeon. The form MUST be counter signed by PI to verify eligibility within 3 working days of the enrolment. The randomization AND observational cohort ID number is allocated by the Tenalea system. Please enter ID numbers as appropriate.
  For randomised participants select treatment allocated and received. For participants not suitable for randomisation please select reason and treatment given.

- **Early injury event and Surgery details:** Please provide **date and time** of the injury. If participant was primary admitted to different hospital, please name the referral centre with the **date and time** of the admission. Provide the details of the index surgery.
- **CT Scan, GCS and Discharge:** enter values from before the operation if known and discharge date and destination if applicable. If patient died, please give the principle cause.

2.3 STAGE 2 - to be returned within 2 weeks of discharge from Intensive Care Unit (ICU).

- **GCS and Discharge:** GCS evaluation at the time of the ICU discharge. Please confirm if the consent has been obtained and fill in the relevant boxes/ forms.
- **Therapy Intensity Level:** Fill in this form every day during participant's ICU stay; please number those days on the top of the form and circle answer that applies (YES or NO). **If patient had an ICP monitoring device in situ** please fill in the other side of the form: ICP/MAP chart.

2.4 STAGE 3 - to be returned within 2 weeks of discharge from Neurosurgical Unit (NSU)

- **Neurosurgical interventions and GCS:** GSC evaluation at the time of NSU discharge. Please list if/when patient had any neurosurgical interventions after the index surgery. Please confirm if the **informed** consent has been obtained and fill in the relevant boxes/ forms.
- **EQ5D and EQ5D proxy:** Depending on the capability of the participant's it can be self-assessment or filled out by the next of kin/friend (proxy version in case of the latter).

STAGE 4 - to be returned as soon as completed, if applicable.

- **Cranioplasty and Shunt:** This form should be completed for those participants who will receive cranyoplasty and /or a shunt.