SCREENING LOGS FOR TBI TRIALS

ScrTrial-TBI = Screening log for TBI trials

1. CDE Variable	ScrTrial_TBI = screening log for TBI trials
2. CDE Definition	This data element aims to document if enrolment criteria for TBI trials were applied appropriate and monitors for the potential of selection bias.
3. Recommended instrument for assessment	Custom made data collection form
4. Description of measure	Multidimensional data collection form
5. Permissible values	We present two examples of possible formats. Both formats are anonymized without patient identification. Patients are listed by consecutive number. All patients with TBI admitted/seen at the study facility who could potentially meet the study enrolment criteria (e.g. seen in the ER; admitted to ICU) over a given time period (e.g. per week, per month). Both patients enrolled and those not enrolled are listed. The relevant inclusion criteria and exclusion criteria for not enrolling patients by number of the in- and exclusion criteria (e.g. inclusion criterion 2,3; exclusion criterion 5). With this format the potential for selection bias can be monitored, but whether in- and exclusion criteria were applied appropriately can not be monitored. In the second format basic data are documented, concerning the most relevant in- and exclusion criteria which permit monitoring whether enrolment criteria were applied appropriately or not. Care has been taken to capture these data in a broad categorical format with the aim of eliminating any potential patient identifiers. The example presented is aimed at a trial in more severe TBI patients, capturing information on most commonly used enrolment criteria: <u>Age</u> - ≤ 18 - 18-20 - 21-30 - 31-40 - 41-50 - 51-60 - 61-70 - ≥71 <u>Day of injury:</u> Day is recorded by number of the weekday with an additional annotation of the time of injury on a 24-hour clock. The actual date is not recorded. <u>Referral:</u> Direct from scene versus secondary referral. <u>Time of admission:</u> Day of the week documented by number and time of admission on 24 hour clock.

	Disposition on admission: Ward/intermediate/high care unit/ICU GCS and pupillary reactivity: CT scan: normal/abnormal Patients randomized: no/yes Reason for not enrolling: 1 = not meeting in/exclusion criteria. Please provide specification by documenting which in/exclusion criteria were violated. 2 = no informed consent 3 = study personnel not informed 4 = logistic (e.g. no study medication) 5 = study on hold This example format captures more detailed information, yet carefully avoids any patient identifiers. We note that the form presented is only intended as a possible example. The format used for a specific study will depend on the design of the study and the study specific enrolment criteria.
6. Classification: Basic / Intermediate / Advanced	Basic: example 1 Intermediate/advanced: example 2.
7. Procedure	Document by consecutive number all TBI patients seen over a given time period that meet the study criteria. For example, for a trial on severe TBI all patients admitted to the ICU and for a study on mild TBI all patients seen in the ER.
8. Comments / Special instructions: Care must be taken to avoid any risk of including patient identifiers in the documentation as for patients not enrolled informed consent will not be requested. The intent to collect screening data and the format used should be reported to the local IRB when submitting the study for IRB approval. From a study perspective it is preferred to transfer the screening log data to the trial coordinating center, but local regulations may require that these data are not transferred outside the study center.	
9. Rationale / justification: Screening logs form an important tool in randomized clinical trials and are essential to reporting trial results according to the consolidated standards of reporting trials (consort guidelines) and to assess the generalizibility of findings. Characteristics of patient populations within a multicenter trial may differ between centers and countries, for example due to aspects of local trauma organisation and consequently may introduce an element of selection bias outside the control of investigators. These observations will limit generalizibility of findings. Further, consistency of accuracy in screening log completion has been shown to be related to center performance in trials. The main reason for collecting screening log data in TBI trials however is to monitor for selection bias and to investigate whether enrolment criteria are being applied appropriately.	
10. References: *Slieker FJA, Kompanje EJO, Murray GD, et al.* Importance of screening logs in clinical trials for severe traumatic brain injury. *Neurosurgery.* 2008;62(6):1321-8. *Schulz KF, Altman DG, Moher D for the CONSORT group.* CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. BMJ 2010;340:697-702. *Kompanje EJ, Maas AI.* Is the Glasgow Coma Scale score protected health information? The effect of new United States regulations (HIPAA) on completion of screening logs in emergency research trials. *Intensive Care Med*. Feb 2006;32(2):313-4.	