DEMOGRAPHICS

DoB/Age = Date of birth / Age

1. CDE Variable	DoB/age = date of birth / age
2. CDE Definition	Age is defined as the time difference between the current date and the date of birth
3. Recommended instrument for assessment	Date of birth: calendar Age: years. In children ≤ 2 years: in months In infants ≤ 2 months: in weeks.
4. Description of measure	DoB: calendar Age: years/months/weeks; numerical.
5. Permissible values	Date: DD-MMM-YYYY 99-999-9999 if unknown Age: Years: 2-120 Months: 2-24 Weeks: 0-9
6. Classification: Basic / Intermediate / Advanced	Basic: age Intermediate/advanced: DoB
7. Procedure	Obtain information from patient/relatives on entry to study.

8. Comments / Special instructions:
Recording date of birth will give the most detailed information required for calculation of age and is recommended as first choice. However, in some studies recording date of birth may elicit discussions on a potential violation of privacy legislation and specifically HIPAA regulations. In these cases, the calculated age should be recorded.

9. Rationale / justification:
Recording age in traumatic brain injury is of great importance. Causes of injury may differ per age group and lead to different types of injury. Age is one of the strongest predictors of outcome in TBI, older patients fairing more poorly than younger patients. Although the association between age and outcome after TBI is commonly reported in the literature by threshold values, in fact the relation between age and outcome is a continuous relation which may be approximated by a linear function. We therefore do not recommend to use threshold values in reporting on the association between age and outcome after TBI.

10. References:
Management and prognosis of severe traumatic brain injury: Age. *J Neurotrauma.* 2000;17:573-581.

Mushkudiani NA, Engel DC, Steyerberg EW, et al. Prognostic value of demographic characteristics in traumatic brain injury: results from the IMPACT study. *J Neurotrauma.* Feb 2007;24(2):259-69.

Recommended time for assessment:
on admission to study

DEMOGRAPHICS

Sex

1. CDE Variable	Sex
2. CDE Definition	Sex describes the state of being male or female, with reference to the biological differences distinguishing organisms on the basis of their reproductive roles.
3. Recommended instrument for assessment	N/A
4. Description of measure	Binary
5. Permissible values	Male or female
6. Classification: Basic / Intermediate / Advanced	Identical
7. Procedure	Self report, interview or visual inspection
8. Comments / Special instructions: In some cases the binary categorisation of sex may be more complex, but these cases are extremely rare and do not necessitate a separate category in the context of TBI studies. When in doubt how to classify sex, we recommend to follow the primary/dominant biological expression.	
9. Rationale / justification: Traumatic brain injury occurs more frequently in young adult males, but the male/female ratio declines with increasing age, reaching an approximate 1 to 1 ratio at ages over 65. Reports on gender related differences in outcome after TBI have raised interest in hormonal influences and generated research into neuroprotective effects of estrogen and progesterone. Some studies indicate poorer outcome in females, but others do not show any association between gender and outcome following TBI.	
10. References: Prognostic value of demographic characteristics in traumatic brain injury: results from the IMPACT study. Mushkudiani et al J Neurotrauma 2007;24:329-37. Do women fare worse: a meta-analysis of gender differences in traumatic brain injury outcome. Farace et al, J Neurosurg 2000;93:539-545.	

Recommended time for assessment: on admission to study

DEMOGRAPHICS

Handed = Handedness

1. CDE Variable	Handed = handedness
2. CDE Definition	Handedness is defined as the preference for using one or the other hand for motor skills (such as writing).
3. Recommended instrument for assessment	N/A
4. Description of measure	Categorical
5. Permissible values	Righthanded/lefthanded/both (ambidexter)/unknown
6. Classification: Basic / Intermediate / Advanced	Advanced
7. Procedure	Obtain information from patient/relatives on entry to study
8. Comments / Special instructions:	
9. Rationale / justification: Handedness is an attribute of humans defined by their unequal distribution of fine motor skill between the left and right hand, and reflects dominance of the contralateral cerebral hemisphere.	
10. References:	

Recommended time for assessment: on admission to study

DEMOGRAPHICS

Race and Ethnicity

<table>
<tr><td>1. CDE Variable</td><td colspan="3">Race and ethnicity</td></tr>
<tr><td>2. CDE Definition</td><td colspan="3">Race and ethnicity are not easily defined. The terms are often used interchangeably. The terms do not constitute a genetic or scientific categorisation, but rather reflect a classification on basis of common history, nationality or geographic distribution. In these terms race nor ethnicity can therefore not be approximated to biological or genetic differences.</td></tr>
<tr><td>3. Recommended instrument for assessment</td><td colspan="3">Exploratory google and pubmed searches have not revealed international or global standards for classification of race. In the absence of global standards, we follow the recommendations as described by the Office of Management and Budget in the US.</td></tr>
<tr><td>4. Description of measure</td><td colspan="3">Categorical.
Race is commonly classified as: Asian, Black, White. In the US a further categorisation of Indian, Alaska Native and Native Hawaiian/Pacific Islander is required.</td></tr>
<tr><td rowspan="4">5. Permissible values</td><td colspan="3">Race (multiple entries permitted)</td></tr>
<tr><td>Basic</td><td>Intermediate</td><td>Advanced</td></tr>
<tr><td>Indian (American)
Alaska Native/ Inuit
Asian
Black
Native Hawaiian/ Pacific Islander
White
N/A
Unknown</td><td>Indian (American)
North American Indian
South/central American Indian
Alaska Native / Inuit
Alaska Native
Inuit
Asian
South Asian
Far Eastern Asian
Black
African American
African
Afro-Caribbean
Native Hawaiian/ Pacific Islander
Native Hawaiian
Pacific Islander
White
North American
South American
European
Middle Eastern
North African
Australian
N/A
Unknown</td><td>Additional to the intermediate classification, add country of birth.
N/A
Unknown</td></tr>
<tr><td colspan="3">Ethnicity</td></tr>
<tr><td colspan="3">Hispanic or Latino
Not Hispanic or Latino
Unknown</td></tr>
</table>

6. Classification: Basic / Intermediate / Advanced	See under 5.
7. Procedure	Not applicable

8. Comments / Special instructions:

In subjects of multiracial origin, multiple categories may be marked. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other however, these concerns are considered to the contrary a reason for recording race in order to guarantee equal access to care*; for those situations in which recording race may not be allowed by local authorities, we recommend to score the option: 'not allowed'. In the US, recording whether subject is of Hispanic or Latino origin is mandated by the OMB.

* Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of subjects enrolled on an annual basis using the ethnic and racial categories listed below.

- Ethnic Categories = Hispanic or Latino; Not Hispanic or Latino; Unknown (individuals not reporting ethnicity)
- Racial Categories = American Indian/Alaska Native; Asian; Native Hawaiian or Other Pacific Islander; Black or African American; White; More Than One Race; Unknown or Not Reported

9. Rationale / justification:

Recording race in TBI studies is considered important for the following reasons:
1. Comparison of populations can help researchers interpret changes in disease trends and assess whether the health of minority groups deviates from expectations. These differences in outcome in some racial groups may reflect disparities in pre-injury health and/or access to health care in the acute phase and during rehabilitation after TBI. These data can therefore inform policy changes aimed at insuring equal access to health care.
2. Despite the dominant impact of interindividual genetic variation, racial differences may explain some differences in predisposition to disease, pathophysiology, clinical outcome or therapy response. The latter may be due to racial variations in drug, pharmacokinetics or pharmacodynamics.

10. References:

OMB mandate: www.whitehouse.gov/omb/fedreg/ombdir15.html

Jorde LB and Wooding SP. Genetic variation, classification and "race". *Nature Genetics.* 2004;36(11):S28-S33

Bhopal R and Donaldson L. White, European, Western, Caucasian, or What? Inappropriate labelling in Research on Race, Ethnicity, and Health. *Amer J of Publ Health*. 1998;88:1303-1307.