BASELINE (TO BE RETURNED AS SOON AS COMPLETED)
PARTCIPANT INFORMATION

PATIENT DETAILS

ALLOCATED SUBJECT ID NUMBER | | - | | | | | | |

Name of the participant (full name)

Date of Birth D D / M M M / Y Y

Gender ☐ Female ☐ Male

Hospital number (optional)

NHS/SSN or any national ID number, if known

E.g. NHS number (UK) - 123456789
OR SSN (USA)-123456789

Participant current address (OR Paste patient sticker With address information)

Participant Contact Phone number 1
Mobile number 2

(Country–code) (Area- code) Number
1 . +44 (1223) (567890)
2.

Name and contact de-tails of the participant GP/local doctor

Name and contact details of the participant's next of kin (please include phone number)

Completed by D D / M M M / Y Y

BASELINE (TO BE RETURNED AS SOON AS COMPLETED)

BASELINE ASSESSMENT

PATIENT DETAILS

Pariticipant Initials: ☐☐☐ **Date of Birth:** DD/MMM/YY

Subject ID: ☐-☐☐☐☐☐☐ **Evaluation Date:** DD/MMM/YY

ACCIDENT DETAILS

Major extra cranial injury requiring hospital admission ☐ Yes ☐ No

Type of Injury ☐ Closed ☐ Penetrating ☐ Blast ☐ Crushed

Place of Injury ☐ Street/Highway/Railway ☐ Home/Domestic ☐ Sport/Recreation

☐ Public Location E.g. bar/hotel/night ☐ Work/School ☐ Military deployment

☐ Other, please specify ☐

INJURY MECHANISM (select as appropriate)

☐ Motor Vehicle occupant ☐ Cyclist ☐ Motor Bike ☐ Pedestrian

☐ Violence /Assault ☐ Gunshot ☐ Suicide attempt ☐ Act of mass violence

☐ Incidental fall ☐ Other non intentional injury ☐ Other penetrating

☐ Other, please specify → ☐

OTHER INJURY DETAILS

EXTRA CRANIAL INJURIES

Externa (Skin)	☐	No	☐	Minor/ Moderate	☐	Severe	☐	Critical	☐ Unsurvivable
Head and Neck	☐	No	☐	Minor/ Moderate	☐	Severe	☐	Critical	☐ Unsurvivable
Spinal (including Cervical , thoracic and lumbar)	☐	No	☐	Minor/ Moderate	☐	Severe	☐	Critical	☐ Unsurvivable
Face	☐	No	☐	Minor/ Moderate	☐	Severe	☐	Critical	☐ Unsurvivable
Thorax /chest	☐	No	☐	Minor/ Moderate	☐	Severe	☐	Critical	☐ Unsurvivable
Abdomen/pelvic	☐	No	☐	Minor/ Moderate	☐	Severe	☐	Critical	☐ Unsurvivable
Extremities	☐	No	☐	Minor/ Moderate	☐	Severe	☐	Critical	☐ Unsurvivable

BASELINE (TO BE RETURNED AS SOON AS COMPLETED)

BASELINE ASSESSMENT

PATIENT DETAILS

Participant Initials: ☐☐☐ **Date of Birth:** DD / MMM / YY

Subject ID: ☐ - ☐☐☐☐☐☐ **Evaluation Date:** DD / MMM / YY

PRE HOSPITAL ADMISSION EVENT

If any delay in transfer, please specify:

Hypoxia episodes prior to admission

☐ No ☐ Suspected ☐ Unknown

☐ Yes, Definite PO_2a < 8 Kpa(60mmHg)/ Sa2a < 90%

Hypotension prior to admission

☐ No ☐ Suspected ☐ Unknown

☐ Yes, Definite Sys BP < 90mmHg

Hypothermia prior to admission

☐ No ☐ Suspected ☐ Unknown

☐ Yes, Definite Temp <35°C

Cardiac Arrest ☐ No ☐ Yes

Seizures ☐ No ☐ Yes ☐ Unknown

Clinical Deterioration ☐ No ☐ Yes ☐ Unknown

Date & Time of deterioration (approx) DD / MMM / YY ☐☐ : ☐☐

VITAL SIGNS AT ADMISSION

Systolic Blood pressure ☐☐☐ mmHg

Diastolic Blood pressure ☐☐☐ mmHg

Heart Rate ☐☐☐ bpm

Core Temperature ☐☐☐.☐ **°C** or **°F** *(Circle appropriately As shown)*

Respiratory rate ☐☐ **Cycles per minute**

Completed by ☐ DD / MMM / YY

Return forms to the RESCUE_ASDH Data Manager by either email (**CRF@RESCUEASDH.ORG**) or fax (+44 1223 596471)

BASELINE (TO BE RETURNED AS SOON AS COMPLETED)

MEDICATION HISTORY (PRIOR TO ADMISSION)

PATIENT DETAILS

Participant Initials: ☐☐☐

Subject ID: ☐ - ☐☐☐☐☐☐

Date of Birth: D D / M M M / Y Y

Evaluation date D D / M M M / Y Y

COAGULANTS

Anticoagulants used ? ☐ Yes ☐ No ☐ Unknown

If Yes, please check box below :

- ☐ Coumarin Derivative (E.g. Acenocoumarol, Warfarin derived)
- ☐ Low-molecular weight heparin
- ☐ Inhibitor of factor Xa (e.g. Xarelto, Rifaxaban)
- ☐ Antithrombin protein therapeutics
- ☐ Direct thrombin inhibitor (e.g. Dabigatran, argratoban, melagatran)
- ☐ Heparin

Platelet aggregation inhibitors used ? ☐ Yes ☐ No ☐ Unknown

If Yes, please check box below :

- ☐ Aspirin
- ☐ Adenosine re-uptake inhibitor (e.g. Persantin, Dipyridamole)
- ☐ ADP receptor inhibitors (e.g. Clopidogrel (plavix), Ticlopidine (Ticlid), parasgre (effient)
- ☐ Glycoprotein IIb/IIIa inhibitors (e.g. Aggrastat)

Reason for Anticoagulants

Cardiac indications

- ☐ Atrial fibrillation
- ☐ Paroxysmal atrial fibrillation
- ☐ Atrial flutter
- ☐ Elective cardioversion
- ☐ Valvular heart disease
- ☐ Mechanical valve replacement
- ☐ Cardiomyopathy
- ☐ Coronary heart disease
- ☐ Left Ventricular aneurysm

Non Cardiac indications

- ☐ Stroke
- ☐ Prevention of thromboembolism asso. with orthopaedic surgery
- ☐ Deep vein thrombosis (DVT)
- ☐ Pulmonary embolism
- ☐ Antiphospholipid syndrome
- ☐ Peripheral arterial thrombosis
- ☐ Mural thrombus

☐ **Other** _____

Completed by ☐ D D / M M M / Y Y

BASELINE (TO BE RETURNED AS SOON AS COMPLETED)

MEDICATION HISTORY (PRIOR TO ADMISSION)

Patient Details

Participant Initials: ☐☐☐ **Date of Birth:** DD/MMM/YY

Subject ID: ☐-☐☐☐☐☐☐ **Evaluation date** DD/MMM/YY

STEROIDS

Steroids used ?

- ☐ Yes, Replacement therapy
  - ☐ Glucocorticoid (e.g. hydrocortisone)
  - ☐ Mineralocorticoid (e.g. Fludrocortisone)
- ☐ Yes, Anti-inflammatory therapy
  - ☐ Short-acting (e.g. Hydrocortisone)
  - ☐ Intermediate acting (e.g. Prednisolone)
  - ☐ Long Acting (e.g. Dexamethasone)
- ☐ Yes, Other _____
- ☐ No
- ☐ No, but uses Antimetabolite/Antifolate drugs (e.g .Methotrexate)
- ☐ Unknown

Reason for Steroids

- ☐ Endocrinological
- ☐ Dermatological disease
- ☐ Autoimmune disease
  - ☐ Systemic
  - ☐ Dermatological
  - ☐ Neurological
  - ☐ GI-tract
- ☐ Other,_____

FULL BLOODS AT ADMISSION

Were the Full Bloods done at admission ☐ Yes ☐ No **If Yes, please fill details below**

☐ **Data Management /Coordination will fill the grey boxes for all sites**

FULL BLOODS	NOT DONE	RESULTS	UNITS (e.g. mg/L)
HAEMOGLOBIN			
HAEMATOCRIT			
WBC			
LYMPHOCYTES			
EOSINOPHILES			
NEUTROPHILES			
MONOCYTES			
BASOPHILES			
PLATELETS			
CLINICAL CHEMISTRY			
GLUCOSE			
UREA			
CREATININE			
AMYLASE			
SODIUM			
POTASSIUM			
COAGULATION TESTS			
PROTHROMBIN TIME			Seconds
INR			

Completed by _____ DD/MMM/YY

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BASELINE (TO BE RETURNED AS SOON AS COMPLETED)

MEDICAL HISTORY & COMORBIDITIES

PATIENT DETAILS

Participant Initials: ☐☐☐ **Date of Birth:** DD/MMM/YY

Subject ID: ☐-☐☐☐☐☐☐ **Evaluation Date:** DD/MMM/YY

MEDICAL HISTORY

Any Medical History ? ☐ Yes ☐ No

Data Collected from ☐ Patient ☐ Next of kin/Family/Friends ☐ GP ☐ Medical Notes/Hospital records

☐ Other _____

If YES, Please fill this form, TICK Yes or unknown, if condition exists. IF NOT ticked, we will assume that the condition does not exist.

	YES	UNKNOWN		YES	UNKNOWN
CARDIOVASCULAR			**NEUROLOGIC**		
Congestive Heart Failure			Cerebrovascular Accident/Disease		
Myocardial Infarction			Dementia		
Arrhythmia			Pre-existing Hemiplegia		
Ischemic Heart Disease			Transient Ischemic Attacks		
Hypertension			Febrile Seizures (Children)		
Thromboembolic			Epilepsy : Partial		
Peripheral Vascular Disease			Epilepsy : Focal		
ENDOCRINE			Epilepsy : Other		
Thyroid Disorder			Headache (non migraine)		
Insulin Dependent Diabetes Mellitus (IDDM)			Migraine headaches		
Non-Insulin Dependent Diabetes Mellitus (NIDDM)			Previous TBI		
Diabetes - caused End organ damage			Number of exposures ☐		
EYE,EAR,NOSE & THROAT			Number of prior Concussions ☐		
Vision (Eye Disease)			**ONCOLOGIC**		
Hearing deficit			Leukemia (Chronic or Acute)		
GASTROINTESTINAL			Lymphoma		
Gastro esophageal Reflux Disease (GERD)			Metastatic Solid Tumors		
GI bleed			Tumours without metastases		
Inflammatory Bowel Disease			Other Cancer_____		
Peptic Ulcer Disease			**PSYCHIATRIC**		
HAEMATOLOGIC			Anxiety		
Anemia			Depression		
HIV Positive/AIDS			Sleep Disorder		
Sickle Cell Disease			Schizophrenia		
HEPATIC			Other Psychiatric disorder_____		
Mild Liver disease (without portal hypertension, includes Chronic hepatitis)			**RENAL**		
Moderate to Severe Liver damage (eg. Cirrhosis)			Insufficiency		
MUSCULOSKELETAL			Failure		
Arthritis			Chronic UTI's		
PULMONARY			> Stage 3, Chronic Kidney disease		
COPD			**DEVELOPMENTAL HISTORY**		
Asthma			Learning Disabilities		
Tuberculosis			Attention Deficit/hyperactivity disorder		
OTHER			Other developmental Disorder _____		
			SKIN		
			Connective Tissue Disease		

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BASELINE (TO BE RETURNED AS SOON AS COMPLETED)

SOCIO-DEMOGRAPHICS

PATIENT DETAILS

Participant Initials: ☐☐☐ **Date of Birth:** DD/MMM/YY

Subject ID: ☐-☐☐☐☐☐☐ **Evaluation Date:** DD/MMM/YY

DEMOGRAPHY

Age ☐☐ Years **Gender** ☐ Female ☐ Male

Weight ☐☐☐☐.☐ kg OR lb **Height** ☐☐☐.☐ cm OR ft

(Circle units for weight and height as appropriate)

Race

White
- ☐ North American
- ☐ South American
- ☐ European
- ☐ Middle Eastern
- ☐ North African
- ☐ Australian

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

Other
- ☐ N/A
- ☐ Unknown
- ☐ Would rather not say

MARITAL STATUS

Current Marital Status

(Select only one)

☐ Single ☐ Married ☐ Living with Partner

☐ Separated ☐ Divorced ☐ Widowed

☐ Would rather not say

Primary person/ people living with the patient

☐ Alone ☐ Spouse including common law partner

☐ Parents ☐ Siblings ☐ Child/Children

☐ Other (care home etc) ☐ Would rather not say

How many persons are living with the patient in the same household ☐☐

BASELINE (TO BE RETURNED AS SOON AS COMPLETED)

SOCIO-DEMOGRAPHICS

PATIENT DETAILS

Participant Initials: ☐☐☐

Date of Birth: DD / MMM / YY

Subject ID: ☐ - ☐☐☐☐☐☐

Evaluation Date: DD / MMM / YY

EDUCATION

Education

Highest diploma/degree attained : Please select only one.

- ☐ None
- ☐ Basic vocational training (no high school diploma or GCSE)
- ☐ Vocational training (post high school)
- ☐ Associate degree
- ☐ Other
- ☐ GCSE/GED/ A Levels
- ☐ High School Diploma/ Secondary School
- ☐ Bachelors degree
- ☐ Masters degree
- ☐ Professional degree (MD , JD, PhD etc.)

EMPLOYMENT

Employment Type

(Select only one)

- ☐ None
- ☐ Manual /Skilled labour
- ☐ Professional
- ☐ Office work
- ☐ Other, please specify

Current employment status *Please select only one.*

- ☐ Employed full time (minimum 35 hrs/week)
- ☐ Employed part time (minimum 20 hrs/week)
- ☐ Home working
- ☐ Not employed
- ☐ Not employed , but looking for work
- ☐ Other, please specify
- ☐ Home maker
- ☐ Student
- ☐ Military
- ☐ Retired
- ☐ Unable to work
- ☐ Prefer not to say

ENROLMENT IN OTHER STUDIES

Is the patient participating in any other Study/Trials ☐ YES ☐ NO

If yes, name of the Study/Trial

- ☐ CENTER-TBI
- ☐ CRASH-3
- ☐ EuroTherm
- ☐ Other, please specify

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BASELINE (TO BE RETURNED AS SOON AS COMPLETED)

SOCIO-DEMOGRAPHICS

PATIENT DETAILS

Participant Initials: ☐☐☐ **Date of Birth:** DD/MMM/YY

Subject ID: ☐-☐☐☐☐☐☐ **Evaluation Date:** DD/MMM/YY

BEHAVIOURAL HISTORY

Tobacco products (Cigarettes, cigar, pipe, Chewing tobacco etc) ☐ Yes, current user ☐ Yes, Past user ☐ No, Never used ☐ Unknown

Number of years used ☐☐ (Years) If past user, when did you stop ☐☐☐☐ (Year)

Alcoholic beverages (Beer, Wine, Spirits etc) ☐ Yes, Daily ☐ Yes, Weekly ☐ Yes, Occasional ☐ No, Never used ☐ Unknown

If yes, please specify average amounts per day/week ☐☐ (Units)

Sedatives or Sleeping pills ☐ Yes, Daily ☐ Yes, Occasional ☐ No, Never used ☐ Unknown

If Yes, please specify number of years used ☐☐ (Years)

Cannabis (marijuana, pot, grass, hash etc) ☐ Yes, Daily ☐ Yes, Occasional ☐ No, Never used ☐ Unknown

If Yes, please specify number of years used ☐☐ (Years)

Other recreational Drugs (name below) ☐ Yes, Daily ☐ Yes, Occasional ☐ No, Never used ☐ Unknown

1._____

2._____

If yes, please specify number of years used ☐☐ (Years)

HANDEDNESS

Please indicate participants preferences in the use of hands in the following activities or objects prior to acquiring their injury

Writing	☐ Always Right	☐ Usually Right	☐ Both Equally	☐ Always Left	☐ Usually Left
Throwing	☐ Always Right	☐ Usually Right	☐ Both Equally	☐ Always Left	☐ Usually Left
Toothbrush	☐ Always Right	☐ Usually Right	☐ Both Equally	☐ Always Left	☐ Usually Left
Spoon	☐ Always Right	☐ Usually Right	☐ Both Equally	☐ Always Left	☐ Usually Left

INSURANCE DETAILS

Insurance status of participant ☐ Insured (Social/Tax-based system) ☐ Unknown ☐ Insured (Private) ☐ Not Insured

Completed by _____ DD/MMM/YY

Return forms to the RESCUE_ASDH Data Manager by either email (**CRF@RESCUEASDH.ORG**) or fax (+44 1223 596471)

ADVERSE EVENTS

Participant Initials: ☐☐☐ **Date of Birth:** DD / MMM / YY

Subject ID: ☐-☐☐☐☐☐☐ **Evaluation Date:** DD / MMM / YY

EXPECTED DISEASE RELATED AND SYSTEMIC ADVERSE EVENTS

	Occurrence¥	Date of onset	Date of resolution	Outcome*	Related**	Severity***	Serious&
PULMONARY							
Pneumonia							
Pneumothorax							
Atelectasis							
Aspiration							
Pleural effusion/empyema							
Ventilator-related complications							
Adult respiratory distress syndrome							
Respiratory failure							
Need for prolonged mechanical or positive pressure airway ventilation							
CARDIAC							
Myocardial infraction							
Arrhythmia							
Heart failure							
Angina							
Pericardial effusion							
Pericarditis							
RENAL							
Urinary tract infection							
Renal failure maybe requiring full renal support							
Renal dysfunction							
Urinary retention							
Haematuria							
THROMBOTIC							
Deep vein thrombosis							
Pulmonary embolism							
Mesenteric thrombosis							
Other thromboses (e.g. limbs)							
HEPATOBILIARY							
Pancreatitis							
Liver failure							
Hepatitis							
BOWEL							
Infective diarrhea or colitis (e.g. Clostridium difficile)							
Diarrhoea of other causes							
Bowel ischaemia							
Ileus							
WOUND OTHER THAN CRANIOTOMY OR CRANIECTOMY							
Infection							
Dehiscence							
OTHER MISCELLANOUS GENERAL COMPLICATIONS							
Decubitus ulcer							
Other infections (e.g. MRSA)							
Anaesthetic related complication							
Anemia, coagulopathy							
Pyrexia							
Septicaemia							

OCCURANCE¥
- 1= OCCURED
- 2 = UNKNOWN
- If left empty, assumed that the event did not happen.

OUTCOME*
- 1= RESOLVED WITH NO RESIDUAL EFFECTS
- 2=RESOLVED WITH RESIDUAL EFFECTS
- 3=ONGOING
- 4=DEATH

RELATED**
- 1=UNRELATED
- 2=UNLIKELY
- 3=POSSIBLY
- 4=PROBABLY
- 5=ALMOST

SEVERITY***
- 1= MILD
- 2=MODERATE
- 3=SEVERE

SERIOUSNESS&
- 1= RESULTS IN DEATH
- 2=IS LIFE THREATENING
- 3=REQUIRES HOSPITALIZATION OR PROLONGATION OF EXISITING HOSPITALIZATION
- 4= RESULTS IN PERSISTANT OR SIGNIFICANT DISABILITY OR INCAPCITY
- 5= IS OTHERWISE CONSIDERED MEDICALLY SIGNIFICANT BY THE INVESTIGATOR

*Return forms to the RESCUE_ASDH Data Manager by either email (**CRF@RESCUEASDH.ORG**) or fax (+44 1223 596471)

BASELINE (TO BE RETURNED WITHIN 2 WEEKS OF DISCHARGE FROM NSU)

ADVERSE EVENTS

Participant Initials: ☐☐☐

Subject ID: ☐-☐☐☐☐☐☐

Date of Birth: DD / MMM / YY

Evaluation Date: DD / MMM / YY

PROCEDURE RELATED ADVERSE EVENTS

	Occurrence	Date of onset	Date of resolution	Outcome*	Related**	Severity***	Serious&
EVENTS if observed at any stage , please include them here.							
External herniation of the brain							
Expansions of mass lesions							
Development of mass lesions							
Inter-operative Vascular Injury							
Stroke							
Surgical Site Infections							
Wound complications other than infections							
Subdural hygromas							
Subdural empyema							
Intracerebral abscess							
Meningitis							
Epilepsy							
Hydrocephalus							
Other_____							
Other_____							
Other_____							

OUTCOME*
1= RESOLVED WITH NO RESID-UAL EFFECTS
2=RESOLVED WITH RESIDUAL EFFECTS
3=ONGOING
4=DEATH

RELATED**
1=UNRELATED
2=UNLIKELY
3=POSSIBLY
4=PROBABLY
5=ALMOST

SEVERITY***
1= MILD
2=MODERATE
3=SEVERE

SERIOUSNESS&
1= RESULTS IN DEATH
2=IS LIFE THREATENING
3=REQUIRES HOSPITALIZATION OR PROLONGA-TION OF EXISIT-ING HOSPITALIZA-TION
4= RESULTS IN PERSISTANT OR SIGNIFICANT DIS-ABILITY OR INCAP-CITY
5= IS OTHERWISE CONSIDERED MEDICALLY SIG-NIFICANT BY THE INVESTIGATOR

OTHER ADVERSE EVENTS

ADVERSE EVENT DESCRIPTION	Date of onset	Date of resolution	Outcome*	Related**	Severity***	Serious&
1.						
2.						
3.						
4.						

PI or delegated staff to verify the collected data accuracy.

Date signed by PI DD / MMM / YY

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