ATACH II				Was this data received? 0 No 0 Yes	

CT Scan– Central Reader Form (Version 5)

3	Tracking ID	___ ___ ___ ___ ___
18	Imaging time point: If 'Other', skip to question 15.	0 Baseline or 24 Hour 0 Other
4	Is cerebral hemorrhage present? If no or unknown, skip to question 6.	0 No 0 Yes 0 Unknown
5	Primary location of parenchymal hemorrhage: If hemorrhage extends to multiple sites, pick primary location.	0 R Thalamus 0 R Basal Ganglia 0 R Lobar 0 L Thalamus 0 L Basal Ganglia 0 L Lobar 0 Pons 0 Cerebellum
6	Subarachnoid hemorrhage:	0 No 0 Yes 0 Unknown
7	Ventricular hemorrhage:	0 No 0 Yes 0 Unknown
8	Hydrocephalus:	0 No 0 Yes 0 Unknown
9	Pineal shift:	__ __ __ mm
12	Volume of the intraparenchymal component (IPH volume)	__ __ __ mm^3
13	Volume of the intraventricular component (IVH volume)	__ __ __ mm^3
11	Edema volume in perihematoma region:	__ __ __ mm^3
14	Septum Pellucidum shift:	__ __ __ mm
15	Total brain volume (TBV)	__ __ __ mm^3
16	Right Hemisphere Volume (RHV)	__ __ __ mm^3
17	Left Hemisphere Volume (LHV)	__ __ __ mm^3

General Comments:

Name of person who collected this data (not for data entry):

ATACH II version 5 07Aug2014

ATACH II		__ __ __ Site ID	__ __ __ __ Subject ID		

Form 00: Eligibility Form (Version 8)

The purpose of this form is to capture eligibility violations.
If an eligibility violation is discovered after randomization, document the violation on this form.

41	Date of Informed Consent:		__ __- __ __ __ - __ __ (dd-mmm-yyyy)	
42	Time of Informed Consent:		__ __ : __ __ (24 hour clock, hh : mm)	
36	Which version of the protocol is approved by your IRB at the time of subject enrollment? Answer the questions on this form corresponding to the protocol version that is IRB approved at your site at the time of subject enrollment. The column to the left of each question specifies the protocol version to which the eligibility criteria apply.		0 Version 2.3 0 Version 3 0 Version 4 0 Version 5 and later	
2	All versions	Date of ICH symptom onset:	__ __- __ __ __ - __ __ (dd-mmm-yyyy)	
3	All versions	Time of ICH symptom onset: IV nicardipine must be able to be initiated within 3.5 hours (for protocol version 4 and earlier) and 4.5 hours (for protocol version 5 and later) of symptom onset for the patient to be eligible for the study. If time of symptom onset is unknown, enter last time known to be normal.	__ __ : __ __ (24 hour clock, hh : mm)	
		INCLUSION CRITERIA: Must be 'yes' to be included in the study		
7	All versions	Clinical signs consistent with the diagnosis of stroke, including impairment of language, motor function, cognition, and/or gaze, vision, or neglect.	0 No	0 Yes
37	Version 3 and later	INR value < 1.5	0 No	0 Yes
8	Version 3 and earlier	For subjects randomized prior to nicardipine infusion start: Admission SBP greater than 180 mmHg but less than 240 mmHg AND WITHOUT spontaneous SBP reduction to below 180 mmHg at the time of randomization. For subjects randomized after nicardipine infusion start: Admission SBP greater than 180 mmHg but less than 240 mmHg AND WITHOUT SBP reduction to below 140 mmHg at the time of randomization.	0 No	0 Yes
40	Version 4 and later	For subjects randomized prior to IV antihypertensive administration: SBP greater than 180 mmHg prior to IV antihypertensive treatment (this includes pre-hospital treatment) AND WITHOUT spontaneous SBP reduction to below 180 mmHg at the time of randomization. For subjects randomized after IV antihypertensive administration: SBP greater than 180 mmHg prior to IV antihypertensive treatment (this includes pre-hospital treatment) AND WITHOUT SBP reduction to below 140 mmHg at the time of randomization. * Note: Patients with SBP < 180 should be monitored for 3.5 hours (for protocol version 4 and earlier) and 4.5 hours (for protocol version 5 and later) from symptom onset as their SBP may rise to eligible levels before the eligibility window closes.	0 No	0 Yes
9	All versions	Informed consent by subject, legally authorized representative, or next of kin.	0 No	0 Yes

Name of person who collected this data (not for data entry):

ATACH II version 8 8aug2012

Form 00: Eligibility Form (Version 8)

10	All versions	Length of intraparenchymal hematoma on CT slice with the largest area of hemorrhage identified: width, number of slices, slice thickness	__ __ . __ cm	
11	All versions	Width of intraparenchymal hematoma on CT slice with the largest area of hemorrhage identified:	__ __ . __ cm	
12	All versions	Height of intraparenchymal hematoma on CT slice with the largest area of hemorrhage identified:	__ __ . __ cm	
13	All versions	Manual hematoma volume (based upon CT slice with the largest area of hemorrhage identified): (length x width x height)/2 The intraparenchymal hematoma must have a manual hematoma volume measurement of less than 60 cc to be included in the study. (Derived variable. Not for WebDCU data entry.)	__ __ . __ cm^3	
		EXCLUSION CRITERIA: Must be 'no' to be included in the study		
14	All versions	ICH is due to previously known neoplasm, AVM, or aneurysm	0 No	0 Yes
15	All versions	Intracerebral hematoma considered to be related to trauma.	0 No	0 Yes
16	All versions	ICH located in infratentorial regions such as pons or cerebellum.	0 No	0 Yes
17	All versions	IVH associated with intraparenchymal hemorrhage and blood completely fills one lateral ventricle or more than half of both ventricles.	0 No	0 Yes
18	All versions	Patient to receive immediate surgical hematoma evacuation.	0 No	0 Yes
19	All versions	Current pregnancy, parturition within previous 30 days, or active lactation.	0 No	0 Yes
38	Version 3 and later	Use of dabigatran within the last 48 hours.	0 No	0 Yes
20	Version 2.3	Use of warfarin within the last 5 days and INR >1.4	0 No	0 Yes
21	All versions	A platelet count less than 50,000/mm^3.	0 No	0 Yes
22	All versions	Known sensitivity to nicardipine.	0 No	0 Yes
23	All versions	Pre-morbid disability requiring assistance in ambulation or activities of daily living.	0 No	0 Yes
24	All versions	Subject's living will precludes aggressive ICU management	0 No	0 Yes
25	All versions	Subject is currently participating in another interventional clinical trial.	0 No	0 Yes

General Comments:

Name of person who collected this data (not for data entry):

Form 00: Eligibility Form (Version 8)

26	Date of first GCS assessed upon arrival at the ED:	__ __- __ __ __ - __ __ __ __ (dd-mmm-yyyy)
27	Time of first GCS assessed upon arrival at the ED:	__ __ : __ __ (24 hour clock, hh : mm)
28	Was the study participant under the influence of sedatives at the time of assessment?	0 No 0 Yes
29	Was the study participant under the influence of paralytics at the time of assessment?	0 No 0 Yes
30	Was the study participant intubated at the time of assessment? If yes, calculate predicted verbal score (see below)	0 No 0 Yes

Algorithm for calculating predicted verbal score for intubated subjects

Motor Score	Eye Opening Score				Predicted Verbal Score
	1	2	3	4	
1	1	1	1	2	
2	1	2	2	2	
3	2	2	3	3	
4	2	3	3	4	
5	3	3	4	4	
6	3	4	4	5	

General Comments:

Name of person who collected this data (not for data entry):

Form 00: Eligibility Form (Version 8)

31	Best eye opening response	0 (4) Spontaneous (eyes open, not necessarily aware) 0 (3) To speech (non-specific response, not necessarily to command) 0 (2) To pain (pain from sternum/limb/supra-orbital/nail bed pressure) 0 (1) None (even to painful stimuli)
32	*If question 30 = no,* Best verbal response for non-intubated subjects	0 (5) Oriented (converses and oriented) 0 (4) Confused (converses but confused, disoriented) 0 (3) Inappropriate (intelligible, no sustained sentences) 0 (2) Incomprehensible (moans/groans, no speech) 0 (1) None (no verbalization of any type)
33	*If question 30 = yes,* Predicted verbal response for intubated subjects (see table on previous page)	0 (5) Oriented (converses and oriented) 0 (4) Confused (converses but confused, disoriented) 0 (3) Inappropriate (intelligible, no sustained sentences) 0 (2) Incomprehensible (moans/groans, no speech) 0 (1) None (no verbalization of any type)
34	Best motor response	0 (6) Obeys Commands (follows simple commands) 0 (5) Localizes Pain (arm attempts to remove from painful stimuli) 0 (4) Withdrawal (arm withdraws to pain, shoulder abducts) 0 (3) Flexor response (withdrawal response or assumption of hemiplegic posture) 0 (2) Extension (shoulder adducted and shoulder and forearm internally rotated) 0 (1) None (to any pain; limbs remain flaccid)
35	Total GCS score (This must be 5 or greater or this subject is not eligible): Total GCS= Q31+Q32+Q34 For intubated subjects, total GCS= Q31+ Q33 + Q34	__ __

General Comments:

Name of person who collected this data (not for data entry):

ATACH II		___ ___ ___ Site ID	___ ___ ___ ___ Subject ID		

Form 01: Demographics (Version 1)

1	Sex:	○ Male ○ Female
2	Ethnicity:	○ Hispanic or Latino ○ Not Hispanic or Latino ○ Unknown / not reported
3	Race: Check all that apply.	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African-American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Other ☐ Unknown / not reported
4	If 'other', specify:	

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? 0 No 0 Yes	

Form 02: Baseline Form (Version 1)

1	Was this subject transferred to the stroke center from another hospital? If no, skip to question 5.	0 No 0 Yes
2	Name of initial/transferring hospital (community hospital):	Drop down box
3	Date of arrival at initial/transferring hospital (community hospital):	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)
4	Time of arrival at initial/transferring hospital (community hospital):	__ __ : __ __ (24-Hour clock, hh : mm)
5	Date of arrival at receiving hospital (stroke center):	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)
6	Time of arrival at receiving hospital (stroke center):	__ __ : __ __ (24-Hour clock, hh : mm)
7	Location of hemorrhage:	0 Basal Ganglia 0 Thalamus 0 Lobar
8	Side of hemorrhage:	0 Left 0 Right

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? 0 No 0 Yes	

Form 03: Medical History (Version 1)

	Central Nervous System Disorders	
1	Previous Stroke/TIA (Do not include the enrolling event.)	0 No 0 Yes 0 Unknown
2	Other Nervous System Disorders	0 No 0 Yes 0 Unknown
	Cardiovascular Disorders	
3	Congestive Heart Failure	0 No 0 Yes 0 Unknown
4	Atrial Fibrillation	0 No 0 Yes 0 Unknown
5	Myocardial Infarction in the previous 3 months	0 No 0 Yes 0 Unknown
6	Previous CABG / Ischemic Heart Disease / Angina Pectoris / PTCA	0 No 0 Yes 0 Unknown
7	Hypertension	0 No 0 Yes 0 Unknown
8	Peripheral Vascular Disease (eg, claudication, fem-pop bypass, AAA surgery)	0 No 0 Yes 0 Unknown
9	Hyperlipidemia	0 No 0 Yes 0 Unknown
10	Cardiac Dysrhythmias	0 No 0 Yes 0 Unknown
	Diabetes	
11	Diabetes mellitus Type 1	0 No 0 Yes 0 Unknown
12	Diabetes mellitus Type 2	0 No 0 Yes 0 Unknown
	Other History	
11	Cigarette smoking	0 Current 0 Former 0 Never 0 Unknown
12	Cocaine use	0 Current 0 Former 0 Never 0 Unknown

General Comments:

Name of person who collected this data (not for data entry):

ATACH II		___ ___ ___ Site ID	___ ___ ___ ___ Subject ID	Was this data collected? O No O Yes	

Form 04: Prior Medications (version 4)

Anti-Hypertensive Medications Prior to Hospitalization			
1	Prescribed anti-hypertensive medication in the 30 days prior to hospitalization (home medications)	O No	O Yes
2	Was the subject compliant with the prescribed anti-hypertensive regimen?	O No	O Yes

General Comments:

Name of person who collected this data (not for data entry):

ATACH II		___ ___ ___ Site ID	___ ___ ___ ___ Subject ID	Was this data collected? O No O Yes	

Form 04: Prior Medications (version 4)

ATACH II version 4 09oct2012

Anti-Diabetic Medications Prior to Hospitalization		
3	Prescribed anti-diabetic medication in the 30 days prior to hospitalization (home medications)	O No O Yes
6	Type of anti-diabetic regimen: Check all that apply.	☐ Injectable insulin ☐ Non-insulin injectable ☐ Oral agent
4	Was the subject compliant with the overall prescribed anti-diabetic regimen?	O No O Yes

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit :	___ ___ ___ Site ID	___ ___ ___ ___ Subject ID		

Form 05: Study Drug Infusion and 24 Hour Monitoring (Version 7)

1	Was nicardipine infused? If no, skip questions 2 and 22.	○ No ○ Yes
2	Was the study drug terminated prior to achieving target blood pressure? If no, skip to question 5.	○ No ○ Yes
3	If question 1 is no or question 2 is yes, Indicate reasons: Check all that apply.	☐ Target BP was spontaneously met (can be checked only if q1=no) ☐ Subject experienced an adverse event ☐ IV access was unable to be established / was lost ☐ Medication was not available ☐ Subject required emergent surgery ☐ Staff error ☐ Subject/LAR request ☐ DNR / Withdrawal of care ☐ Death ☐ Other
4	If 'other', specify:	
22	Start date/time of the nicardipine infusion: This is the date that nicardipine was first started, regardless of when randomization occurred.	__ __ - __ __ __ - __ __ __ __ / __ __ : __ __ (24 hour clock, hh:mm) dd-mmm-yyyy hh:mm
7	Blood pressure at the time of initial presentation to the first ED (SBP/DBP)	__ __ __ / __ __ __ mm Hg
23	Date/time of BP measurement at the time of initial presentation to the first ED:	__ __ - __ __ __ - __ __ __ __ / __ __ : __ __ (24 hour clock, hh:mm) dd-mmm-yyyy hh:mm
19	BP measurement that first met the eligibility requirement of SBP >180 mm [(prior to infusion of any antihypertensive medications) (SBP/DBP)]	__ __ __ / __ __ __ mm Hg
24	Date/time when BP first met the eligibility requirement of SBP >180 mm (prior to infusion of any antihypertensive medications):	__ __ - __ __ __ - __ __ __ __ / __ __ : __ __ (24 hour clock, hh:mm) dd-mmm-yyyy hh:mm
9	Blood pressure immediately prior to randomization (SBP/DBP):	__ __ __ / __ __ __ mm Hg
General Comments:		
Name of person who collected this data (not for data entry):		

Form 05: Study Drug Infusion and 24 Hour Monitoring (Version 7)

10 A. Time from randomization	Start date/time-stop date/time from local time of randomization Derived from Form 33 Question 7. Not for data entry.	I. Start (24 hour clock hh:mm)	J. End (24 hour clock ,hh:mm)	B. Highest SBP (mm Hg)	C. Lowest SBP (mm Hg)	D. Maximum heart rate (beats/min)	E. Minimum heart rate (beats/min)	F. Maximum GCS	G. Maximum Nicardipine infusion rate (mg/hr)	H. Total dose of secondary agent administered (mg)
0-15 min				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>15-30 min				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>30-45 min				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>45-60 min				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>1-2 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>2-3 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>3-4 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>4-5 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>5-6 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>6-7 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>7-8 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>8-9 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>9-10 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>10-11 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>11-12 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___

General Comments:

Name of person who collected this data (not for data entry):

Form 05: Study Drug Infusion and 24 Hour Monitoring (Version 7)

A. Time from randomization	Start date/time-stop date/time from local time of randomization Derived from Form 33 Question 7 Not for data entry in Columns I and J.	I. Start (24 hour clock hh:mm)	J. End (24 hour clock hh:mm)	B. Highest SBP (mm Hg)	C. Lowest SBP (mm Hg)	D. Maximum heart rate (beats/min)	E. Minimum heart rate (beats/min)	F. Maximum GCS	G. Maximum Nicardipine infusion rate (mg/hr)	H. Total dose of secondary agent administered (mg)
>12-13 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>13-14 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>14-15 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>15-16 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>16-17 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>17-18 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>18-19 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>19-20 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>20-21 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>21-22 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>22-23 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___
>23-24 hr				___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___	___ ___ ___	___ ___ ___

15	Name of secondary agent used, if applicable:	○ Labetalol ○ Urapidil ○ Diltiazem ○ Other
16	If 'other', specify:	
13	Total fluid intake during the first 24 hours post randomization? (oral and IV):	___ ___ ___ ___ ml
14	Total fluid output during the first 24 hours post randomization?	___ ___ ___ ___ ml

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? 0 No 0 Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

Form 06: Daily BP Monitoring (Version 1)

Maximum Blood pressures = 2 highest readings for the day separated by at least 1 hour.
Minimum Blood pressures = 2 lowest readings for the day separated by at least 1 hour.

1	Maximum SBP 1:	__ __ __ mm Hg
2	Maximum SBP 2:	__ __ __ mm Hg
3	Minimum SBP 1:	__ __ __ mm Hg
4	Minimum SBP 2:	__ __ __ mm Hg

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit: Discharge	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? O No O Yes	

Form 07: Concomitant Investigations and Procedures (Version 4)

	Mechanical Ventilation	
1	Did participant receive mechanical ventilation prior to discharge? (If no, skip to question 5)	O No O Yes
2	Number of days of intubation:	__ __ __ (days)
3	Date of final extubation:	__ __- __ __ __ - __ __ __ __ (dd-mmm-yyyy)
11	Did participant receive a tracheostomy prior to discharge? (If no, skip to question 5)	O No O Yes
4	Date of tracheostomy:	__ __- __ __ __ - __ __ __ __ (dd-mmm-yyyy)
	Intraventricular catheter	
5	Did participant receive an intraventricular catheter prior to discharge? (If no, skip to question 8)	O No O Yes
6	Date of insertion:	__ __- __ __ __ - __ __ __ __ (dd-mmm-yyyy)
7	Total days of ventricular drainage:	__ __ __ (days)
	Surgical evacuation / decompression	
8	Did participant receive a surgical evacuation/ decompression prior to discharge? (If no, skip to question 10)	O No O Yes
9	Date of evacuation:	__ __- __ __ __ - __ __ __ __ (dd-mmm-yyyy)

General Comments:

Name of person who collected this data (not for data entry):

ATACH II		__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? O No O Yes	

Form 07: Concomitant Investigations and Procedures (Version 4)

List any other concomitant investigations and procedures, excluding brain imaging (CT scans, MRIs, and CTAs) performed through day 7 or discharge, whichever comes first.

	B. Name of Investigation/Procedures	C. Start date (dd-mmm-yyyy)	D. Start time (24-hour clock, hh:mm)	E. Is this procedure related to an Adverse Event? If yes, complete AE CRF.
10-1		__ __ - __ __ __ - __ __ __ __	__ __ : __ __	O No O Yes
10-2		__ __ - __ __ __ - __ __ __ __	__ __ : __ __	O No O Yes
10-3		__ __ - __ __ __ - __ __ __ __	__ __ : __ __	O No O Yes
10-4		__ __ - __ __ __ - __ __ __ __	__ __ : __ __	O No O Yes
10-5		__ __ - __ __ __ - __ __ __ __	__ __ : __ __	O No O Yes
10-6		__ __ - __ __ __ - __ __ __ __	__ __ : __ __	O No O Yes
10-7		__ __ - __ __ __ - __ __ __ __	__ __ : __ __	O No O Yes
10-8		__ __ - __ __ __ - __ __ __ __	__ __ : __ __	O No O Yes
10-9		__ __ - __ __ __ - __ __ __ __	__ __ : __ __	O No O Yes
10-10		__ __ - __ __ __ - __ __ __ __	__ __ : __ __	O No O Yes

General Comments:

Name of person who collected this data (not for data entry):

ATACH II version 4 23Jul2013

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? ○No ○Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

Form 08: Glasgow Coma Scale (Version 2)

1	Time of GCS assessment:	__ __ : __ __ (24 hour clock, hh : mm)
2	Was the study participant under the influence of sedatives at the time of assessment?	○ No ○ Yes
3	Was the study participant under the influence of paralytics at the time of assessment?	○ No ○ Yes
4	Was the study participant intubated at the time of assessment? If yes, use predicted verbal score (see below). If yes, answer question 5 and then skip to question 7. If no, answer question 5 and 6, then skip to question 8.	○ No ○ Yes

Algorithm for calculating predicted verbal score for intubated subjects

Motor Score	Eye Opening Score				Predicted Verbal Score
	1	2	3	4	
1	1	1	1	2	
2	1	2	2	2	
3	2	2	3	3	
4	2	3	3	4	
5	3	3	4	4	
6	3	4	4	5	

General Comments:

Name of person who collected this data (not for data entry):

ATACH II version 2 29Feb2012

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? ○No ○Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

Form 08: Glasgow Coma Scale (Version 2)

5	Best eye opening response	○ (4) Spontaneous (eyes open, not necessarily aware) ○ (3) To speech (non-specific response, not necessarily to command) ○ (2) To pain (pain from sternum/limb/supra-orbital/nail bed pressure) ○ (1) None (even to painful stimuli)
6	*If question 4 = no,* Best verbal response for non-intubated subjects	○ (5) Oriented (converses and oriented) ○ (4) Confused (converses but confused, disoriented) ○ (3) Inappropriate (intelligible, no sustained sentences) ○ (2) Incomprehensible (moans/groans, no speech) ○ (1) None (no verbalization of any type)
7	*If question 4 = yes,* Predicted verbal response for intubated subjects (see table on previous page)	○ (5) Oriented (converses and oriented) ○ (4) Confused (converses but confused, disoriented) ○ (3) Inappropriate (intelligible, no sustained sentences) ○ (2) Incomprehensible (moans/groans, no speech) ○ (1) None (no verbalization of any type)
8	Best motor response	○ (6) Obeys Commands (follows simple commands) ○ (5) Localizes Pain (arm attempts to remove from painful stimuli) ○ (4) Withdrawal (arm withdraws to pain, shoulder abducts) ○ (3) Flexor response (withdrawal response or assumption of hemiplegic posture) ○ (2) Extension (shoulder adducted and shoulder and forearm internally rotated) ○ (1) None (to any pain; limbs remain flaccid)
9	Total GCS score: Total GCS= Q5 + Q6 + Q8 For intubated subjects, total GCS= Q5 + Q7 + Q8	__ __

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? 0 No 0 Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

Form 09: Modified Rankin Scale (Version 4)

The assessor must be blinded to study treatment.

3	Who provided the information for this assessment?	0 Study participant 0 Proxy 0 Both
1	Rankin Scale	0 (0) No symptoms at all 0 (1) No significant disability despite symptoms; able to carry out all usual duties and activities 0 (2) Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance 0 (3) Moderate disability requiring some help, but able to walk without assistance 0 (4) Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance 0 (5) Severe disability; bedridden, incontinent, and requiring constant nursing care and attention
4	First name of assessor:	__ __
5	Last name of assessor: The assessor must be a study team member who has completed mRS certification.	__ __

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? O No O Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

Form 10: NIH Stroke Scale (Version 3)

The baseline NIHSS is the first on taken upon ED arrival. Administer stroke scale items in the order listed. Record performance in each category after each subscale exam. Do not go back and change scores. Follow directions provided for each exam technique. Scores should reflect what the patient does, not what the clinician thinks the patient can do. The clinician should record answers while administering the exam and work quickly. Except where indicated, the patient should not be coached (i.e., repeated requests to patient to make a special effort).

24	Time of assessment:	__ __ : __ __ (24 hour clock, hh : mm)
1	(1a) Level of Consciousness The investigator must choose a response, even if a full evaluation is prevented by such obstacles as an endotracheal tube, language barrier, orotracheal trauma/bandages. A 3 is scored only if the patient makes no movement (other than reflexive posturing) in response to noxious stimulation. Coma score "3".	O 0 = Alert; keenly responsive O 1 = Not alert, but arousable by minor stimulation to obey, answer or respond O 2 = Not alert, requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped) O 3 = Responds only with reflex motor or autonomic effects or totally unresponsive, flaccid, areflexic (Complete form using coma scoring)
2	(1b) LOC Questions The patient is asked the month and his/her age. The answer must be correct - there is no partial credit for being close. Aphasic and stuporous patients who do not comprehend the questions will score 2. Patients unable to speak because of endotracheal intubation, orotracheal trauma, severe dysarthria from any cause, language barrier or any other problem not secondary to aphasia are given a 1. It is important that only the initial answer be graded and that the examiner not "help" the patient with verbal or non-verbal cues. Coma score "2".	O 0 = Answers both questions correctly O 1 = Answers one question correctly O 2 = Answers neither question correctly
3	(1c) LOC Commands The patient is asked to open and close the eyes and then to grip and release the non-paretic hand. Substitute another one step command if the hands cannot be used. Credit is given if an unequivocal attempt is made but not completed due to weakness. If the patient does not respond to command, the task should be demonstrated to them (pantomime) and score the result (i.e., follows none, one or two commands). Patients with trauma, amputation, or other physical impediments should be given suitable one-step commands. Only the first attempt is scored. Coma score "2".	O 0 = Performs both tasks correctly O 1 = Performs one task correctly O 2 = Performs neither task correctly
4	(2) Best Gaze Only horizontal eye movements will be tested. Voluntary or reflexive (oculocephalic) eye movements will be scored but caloric testing is not done. If the patient has a conjugate deviation of the eyes that can be overcome by voluntary or reflexive activity, the score will be 1. If a patient has an isolated peripheral nerve paresis (CN III, IV or VI) score a 1. Gaze is testable in all aphasic patients. Patients with ocular trauma, bandages, pre-existing blindness or other disorder of visual acuity or fields should be tested with reflexive movements and a choice made by the investigator. Establishing eye contact and then moving about the patient from side to side will occasionally clarify the presence of a partial gaze palsy. Coma score as examined.	O 0 = Normal O 1 = Partial gaze palsy. This score is given when gaze is abnormal in one or both eyes, but where forced deviation or total gaze paresis are not present O 2 = Forced deviation, or total gaze paresis not overcome by the oculocephalic maneuver

General Comments:

Name of person who collected this data (not for data entry):

Form 10: NIH Stroke Scale (Version 3)

5	(3) Visual Visual fields (upper and lower quadrants) are tested by confrontation, using finger counting or visual threat as appropriate. Patient must be encouraged, but if they look at the side of the moving fingers appropriately, this can be scored as normal. If there is unilateral blindness or enucleation, visual fields in the remaining eye are scored. Score 1 only if a clear-cut asymmetry, including quadrantanopia is found. If patient is blind from any cause score 3. Double simultaneous stimulation is performed at this point. If there is extinction patient receives a 1 and the results are used to answer question 22. Score as examined, using bilateral threat.	O 0 = No visual loss O 1 = Partial hemianopia O 2 = Complete hemianopia O 3 = Bilateral hemianopia (blind including cortical blindness)
6	(4) Facial Palsy Ask, or use pantomime to encourage the patient to show teeth or raise eyebrows and close eyes. Score symmetry of grimace in response to noxious stimuli in the poorly responsive or non-comprehending patient. If facial trauma/bandages, orotracheal tube, tape or other physical barrier obscures the face, these should be removed to the extent possible. Coma Score "3".	O 0 = Normal symmetrical movement O 1 = Minor paralysis (flattened nasolabial fold, asymmetry of smiling) O 2 = Partial paralysis (total or near total paralysis of lower face) O 3 = Complete paralysis of one or both sides (absence of facial movement in the upper and lower face)
7	(5a) Motor Arm Left The limb is placed in the appropriate position: extend the arms (palms down) 90 degrees (if sitting) or 45 degrees (if supine) and the leg 30 degrees (always tested supine). Drift is scored if the arm falls before 10 seconds or the leg before 5 seconds. The aphasic patient is encouraged using urgency in the voice and pantomime but not noxious stimulation. Each limb is tested in turn, beginning with the non-paretic arm. Only in cases of amputation or joint fusion at the shoulder or hip can the examiner indicate no score and an explanation must be provided. Coma Score "4".	O 0 = No drift, limb holds 90 (or 45) degrees for full 10 seconds O 1 = Drift, limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed O 2 = Some effort against gravity, limb cannot get to or maintain (if cued) 90 degrees O 3 = No effort against gravity, limb falls O 4 = No movement O Amputation, joint fusion
8	Explain if amputation or joint fusion (Motor Arm Left):	
9	(5b) Motor Arm Right The limb is placed in the appropriate position: extend the arms (palms down) 90 degrees (if sitting) or 45 degrees (if supine) and the leg 30 degrees (always tested supine). Drift is scored if the arm falls before 10 seconds or the leg before 5 seconds. The aphasic patient is encouraged using urgency in the voice and pantomime but not noxious stimulation. Each limb is tested in turn, beginning with the non-paretic arm. Only in cases of amputation or joint fusion at the shoulder or hip can the examiner indicate no score and an explanation must be provided. Coma score "4".	O 0 = No drift, limb holds 90 (or 45) degrees for full 10 seconds O 1 = Drift, limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed O 2 = Some effort against gravity, limb cannot get to or maintain (if cued) 90 degrees O 3 = No effort against gravity, limb falls O 4 = No movement O Amputation, joint fusion
10	Explain if amputation or joint fusion (Motor Arm Right):	

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? O No O Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

Form 10: NIH Stroke Scale (Version 3)

11	(6a) Motor Leg Left The limb is placed in the appropriate position: extend the arms (palms down) 90 degrees (if sitting) or 45 degrees (if supine) and the leg 30 degrees (always tested supine). Drift is scored if the arm falls before 10 seconds or the leg before 5 seconds. The aphasic patient is encouraged using urgency in the voice and pantomime but not noxious stimulation. Each limb is tested in turn, beginning with the non-paretic arm. Only in cases of amputation or joint fusion at the shoulder or hip can the examiner indicate no score and an explanation must be provided. Coma score "4".	O 0 = No drift, leg holds 30 degrees position for full 5 seconds O 1 = Drift, leg falls by the end of the 5 second period but does not hit bed O 2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity O 3 = No effort against gravity; leg falls to bed immediately O 4 = No movement O Amputation, joint fusion
12	Explain if amputation/ joint fusion (Motor Leg Left):	
13	(6b) Motor Leg Right The limb is placed in the appropriate position: extend the arms (palms down) 90 degrees (if sitting) or 45 degrees (if supine) and the leg 30 degrees (always tested supine). Drift is scored if the arm falls before 10 seconds or the leg before 5 seconds. The aphasic patient is encouraged using urgency in the voice and pantomime but not noxious stimulation. Each limb is tested in turn, beginning with the non-paretic arm. Only in cases of amputation or joint fusion at the shoulder or hip can the examiner indicate no score and an explanation must be provided. Coma score "4".	O 0 = No drift, leg holds 30 degrees position for full 5 seconds O 1 = Drift, leg falls by the end of the 5 second period but does not hit bed O 2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity O 3 = No effort against gravity; leg falls to bed immediately O 4 = No movement O Amputation, joint fusion
14	Explain if amputation/ joint fusion (Motor Leg Right):	
15	(7) Limb Ataxia This item is aimed at finding evidence of a unilateral cerebellar lesion. Test with eyes open. In case of visual defect, insure testing is done in intact visual field. The finger-nose-finger and heel-shin tests are performed on both sides, and ataxia is scored only if present out of proportion to weakness. Ataxia is absent in the patient who cannot understand or is paralyzed. Only in the case of amputation or joint fusion, the examiner should record the score as untestable (UN), and clearly write the explanation for this choice. In case of blindness, test by having the patient touch nose from extended arm position. Coma score "0".	O 0 = Absent O 1 = Present in one limb O 2 = Present in two limbs O Amputation or joint fusion
16	Explain if amputation or joint fusion (Limb Ataxia):	

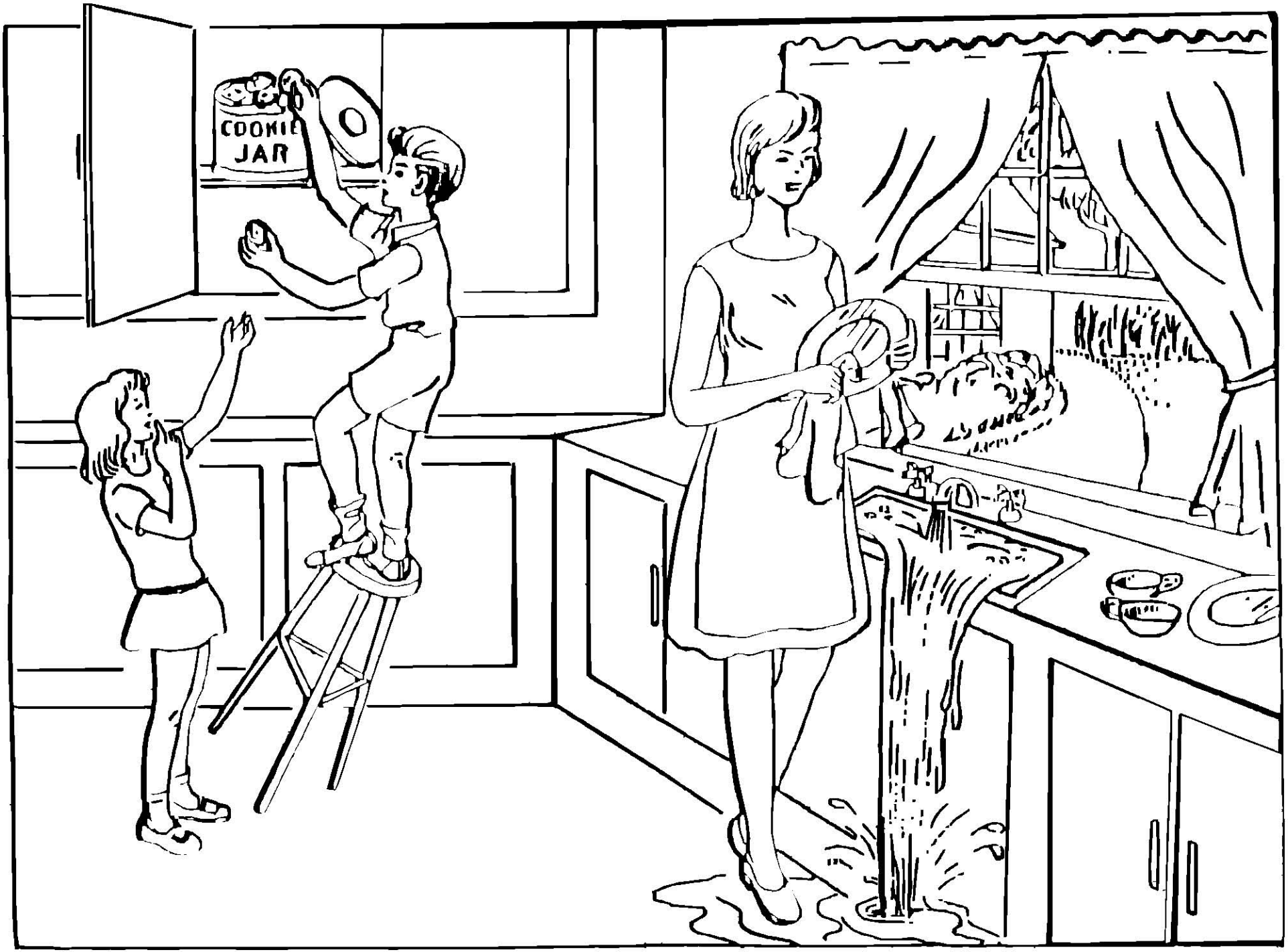
General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? O No O Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

Form 10: NIH Stroke Scale (Version 3)

17	(8) Sensory Sensation or grimace to pin prick when tested, or withdrawal from noxious stimulus in the obtunded or aphasic patient. Only sensory loss attributed to stroke is scored as abnormal and the examiner should test as many body areas [arms (not hands), legs, trunk, face] as needed to accurately check for hemisensory loss. A score of 2, "severe or total," should only be given when a severe or total loss of sensation can be clearly demonstrated. Stuporous and aphasic patients will therefore probably score 1 or 0. The patient with brain stem stroke who has bilateral loss of sensation is scored 2. If the patient does not respond and is quadriplegic score 2. Patients in coma (item 1a=3) are arbitrarily given a 2 on this item. Coma Score "2".	O 0 = Normal; no sensory loss O 1 = Mild to moderate sensory loss; patient feels pinprick is less sharp or is dull on the affected side; or there is a loss of superficial pain with pinprick but patient is aware he/she is being touched O 2 = Severe to total sensory loss; patient is not aware of being touched in the face, arm & leg
18	(9) Best Language A great deal of information about comprehension will be obtained during the preceding sections of the examination. The patient is asked to describe what is happening in the attached picture, to name the items on the attached naming sheet, and to read from the attached list of sentences. Comprehension is judged from responses here as well as to all of the commands in the preceding general neurological exam. If visual loss interferes with the tests, ask the patient to identify objects placed in the hand, repeat, and produce speech. The intubated patient should be asked to write. The patient in coma (question 1a=3) will arbitrarily score 3 on this item. The examiner must choose a score in the patient with stupor or limited cooperation but a score of 3 should be used only if the patient is mute and follows no one step commands. Coma Score "3".	O 0 = No aphasia, normal O 1 = Mild to moderate aphasia; some obvious loss of fluency or facility of comprehension without significant limitation on ideas expressed on form of expression O 2 = Severe aphasia; all communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener; listener carries burden of communication O 3 = Mute, global aphasia; no usable speech or auditory comprehension
19	(10) Dysarthria If patient is thought to be normal an adequate sample of speech must be obtained by asking patient to read or repeat words from the attached list. If the patient has severe aphasia, the clarity of articulation of spontaneous speech can be rated. Only if the patient is intubated or has other physical barrier to producing speech, may the item be not scored, and the examiner must clearly write an explanation. Do not tell the patient why he/she is being tested. Coma Score "2".	O 0 = Normal O 1 = Mild to moderate; patient slurs at least some words and at worst, can be understood with some difficulty O 2 = Severe; patient's speech is so slurred as to be unintelligible in the absence of or out of proportion to any dysphasia, or is mute/ anarthric O Intubated or other physical barrier
20	Explain if intubated or other physical barrier (Dysarthria):	
21	(11) Extinction and Inattention (Neglect) Sufficient information to identify neglect may be obtained during the prior testing. If the patient has a severe visual loss preventing visual double simultaneous stimulation, and the cutaneous stimuli are normal, the score is normal. If the patient has aphasia but does appear to attend to both sides, the score is normal. The presence of visual spatial neglect or anosagnosia may also be taken as evidence of abnormality. Since the abnormality is scored only if present, the item is never untestable. Coma Score "2".	O 0 = No abnormality O 1 = Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities O 2 = Profound hemi-inattention or hemi-inattention to more than one modality; does not recognize own hand or orients to only one side of space
22	NIH Stroke Scale score:	___ ___
25	First name of assessor:	
26	Last name of assessor: The assessor must be a study team member who has completed NIHSS certification.	
General Comments:		
Name of person who collected this data (not for data entry):		


JAR

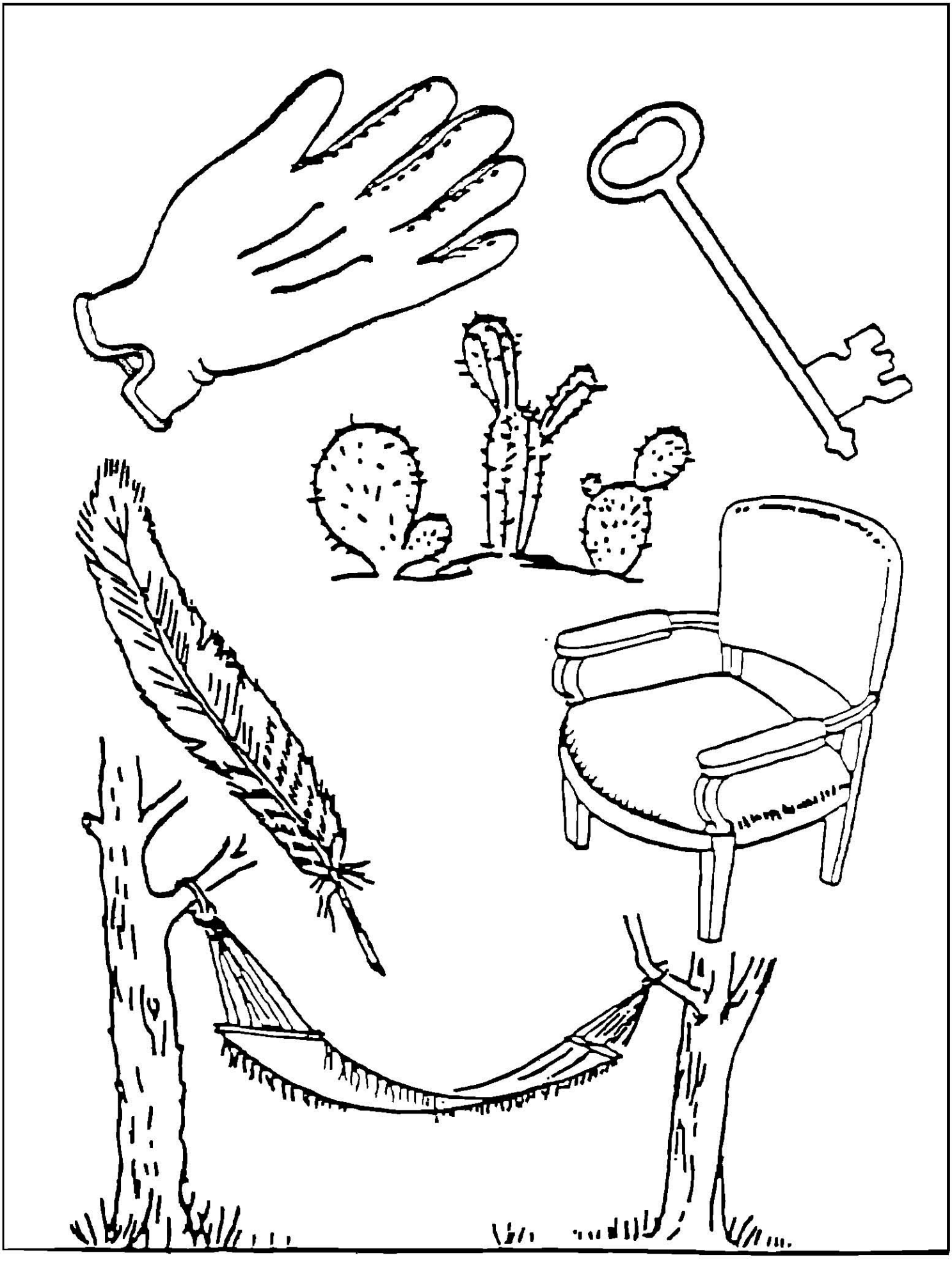
You know how.

Down to earth.

I got home from work.

Near the table in the dining room.

They heard him speak on the radio last night.



MAMA

TIP – TOP

FIFTY – FIFTY

THANKS

HUCKLEBERRY

BASEBALL PLAYER

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID		

Form 11: Hospital Discharge Summary (Version 1)

1	Date of discharge (or death, whichever comes first):	__ __- __ __ __ - __ __ __ __ (dd-mmm-yyyy)
2	Total number of days in ICU:	__ __ __ (days)
3	Subject was discharged to:	O Home (house/condo/apt, etc.) O Acute rehabilitation facility (moderate intensity of 1 or more therapy types, multidisciplinary services performed in an acute care hospital) O Sub-acute rehabilitation facility (continued therapy and reeducation that does not require continuous care and supervision) O Long-term acute care facility (patients with serious medical problems that require intense, special treatment for a long time (usually about 20-30 days) O Skilled nursing facility (patient's need of care or treatment that can only be done by licensed nurses) O Assisted living facility (needing assistance with ADLs but wishing to live independently) O Nursing home care (usually long-term) of patients who are not sick enough to need hospital care, but are not able to remain at home O Morgue/Funeral home (Death-Complete End of Study form) O Shelter (independent) O Other O Unknown

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit : Day 7 or Discharge whichever comes first	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? O No O Yes	

Form 12: Concomitant Medications (version 4)

Anti-Hypertensive Medications from Stroke Symptom Onset through End of Study Treatment (24 hours post randomization).

1	Were any anti-hypertensive medications <u>administered</u>, excluding randomized nicardipine treatment, from stroke symptom onset through the end of study treatment (24 hours post randomization). Include nicardipine administered prior to randomization. If 'no', skip to question 3.	O No O Yes

Complete a row for each prescription antihypertensive medication taken from stroke symptom onset through the end of study treatment (24 hours post randomization).

	A. When was the antihypertensive administered?	C. Name of antihypertensive	D. Route	E. Total amount of antihypertensive administered during this time period (mg)
2-1	O From stroke symptom onset to randomization O Post randomization to the end of study treatment (24 hours)		O Oral O IV	
2-2	O From stroke symptom onset to randomization O Post randomization to the end of study treatment (24 hours)		O Oral O IV	
2-3	O From stroke symptom onset to randomization O Post randomization to the end of study treatment (24 hours)		O Oral O IV	
2-4	O From stroke symptom onset to randomization O Post randomization to the end of study treatment (24 hours)		O Oral O IV	

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? O No O Yes	

Form 12: Concomitant Medications (version 4)

Ordered/Prescribed Oral Antihypertensive Regimen through Day 7 or Discharge, whichever comes first.			
3	Was the subject ordered/prescribed a scheduled oral antihypertensive regimen through Day 7 or Discharge, whichever comes first? If 'no', skip to question 5.	O No O Yes	
Complete a row for each oral antihypertensive medication ordered/prescribed through Day 7 or Discharge, whichever comes first.			
	B. Name of oral antihypertensive	C. Total ordered/prescribed daily dose of oral antihypertensive (mg)	D. Start date (dd-mmm-yyyy)
4-1			
4-2			
4-3			
4-4			

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? O No O Yes	

Form 12: Concomitant Medications (version 4)

Insulin Given to Control Blood Sugar from Randomization through 72 hours post randomization.				
5	Was insulin given from randomization (receipt of randomization assignment) through 72 hours post randomization to control the subject's blood sugar ? If 'no', form is complete.		O No O Yes	
Complete a row for each insulin given from randomization (receipt of randomization assignment) through 72 hours post randomization to control the subject's blood sugar.				
	A. When was the insulin given?	C. Name of insulin medication	D. Route	E. Total dose of insulin (units)
6-1	O 0-24 hours O >24-48 hr O >48-72 hr		O Injection O IV O Oral	___ ___ ___
6-2	O 0-24 hours O >24-48 hr O >48-72 hr		O Injection O IV O Oral	___ ___ ___
6-3	O 0-24 hours O >24-48 hr O >48-72 hr		O Injection O IV O Oral	___ ___ ___
6-1	O 0-24 hours O >24-48 hr O >48-72 hr		O Injection O IV O Oral	___ ___ ___
6-2	O 0-24 hours O >24-48 hr O >48-72 hr		O Injection O IV O Oral	___ ___ ___
6-3	O 0-24 hours O >24-48 hr O >48-72 hr		O Injection O IV O Oral	___ ___ ___
General Comments:				
Name of person who collected this data (not for data entry):				

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? ○No ○Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

Form 13: Follow Up Evaluation (Version 2)

1	With whom was the follow-up interview conducted?	○ Study participant alone ○ Relative/caregiver/friend ○ Study participant plus relative/caregiver/friend
2	Type of visit:	○ Office visit ○ Telephone interview
3	Has the subject experienced any Serious Adverse Events since last contact? (If yes, complete AE form.)	○ No ○ Yes
5	Residing at time of follow-up:	○ Home (house/condo/apt, etc.) ○ Acute rehabilitation facility (moderate intensity of 1 or more therapy types, multidisciplinary services performed in an acute care hospital) ○ Sub-acute rehabilitation facility (continued therapy and reeducation that does not require continuous care and supervision) ○ Long-term acute care facility (patients with serious medical problems that require intense, special treatment for a long time (usually about 20-30 days) ○ Skilled nursing facility (patient's need of care or treatment that can only be done by licensed nurses) ○ Assisted living facility (needing assistance with ADLs but wishing to live independently) ○ Nursing home care (usually long-term) of patients who are not sick enough to need hospital care, but are not able to remain at home ○ Shelter (independent) ○ Other
6	Is subject currently taking oral antihypertensive medication? Compliance is considered to be adherence to the dosing instructions sufficient to achieve the intended therapeutic benefit.	○ No ○ Yes, and subject is compliant with the medication ○ Yes, but subject is **non**-compliant with the medication
7	Is the subject currently taking statins? Compliance is considered to be adherence to the dosing instructions sufficient to achieve the intended therapeutic benefit.	○ No ○ Yes, and subject is compliant with the medication ○ Yes, but subject is **non**-compliant with the medication
8	If no, is there a documented LDL measurement of < 100 mg/dL?	○ No ○ Yes
General Comments:		
Name of person who collected this data (not for data entry):		

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? 0 No 0 Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

Form 14: Recurrent Stroke (Version 1)

1	Did the subject experience a recurrent stroke since last contact? If this is the Day 7/ Discharge visit, did the subject experience a recurrent stroke since randomization? If no, form is complete	0 No 0 Yes
2	What was the maximum NIHSS score recorded within 24 hours of the recurrent stroke?	0 < 4 0 4-9 0 ≥ 10
3	Was the recurrent stroke confirmed by CT/MRI?	0 No 0 Yes
4	Type of stroke:	0 Intracerebral hemorrhage 0 Ischemic stroke 0 Other
5	If 'other', specify:	
6	Location of stroke:	0 Same site as original hemorrhage 0 Different site from original hemorrhage
7	Date of recurrent stroke:	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy)

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? 0 No 0 Yes	

Form 15: Labs (Version 5)

Instructions: Please convert to the requested units, as needed.

If any values are abnormal and clinically significant, complete the AE form.

If any lab is not done, leave blank and dismiss warning.

	Hematology	
1	Blood draw date	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)
2	Blood draw time	__ __ : __ __ (24-Hour clock, hh : mm)
3	Total white blood cell count	___ ___ ___ x 10^9 / L
4	Hemoglobin	___ ___ . ___ gm/dL
6	Hematocrit	___ ___ %
7	Platelet count	___ ___ ___ x 10^3 / mm^3
8	Activated partial thromboplastin time Required at the baseline visit only.	___ ___ ___ sec
9	INR Required at the baseline visit only.	___ ___ ___ . ___
	Chemistry	
11	Serum glucose	___ ___ ___ mg/dL
	Electrolytes (MEq = mmol)	
12	Sodium	___ ___ ___ mmol/L
13	Potassium	___ . ___ mmol/L
14	Chloride	___ ___ mmol/L
15	Carbon Dioxide (CO_2) or Bicarbonate (HCO_3)	___ ___ ___ mmol/L
	Kidney Function Test	
16	Blood Urea Nitrogen (BUN)	___ ___ mg/dL
17	Creatinine	___ . ___ mg/dL

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? O No O Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

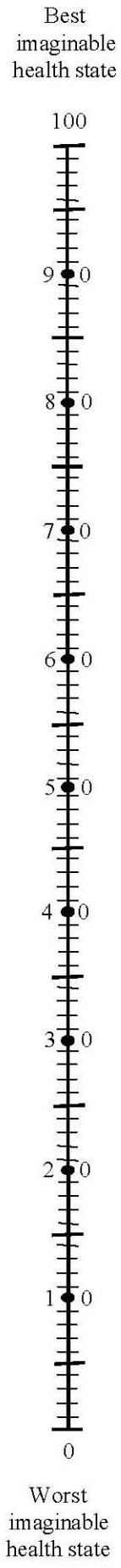
Form 16: EuroQol (Version 3)

1	With whom was this assessment conducted?	O Study participant alone O Relative/caregiver/friend O Study participant plus relative/caregiver/friend
Questions 2 through 6 and page 2 are to be completed by the patient or his/her proxy. Instructions for the study participant: By placing a check mark in each group below, please indicate which statement best describes your own health state today. Instructions for the proxy: By placing a check mark in each group below, please indicate which statement best describes how you feel the study participant perceives his/her health state today.		
2	Mobility	O I have no problems in walking O I have some problems in walking O I am confined to bed
3	Self-Care	O I have no problems with self-care O I have some problems washing or dressing myself O I am unable to wash or dress myself
4	Usual Activities (e.g. work, study, housework, family or leisure activities)	O I have no problems with performing my usual activities O I have some problems with performing my usual activities O I am unable to perform my usual activities
5	Pain / Discomfort	O I have no pain or discomfort O I have some moderate pain or discomfort O I have extreme pain or discomfort
6	Anxiety / Depression	O I am not anxious or depressed O I am moderately anxious or depressed O I am extremely anxious or depressed
Study participant/proxy, please turn to page 2 of this form and complete the assessment. The questions below are to be completed by examiner.		
7	Examiner Verified Score of visual analog scale	__ __ __ (0 -100)
General Comments:		
Name of person who collected this data (not for data entry):		

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? 0 No 0 Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

Form 17: Day 90 Blood Pressure (Version 1)

1	Maximum systolic blood pressure (SBP):	__ __ __ mm Hg
2	Maximum diastolic blood pressure (DBP):	__ __ __ mm Hg

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? 0 No 0 Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

Form 18: Blindedness Questionnaire for Blinded Assessor (Version 2)

1	As the blinded assessor, to which treatment do you think the participant was randomized?	0 Intensive treatment 0 Standard treatment
2	How sure are you of this answer?	0 Very sure 0 Somewhat sure 0 Not sure at all (it's a guess)

General Comments:

Name of person who collected this data (not for data entry):

ATACH II version 2 13July2011

ATACH II	Visit :	___ ___ ___ Site ID	__ __ __ __ Subject ID	Was this data collected? O No O Yes	

Form 20: Adverse Events (Version 3)

All AEs occurring from randomization through Day 7 or hospital discharge (whichever occurs first) must be reported
After Day 7 or discharge (whichever occurs first), only serious AEs must be reported.

1	Name of the adverse event: (100 character max)	
2	Did this event cause neurological deterioration? Neurological deterioration is defined as a decrease of ≥2 on GCS OR increase of ≥4 points on NIHSS (from baseline) that is not related to sedation/hypnotic use and is sustained for at least 8 hours.	O No O Yes
3	Severity: (Please refer to NCI Common Terminology Criteria for Adverse Events. See http://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_5x7.pdf) If the AE was not fatal, skip to question 7.	O Mild O Moderate O Severe O Life threatening / Disabling O Fatal
4	Date of death:	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)
5	Time of death:	___ ___ : ___ ___ (24 hour clock hh:mm)
7	Is the AE serious?	O No O Yes
8	Date of AE onset:	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)
9	Time of AE onset:	___ ___ : ___ ___ (24 hour clock hh:mm)
10	Outcome: If outcome is 'Continuing', skip to question 12.	O Resolved O Resolved w/sequelae O Continuing (Follow up is required) O Continuing at end of study (No follow up is required) O Continuing at time of death
11	Date of AE resolution:	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)

General Comments:

Name of person who collected this data (not for data entry):

Form 20: Adverse Events (Version 3)

12	Relationship to study treatment:	O Unrelated • The temporal relationship between treatment exposure and the adverse event is unreasonable or incompatible and/or adverse event is clearly due to extraneous causes (e.g., underlying disease, environment) O Unlikely (must have 2) • May have reasonable or only tenuous temporal relationship to intervention. • Could readily have been produced by the subject's clinical state, or environmental or other interventions. • Does not follow known pattern of response to intervention. • Does not reappear or worsen with reintroduction of intervention. O Possibly (must have 2) • Has a reasonable temporal relationship to intervention. • Could not readily have been produced by the subject's clinical state or environmental or other interventions. • Follows a known pattern of response to intervention. O Probably (must have 3) • Has a reasonable temporal relationship to intervention. • Could not readily have been produced by the subject's clinical state or have been due to environmental or other interventions. • Follows a known pattern of response to intervention. • Disappears or decreases with reduction in dose or cessation of intervention. O Definitely (must have all 4) • Has a reasonable temporal relationship to intervention. • Could not readily have been produced by the subject's clinical state or have been due to environmental or other interventions. • Follows a known pattern of response to intervention. • Disappears or decreases with reduction in dose or cessation of intervention and recurs with re-exposure.
14	Actions taken for this event: (Check all that apply)	☐ None ☐ Premature discontinuation of study drug ☐ Medication / medication change ☐ Bed-side procedure ☐ Surgery ☐ New hospitalization / prolonged hospitalization ☐ Other ☐ Unknown
14	If other, specify:	

General Comments:

Name of person who collected this data (not for data entry):

Form 20: Adverse Events (Version 3)

If the AE is not serious, this form is complete.
If the AE is serious, complete the information below.

15	Describe the event in detail: Include a description of what happened and a summary of all relevant clinical information (medical status prior to the event, signs and/or symptoms, differential diagnosis for the event in question, clinical course, treatment outcome, etc) DO NOT identify any study participant, physician, or institution by name.	
16	Relevant tests/laboratory data, including dates:	
17	Relevant history, including pre-existing medical conditions:	
18	Name of reviewing site investigator:	
19	Date of site investigator review:	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)

Please note that Event Packets must be uploaded for all Serious Adverse Events.
The Clinical Site will work with the Local Project Manager to prepare Event Packets, including copies of discharge summaries, neurology, cardiology or other consultation notes, head imaging reports, appropriate laboratory values, and a narrative summary, with all unique identifiers removed.

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit: End of Study	__ __ __ Site ID	__ __ __ __ Subject ID		

Form 21: End of Study (Version 5)

1	What was the primary reason for ending the study? If 'lost to follow up', answer questions 12 and 13, then skip to question 14.	O Study completed O Consent withdrawn (specify below) O Lost to follow-up O Death (Complete AE CRF) O Other (specify below)
2	If primary reason for ending study is 'consent withdrawn' or 'other, specify:	
12	If primary reason for ending study is 'lost to follow-up', were at least five attempts made to contact the subject over the course of two weeks and a certified letter sent?	O No O Yes
13	If no, specify details:	
3	Date of end of study: For subjects who complete the study, 'end of study' date is the date of the Day 90 visit. For subjects who withdraw consent, 'end of study' date is the date of the withdrawal of consent. For subjects who die, 'end of study' date is the date of death.	__ __- __ __ __ - __ __ __ __ (dd-mmm-yyyy)
	If the subject did not die prior to end of study, skip to question 10.	
4	Presumed primary cause of death:	O Transtentorial herniation and/or brainstem compression O Sepsis or infection O Cardiovascular compromise O Respiratory arrest O Other
5	If 'other' presumed primary cause of death, specify:	
6	Was there withdrawal of care?	O No O Yes
7	If yes, when was the withdrawal of care signed?	__ __- __ __ __ - __ __ __ __ (dd-mmm-yyyy)
8	Was there a DNR order?	O No O Yes
9	If yes, when was the DNR order signed?	__ __- __ __ __ - __ __ __ __ (dd-mmm-yyyy)
	The site PI must review and affirm the accuracy of the information reflected in all of the case report forms for this study participant. Please complete the section below after this review and affirmation is complete.	
14	First name of reviewing principal investigator:	
15	Last name of reviewing principal investigator:	
	Signature of reviewing principal investigator	
11	Date of PI review and affirmation:	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)
General Comments:		
Name of person who collected this data (not for data entry):		

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ATACH II		__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? O No O Yes	

Form 22: Imaging (Version 9)

Refer to the Clinical Site Imaging Procedures SoP for detailed instructions regarding preparation, labeling, and shipment of images.
Complete the section below for the protocol-required imaging (baseline and 24 hour).

1	Date of baseline image	__ __- __ __ __ - __ __ (dd-mmm-yyyy)
2	Time of baseline image	__ __ : __ __ (24-Hour clock, hh : mm)
3	Baseline Image Tracking ID number (Not for data entry. Generated by WebDCU™)	
4	Date of 24 hour image	__ __- __ __ __ - __ __ (dd-mmm-yyyy)
5	Time of 24 hour image	__ __ : __ __ (24-Hour clock, hh : mm)
6	24 Hour Image Tracking ID number (Not for data entry. Generated by WebDCU™)	

Complete this section for any additional imaging performed, as per standard care.

	A. Date of imaging (dd-mmm-yyyy)	B. Time of imaging (24 hour clock hh:mm)	C. Type of imaging	D. Check the box if the image will be shipped to UMN. For CT/MRI, this row is complete.	E. Was CTA adjusted to body mass?	F. Was saline push done for CTA?	G. If yes, saline push volume (mL)	H. CT Image Tracking ID number (Not for data entry. Generated by WebDCU™)
7-1		__ __ : __ __	O CT O CTA O MRI	☐	O No O Yes	O No O Yes	__ __ __ __	
7-2		__ __ : __ __	O CT O CTA O MRI	☐	O No O Yes	O No O Yes	__ __ __ __	
7-3		__ __ : __ __	O CT O CTA O MRI	☐	O No O Yes	O No O Yes	__ __ __ __	
7-4		__ __ : __ __	O CT O CTA O MRI	☐	O No O Yes	O No O Yes	__ __ __ __	
7-5		__ __ : __ __	O CT O CTA O MRI	☐	O No O Yes	O No O Yes	__ __ __ __	
8	Projected date subject's images will be shipped to UMN:		__ __- __ __ __ - __ __ (dd-mmm-yyyy)					

General Comments:

Name of person who collected this data (not for data entry):

ATACH II	Visit :	__ __ __ Site ID	__ __ __ __ Subject ID	Was this data collected? 0 No 0 Yes	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) Date of assessment

Form 23: Blindedness Questionnaire for Participant/Proxy (Version 2)

The assessor must be blinded to study treatment.

1	Who provided the information for this assessment?	0 Study participant 0 Proxy 0 Both
2	As the study participant/proxy, to which treatment do you think the study participant was randomized?	0 Intensive treatment 0 Standard treatment
3	How sure are you of this answer?	0 Very sure 0 Somewhat sure 0 Not sure at all (it's a guess)

General Comments:

Name of person who collected this data (not for data entry):

ATACH II		__ __ __ Site ID	__ __ __ __ Subject ID		

Form 33: Randomization (Version 3)

This form must be data entered and submitted into WebDCU™ to randomize a subject.

1. Confirm eligibility criteria. Then data enter this form, and click save. Address any rule violations, then click submit.
2. WebDCU™ will display the randomization treatment assigned to that subject."

1	Is this subject eligible for randomization? By submitting this form and performing the randomization, the enrolling investigator attests that all eligibility criteria were met.	○ No ○ Yes
2	Age Subject must be ≥18 years old or randomization will be blocked.	__ __ years
3	IVH:	○ Present ○ Absent
4	Baseline GCS Baseline GCS must be in the range of 5 – 15 or randomization will be blocked.	__ __ (5 — 15)
7	Date/time of randomization:	__ __ - __ __ __ - __ __ __ __ (dd-mmm-yyyy) / __ __ : __ __ (hh:mm) (24 hour clock, hh:mm)

General Comments:

Name of person who collected this data (not for data entry):

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