ICECAP Data Collection Schedule Version 1

Ready for programming	Form #	CRF	Baseline	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Hospital Discharge	Day 30 +/- 15 days	Day 90 +/- 15 days	End of Study
	N/A	Subject Enrollment	XM											
	F101	Eligibility	XM											
	F102	Randomization	XM											
	F296	Demographics	XM											
	F502	EMS Code Review	XM											
	F506	ED Code Review and Treatment	XM											
	F106	Medical History	X											
	F117	Vital Signs	X											
	F105	Laboratory Tests	X											
	F509	Brain Imaging	ORM	ORM	ORM	ORM	ORM	ORM	ORM	ORM	ORM			
	F175	Full Outline of Unresponsiveness Score (FOUR)		XRM	XRM	XRM	XRM	XRM	XRM	XRM				
	F501	Daily Temperature Log		XM	XM	XM	XM	XM	XM	XM				
	F505	Daily Seizure Monitoring		XM	XM	XM	XM	XM	XM	XM				
	F507	Daily Electrolye Log		XM	XM	XM	XM	XM	XM	XM				
	F510	Daily Selected Medications		XM	XM	XM	XM	XM	XM	XM				
	F508	Daily Glucose Transgressions		XM	XM	XM	XM	XM	XM	XM				
	F503	Daily Physiological Assessments		XM	XM	XM	XM	XM	XM	XM				
	F504	Neuro Prognostication/Brain Death			OR	OR	OR	XRM	OR	OR	OR			
	F123	Hospital Discharge									XM			
	F144	Modified Rankin Scale										X	X	
	F136	Controlled Oral Word Association Test											XM	
	F152	Stroop Color and Word Test											XM	
	F298	Rey Auditory Verbal Learning Test											XM	
	F154	Trail Making											XM	
	F511	NIH Tool Box Central Data Entry											X^	
	F104	Adverse Event		ORM	ORM	ORM	ORM	ORM	ORM	ORM	ORM	ORM	ORM	
	F127	Med Watch		OR[C1]	OR[C1]	OR[C1]	OR[C1]	OR[C1]	OR[C1]	OR[C1]	OR[C1]	OR[C1]	OR[C1]	
	F126	End of Study												XM

X = Required
O = Optional
R = Repeatable
M= Monitor verfication required
C1 = MedWatch is required per SM review
^ = Completed centrally

Form 101: Eligibility Version 1 (12-Mar-2020)

Q01	Protocol version	O Version 1	
Inclusion Criteria			
Q02	Age greater than or equal to 18 years	O No	O Yes
Q03	Coma after resuscitation from out of hospital cardiac arrest *Coma is operationally defined as when patient is intubated and is unable to follow commands.*	O No	O Yes
Q04	Cooled to less than 34 degrees Celsius within 240 minutes of cardiac arrest *Time of cardiac arrest is defined as time of the 911 call or EMS witnessed first arrest.*	O No	O Yes
Q05	Definitive temperature control device initiated	O No	O Yes
Q06	Enrollment within 6 hours of initiation of cooling *Enrollment is defined as the time of randomization. Initiation of cooling is defined as the time of initiation of a definitive temperature control device.*	O No	O Yes
Q07	Informed consent from LAR including intent to maintain life support for 96 hours	O No	O Yes
Exclusion Criteria			
Q08	Hemodynamic instability *Defined as systolic blood pressure less than 80 mm Hg refractory to aggressive management.*	O No	O Yes
Q09	Pre-existing neurological disability or condition that confounds outcome determination	O No	O Yes
Q10	Pre-existing terminal illness, unlikely to survive to outcome determination	O No	O Yes
Q11	Planned early withdrawal of life support	O No	O Yes
Q12	Presumed sepsis as etiology of arrest	O No	O Yes
Q13	Prisoner	O No	O Yes

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 102: Randomization Version 1 (12-Mar-2020)

Before this form can be submitted and a randomized treatment assigned to this subject, the Subject Enrollment form and Form 101 Eligibility must be submitted in WebDCU™ with all eligibility criteria met.

C. Randomization result

C01	Subject randomization successfully completed	0 No 0 Yes
C02	Randomized by	
C03	Randomized on *24-hour local time*	
C04	Treatment assignment	

A. Eligibility confirmation for randomization

A01	At the time of randomization, it is deemed that the subject meets all eligibility criteria	0 No 0 Yes
A02	No protocol violations recorded on Form 101 *Derived from F101 Eligibility.*	0 No 0 Yes

B. Baseline covariates adjusted by randomization algorithm

B01	Initial rhythm of the patient's first out of hospital cardiac arrest	0 Shockable 0 Non-shockable

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 104: Adverse Event Version 1 (12-Mar-2020)

This CRF is optional and should only be completed if the subject experiences a reportable Adverse Event. Reportable AEs include:

All non serious adverse events are collected through day 4.
All serious adverse events (SAEs) occurring until participation in study has ended.

Q01	Adverse Event Name *Brief description of event*	
LLT	AE MedDRA Term	
PT	AE preferred term *Derived from LLT.*	

Grade refers to the severity of the AE. The Common Terminology Criteria for Adverse Events (CTCAE) displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline:

- *Grade 1 - Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.*
- *Grade 2 - Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental Activities of Daily Living.*
- *Grade 3 - Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care Activities of Daily Living.*
- *Grade 4 - Life-threatening consequences; urgent intervention indicated.*
- *Grade 5 - Death related to AE.*

Q02	Grade	O Grade 1 O Grade 2 O Grade 3 O Grade 4 O Grade 5
Q03	Serious	O No O Yes
Q04	Relatedness to study intervention *Refer to the trial's relatedness algorithm in the MoP.*	O Unrelated O Unlikely O Reasonable possibility O Definitely
Q05	Date of onset	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy
Q06	Time of onset	___ ___ : ___ ___ 24 hour clock hh:mm
Q07	Outcome	O Resolved O Resolved with sequelae O Continuing (Follow up is required) O Continuing at end of study (No follow up is required) O Continuing at time of death O Unknown
Q08	*If Q07 is 'Resolved' or 'Resolved with sequelae'* — Date of resolution	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Q12		Type of event *See study definitions of each event type in the MoP.* *Pneumonia includes ventilator associated events.* *Other infections includes urinary tract infection and bacteremia.* *Select 'Other adverse event' if the study definition for the event type is not met.*	O Pneumonia O Other infection O Malignant cardiac arrhythmia O Seizures O Neurological worsening O Electrolyte abnormalities O Venous thrombotic disease O Coagulopathies O Other adverse event
Q20		Duration of cooling modified from that allocated because of this event	O No O Yes
Q21		Event attributable to a specific definitive cooling device	O No O Yes
Q22	*If Q21 is 'Yes'*	Type of definitive temperature control device to which the event is attributable	O Arctic Sun (Medivance—Bard—BD) O Thermogard (Zoll—Previously Alsius—Previously Coolgard) O Blanketrol (Cincinnati Sub-Zero— Gentherm—Zoll STx) O Medi-Therm (Gaymar—Stryker) O Altrix (Stryker) O Other
Q23	*If Q22 is 'Thermogard'*	Type of catheter placed	O Quattro O Icy O Cool Line O Solex 7
Q24	*If Q22 is 'Blanketrol'*	Model used	O Blanketrol II O Blanketrol III O Zoll STx
Q25	*If Q22 is 'Medi-Therm'*	Medi-Therm model used	O Medi-Therm II O Medi-Therm III
Q26	*If Q22 is 'Blanketrol, Medi-Therm, or Altrix'*	Type of cooling	O Surface Pads O EnsoETM esophageal device (Attune) O Both
Q27	*If Q22 is 'Other'*	Other device	

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Complete the remainder of the form for SAEs only.

Q15	Describe the event or problem *Provide a concise narrative describing the timing of the enrollment and event, the nature of the event, treatments provided, and resolution.*	
Q16	Relevant tests / laboratory data, including dates	
Q17	Other relevant history, including pre-existing medical conditions	
Q18	Last name of reporting site investigator	
Q19	Date of reporting site investigator signature	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 105: Laboratory Tests Version 1 (12-Mar-2020)

Collect laboratory tests results from blood collected closest to the time of initiation of a definitive temperature control device. This may be before or after initiation.

Q01	Hemoglobin	_____ g/dL
Q02	INR	_____
Q03	Sodium	_____ mEq/L
Q04	BUN	_____ mg/dL
Q05	Creatinine	_____ mg/dL
Q06	Glucose	_____ mg/dL
Q07	Arterial blood gas pH	_____
Q08	Arterial blood gas PaO2	_____
Q09	Arterial blood gas PaCO2	_____
Q10	Arterial blood gas lactate	_____

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 106: Medical History

If the medical record or other source of medical history does not state whether an element of the history is present or absent, then select unknown for that element. Components of the Charlson Comorbidity Index are marked with 'CCI'.

Neurological

Q01		Neurological history	O No	O Yes	O Unknown
Q02	*If Q01 is 'Yes'*	Dementia *Chronic cognitive deficit* *CCI*	O No	O Yes	O Unknown
Q03		Stroke or TIA *Either ischemic or hemorrhagic* *CCI*	O No	O Yes	O Unknown
Q04		Hemiplegia *CCI*	O No	O Yes	O Unknown

Cardiovascular

Q05		Cardiovascular history	O No	O Yes	O Unknown
Q06	*If Q05 is 'Yes'*	Percutaneous coronary intervention	O No	O Yes	O Unknown
Q07		Coronary artery bypass grafting	O No	O Yes	O Unknown
Q08		Non-ischemic cardiomyopathy	O No	O Yes	O Unknown
Q09		Implantable cardioverter defibrillator	O No	O Yes	O Unknown
Q10		Atrial fibrillation or flutter	O No	O Yes	O Unknown
Q11		Hypertension with pharmacologic treatment	O No	O Yes	O Unknown
Q12		Myocardial infarction *History of definite or probable MI (EKG or biomarker changes)* *CCI*	O No	O Yes	O Unknown
Q13		Congestive Heart Failure *CCI*	O No	O Yes	O Unknown
Q14		Peripheral vascular disease *CCI*	O No	O Yes	O Unknown

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 106: Medical History Version 1 (12-Mar-2020)

Oncologic History			
Q15		Oncologic History	O No O Yes O Unknown
Q16	*If Q15 is 'Yes'*	Solid tumor *CCI*	O Localized O Metastatic O None O Unknown
Q17		Leukemia *CCI*	O No O Yes O Unknown
Q18		Lymphoma *CCI*	O No O Yes O Unknown
Other comorbidities			
Q19		Connective tissue disease *CCI*	O No O Yes O Unknown
Q20		Peptic ulcer disease *Any history of treatment for ulcer disease or history of ulcer bleeding.*	O No O Yes O Unknown
Q21		Liver disease *Mild includes chronic hepatitis or cirrhosis without portal hypertension.* *Moderate includes cirrhosis and portal hypertension but no variceal bleeding history.* *Severe includes cirrhosis and portal hypertension with variceal bleeding history.* *CCI*	O Mild O Moderate to severe O None O Unknown
Q22		Diabetes mellitus *CCI*	O Uncomplicated O End-organ damage O None or diet-controlled O Unknown
Q23		Moderate to severe chronic kidney disease *Moderate includes creatinine >3 mg/dL (0.27 mmol/L).* *Severe includes dialysis, status post kidney transplant, uremia.* *CCI*	O Moderate O Severe O None O Unknown
Q24		Chronic Obstructive Pulmonary Disease *CCI*	O No O Yes O Unknown
Q25		Acquired Immunodeficiency Syndrome *CCI*	O No O Yes O Unknown

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Social

Active includes ongoing treatment or recent exacerbation in the previous 12 months.
Inactive includes previous history but no ongoing treatment or exacerbation in the previous 12 months.

Q26	Substance abuse disorder *Other than alcohol*	O No O Active O Inactive O Unknown
Q27	Alcohol abuse	O No O Active O Inactive O Unknown
Q28	Tobacco use *Refers to daily smoking*	O At the present time O Previous use O Never O Unknown

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 117: Vital Signs Version 1 (12-Mar-2020)

Collect the vital signs recorded closest to the time of initiation of a definitive temperature control device. This may be before or after initiation.

Qb	Date vital signs collected	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Qc	Time vital signs collected	___ ___ : ___ ___ 24 hour clock hh:mm
Q01	Systolic blood pressure	_____ mmHg
Q02	Diastolic blood pressure	_____ mmHg
Q03	Heart rate	_____ beats/min
Q04	Respiratory rate	_____ beats/min
Q05	Oxygen saturation	__ __ . __ %

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

ICECAP	Subject:

Form 123: Hospital Discharge Version 1 (12-Mar-2020)

Q01		Subject alive at hospital discharge	O No O Yes
Q02	*If Q01 is 'No'*	Time of death	___ ___ : ___ ___ 24 hour clock hh:mm
Q03	*If Q01 is 'Yes'*	Discharge location *Rehabilitation facility includes acute or subacute facilities.*	O Home O Rehabilitation facility O Assisted living facility O Skilled nursing facility O Long term acute care O Hospice
Q04		Date of hospital discharge	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q05		Date of first transfer out of intensive care unit	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q06		Percutaneous coronary intervention performed during this hospitalization	O No O Yes
Q07		Coronary artery bypass grafting performed during this hospitalization	O No O Yes
Q08		AICD or pacemaker implanted during this hospitalization	O No O Yes
Q09		Continuous or intermittent hemodialysis used during this hospitalization	O No O Yes
Q10		Most probable cause of the initial cardiac arrest *Cardiac includes acute ischemia, primary arrhythmia, and heart failure.* *Respiratory includes respiratory failure/arrest.* *Other medical includes pulmonary embolism.* *Other includes trauma.*	O Cardiac O Respiratory O Neurological O Other medical O Overdose/Poisoning O Other O Unknown

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Q11	Withdrawal of life sustaining treatments		O No O Yes
Q12	*If Q11 is 'Yes'*	Date of withdrawal of life sustaining treatments	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q13		Time of withdrawal of life sustaining treatments	___ ___ : ___ ___ 24 hour clock hh:mm
Q14		Primary rationale for withdrawal of life sustaining treatments *As determined by treatment team and LAR.*	O Poor neurologic prognosis O Poor cardiac prognosis O Other poor prognosis or other reason
Q15	*If Q14 is 'Other poor prognosis'*	Other rationale for withdrawal of life sustaining treatments	

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

ICECAP	Subject:

Form 126: End of Study Version 1 (12-Mar-2020)

Q02	Primary reason for subject's end of study	0 Study completed 0 Death 0 Lost to follow-up 0 Consent withdrawn 0 Other

Definition for Q03 Date of subject's end of study:
For death, enter date of death.
For lost to follow-up, enter date subject was last known to be alive.
For consent withdrawn, enter date consent withdrawn.
For other, enter date of last day in study.

Q03	*If Q02 is not 'Study completed'*	Date of subject's end of study	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy
Q04	*If Q02 is not 'Study completed' or 'Death'*	Detailed explanation of subject's end of study	

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.

Q10	First/given name of reviewing site PI	
Q11	Last/family name of reviewing site PI	
Q12	Date of site PI review and affirmation	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy
	Signature of site PI *Not for data entry*	

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 136: Controlled Oral Word Association Test Version 1 (12-Mar-2020)

Qa	Data Collected	0 No 0 Yes
Qb	Date of assessment	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy
Q01	Total score (FAS) *Score includes total number of correct answers (F, A, and S combined).*	__ __ __
Q02	Total score for animals *Score includes total number of animals correctly named.*	__ __

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 144: Modified Rankin Scale Version 1 (12-Mar-2020)

Qa		Data collected	O No O Yes
Qb		Date of assessment	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q01		Modified Rankin Scale	O (0) No symptoms at all O (1) No significant disability despite symptoms; able to carry out all usual duties and activities O (2) Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance O (3) Moderate disability; requiring some help, but able to walk without assistance O (4) Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance O (5) Severe disability; bedridden, incontinent, and requiring constant nursing care and attention
Q02	*If visit is 'Day 90'*	Assessor	O Blinded central assessor O Site personnel

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 152: Stroop Color and Word Test Version 1 (12-Mar-2020)

Qa	Data collected	0 No 0 Yes
Qb	Date of assessment	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy
Q01	Number correct on word reading trial	__ __ __
Q02	Number correct on color naming trial	__ __ __
Q03	Number correct on interference trial	__ __ __

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

ICECAP	Subject:

Form 154: Trail Making Version 1 (12-Mar-2020)

Qa		Data collected	O No O Yes
Qb		Date of assessment	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Part A			
Q01		Part A completed within 100 seconds	O No O Yes
Q02	*If Q01 is 'Yes'*	Time in seconds Part A	___ ___ ___
Part B			
Q03		Part B completed within 300 seconds	O No O Yes
Q04	*If Q03 is 'Yes'*	Time in seconds Part B	___ ___ ___
Q05		Hand used	O Dominant O Non-dominant
General comments			

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

http://www.rgpeo.com/media/53150/trails%20a%20and%20b.pdf

Form 175: Full Outline of Unresponsiveness Score (FOUR) Version 1 (12-Mar-2020)

The FOUR score is a standardized neurological exam optimized for use in individuals with severely impaired consciousness. When and if possible, participants should be scored during periods of reduced sedation. Generally, record only the best score of the day, but if necessary to describe substantial changes during the course of the day, the form may be repeated.

Qa	Data collected	0 No 0 Yes
Qb	Date of assessment	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy
Qc	Time of assessment	___ ___ : ___ ___ 24 hour clock hh:mm
Q01	Eye Response	0 0 = eyelids remain closed with pain 0 1 = eyelids closed, but open to pain 0 2 = eyelids closed, but open to loud voice 0 3 = eyelids open but not tracking 0 4 = eyelids open or opened, tracking, or blinking to command
Q02	Motor Response	0 0 = no response to pain or generalized myoclonus status 0 1 = extension response to pain 0 2 = flexion response to pain 0 3 = localizing to pain 0 4 = thumbs-up, fist, or peace sign
Q03	Brainstem reflexes	0 0 = absent pupil, corneal and cough reflex 0 1 = pupil and corneal reflexes absent 0 2 = pupil or corneal reflexes absent 0 3 = one pupil wide and fixed 0 4 = pupil and corneal reflexes present
Q04	Respiration	0 0 = breathes at ventilator rate or apnea 0 1 = breathes above ventilator rate 0 2 = not intubated, irregular breathing 0 3 = not intubated, Cheyne-Stokes breathing pattern 0 4 = not intubated, regular breathing pattern

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 296: Demographics

Version 1 (12-Mar-2020)

Q01	Sex	O Male O Female
Q02	Ethnicity	O Hispanic or Latino O Not Hispanic or Latino O Unknown
Q03	Race *Check all that apply.*	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown
Q04	Age	__ __ years

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

ICECAP	Subject:

Form 298: Rey Auditory Verbal Learning Test Version 1 (12-Mar-2020)

Qa	Data collected	O No O Yes
Qb	Date of assessment	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q01	Trial 1 *Total number of correct words recalled.*	___ ___
Q02	Trial 2 *Total number of correct words recalled.*	___ ___
Q03	Trial 3 *Total number of correct words recalled.*	___ ___
Q04	Trial 4 *Total number of correct words recalled.*	___ ___
Q05	Trial 5 *Total number of correct words recalled.*	___ ___
Q06	Interference trial *Total number of correct words recalled.*	___ ___
Q07	Immediate delay *Total number of correct words recalled.*	___ ___
Q08	Delayed recall *Total number of correct words recalled.*	___ ___
Q09	Recognition trial—True positives *Total number of words that subject said were on List A that were on List A.*	___ ___
Q10	Recognition trial—False positives *Total number of words that subject said were on List A that were not on List A.*	___ ___
Q11	Assessor first name	
Q12	Assessor last name	

General comments

Assessor signature and date *Not for data entry*	_____ *Signature* _____ *Date*

Form 501: Daily Temperature Log

Core temperature should be monitored every hour continuously throughout cooling and rewarming.

Qa	Data collected	O No O Yes
Qb	Date	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q01	Clinically significant temperature excursions	O No O Yes
Q02	*If Q01 is 'Yes'* Details of temperature excursion	

	QA. Hour	QB. Esophageal °C	QC. Bladder °C	QD. Intravascular °C	QE. Rectal °C
Q03-1	00				
Q03-2	01				
Q03-3	02				
Q03-4	03				
Q03-5	04				
Q03-6	05				
Q03-7	06				
Q03-8	07				
Q03-9	08				
Q03-10	09				
Q03-11	10				
Q03-12	11				
Q03-13	12				
Q03-14	13				
Q03-15	14				
Q03-16	15				
Q03-17	16				
Q03-18	17				
Q03-19	18				
Q03-20	19				
Q03-21	20				
Q03-22	21				
Q03-23	22				
Q03-24	23				

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 502: EMS Code Review Version 1 (12-Mar-2020)

Qa		Data collected	O No O Yes
Q01	Bystander-identified or EMS-witnessed cardiac arrest		O Bystander-identified O EMS-witnessed
Q02	*If Q01 is 'Bystander-identified'*	Date of 911 call	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q03		Time of 911 call	___ ___ : ___ ___ 24 hour clock hh:mm
Q04		Date of dispatch	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q05		Time of dispatch	___ ___ : ___ ___ 24 hour clock hh:mm
Q06		Date of EMS arrival on scene	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q07		Time of EMS arrival on scene	___ ___ : ___ ___ 24 hour clock hh:mm
Q08	*If Q01 is 'EMS-witnessed'*	Date of reported cardiac arrest	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q09		Time of reported cardiac arrest	___ ___ : ___ ___ 24 hour clock hh:mm
Q10		Scene of cardiac arrest	O Home/Residence O Public/Commercial building O Street/Highway O Nursing home O Healthcare facility O Place of recreation O Industrial place O Transport center O Work O Other
Q11		Chest compressions performed	O No O Yes
Q12	*If Q11 is 'Yes'*	Initiator of CPR	O EMS O Bystander
Q13		AED applied	O No O Yes
Q14	*If Q13 is 'Yes'*	Applier of AED	O EMS O Bystander
Q15		Shock delivered by AED	O No O Yes

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Q16		First monitored rhythm at arrival of EMS personnel	O Ventricular fibrillation O Ventricular tachycardia O Asystole O Pulseless electrical activity O Unknown O Other
Q17	*If Q11 is 'Yes'*	Use of active mechanical CPR device	O No O Yes, LUCAS O Yes, Autopulse
Q18		Number of shocks delivered	___ ___
Q19	*If Q18 is greater than 0*	Date first shock delivered	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q20		Time first shock delivered	___ ___ : ___ ___ 24 hour clock hh:mm
Q21		Advanced airway successfully placed in the field	O No O Yes
Q22	*If Q21 is 'Yes'*	Most definitive airway that was successfully performed *Supraglottic includes combitube, king airway, LMA etc.* *Endotracheal intubation includes oral/nasal.*	O Supraglottic O Endotracheal intubation
Q23		Cumulative dose of epinephrine	___ ___ mg
Q24	*If Q23 is greater than 0*	Route of epinephrine	O Intravenous O Intraosseous
Q25	*If Q24 is 'Intraosseous'*	Location of intraosseous	O Upper extremity O Lower extremity O Other
Q26		Sustained ROSC achieved *Restoration of pulse or blood pressure for 20 consecutive minutes with no chest compressions.*	O No O Yes
Q27	*If Q26 is 'Yes'*	ROSC sustained at the end of EMS care	O Pulseless at end of EMS care O Pulse at end of EMS care
Q28		Date of EMS arrival at hospital	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q29		Time of EMS arrival at hospital	___ ___ : ___ ___ 24 hour clock hh:mm

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

ICECAP	Subject: ___ ___ ___ ___	

Form 503: Daily Physiological Assessments Version 1 (12-Mar-2020)

For each hour, indicate if, during that hour, there were any reliable measurements of oxygen saturation or mean arterial pressure (MAP) outside of the ranges described in the MoP. For each hour, indicate the maximum number of different vasopressor infusions administered in that hour. For each hour, indicate the highest bedside shivering assessment scale score documented in that hour.

Qa				Data collected	0 No	0 Yes	
Qb				Date	___ ___ - ___ ___ ___ - ___ ___ ___ ___ (dd-mmm-yyyy)		
	QA. Hour	B. O2 sat status N=Normal A=Abnormal U= Unknown	*If QB is 'A'* C. O2 Sat (%)	D. MAP status N=Normal A=Abnormal U= Unknown	*If QD is 'A'* E. MAP	F. Number of continuous vasopressor infusions *0-4*	G. Bedside Shivering Assessment Scale *0-3*
Q01-1	00	__	__ __ . __	__	__ __	__	__
Q01-2	01	__	__ __ . __	__	__ __	__	__
Q01-3	02	__	__ __ . __	__	__ __	__	__
Q01-4	03	__	__ __ . __	__	__ __	__	__
Q01-5	04	__	__ __ . __	__	__ __	__	__
Q01-6	05	__	__ __ . __	__	__ __	__	__
Q01-7	06	__	__ __ . __	__	__ __	__	__
Q01-8	07	__	__ __ . __	__	__ __	__	__
Q01-9	08	__	__ __ . __	__	__ __	__	__
Q01-10	09	__	__ __ . __	__	__ __	__	__
Q01-11	10	__	__ __ . __	__	__ __	__	__
Q01-12	11	__	__ __ . __	__	__ __	__	__
Q01-13	12	__	__ __ . __	__	__ __	__	__
Q01-14	13	__	__ __ . __	__	__ __	__	__
Q01-15	14	__	__ __ . __	__	__ __	__	__
Q01-16	15	__	__ __ . __	__	__ __	__	__
Q01-17	16	__	__ __ . __	__	__ __	__	__
Q01-18	17	__	__ __ . __	__	__ __	__	__
Q01-19	18	__	__ __ . __	__	__ __	__	__
Q01-20	19	__	__ __ . __	__	__ __	__	__
Q01-21	20	__	__ __ . __	__	__ __	__	__
Q01-22	21	__	__ __ . __	__	__ __	__	__
Q01-23	22	__	__ __ . __	__	__ __	__	__
Q01-24	23	__	__ __ . __	__	__ __	__	__

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Source: https://emcrit.org/wp-content/pdf/BSAS%20Nursing.pdf

Form 504: Neuro Prognostication/Brain Death

This form is required and must be used to report neuroprognostication performed or omitted on day 5. This form is optional on other days when it should be used as needed to document all brain death exams prior to or after day 5, or if needed to document other neuroprognostications performed on subsequent days.

Q01	Neuro prognostication or brain death exam performed		O Yes O No, following commands O No, omitted
Q02	*If Q01 is 'No, omitted'*	Reason neuro prognostication omitted	
Q03	*If Q01 is 'Yes'*	Date of neuro prognostication or brain death exam	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy
Q04		Time of neuro prognostication or brain death exam	___ ___ : ___ ___ 24 hour clock hh:mm
Q05		Sufficient time since last dose of paralytics/ sedation	O No O Yes
Q06		Sufficient time since rewarming	O No O Yes
Q07		Quantitative pupilometer used	O No O Yes O Not documented
Q08		Pupillary light reflexes	O Absent bilaterally O Absent unilaterally O Present bilaterally O Not assessed
Q09		Eye response	O 0 = eyelids remain closed with pain O 1 = eyelids closed, but open to pain O 2 = eyelids closed, but open to loud voice O 3 = eyelids open but not tracking O 4 = eyelids open or opened, tracking, or blinking to command
Q10		Motor Response	O 0 = no response to pain or generalized myoclonus status O 1 = extension response to pain O 2 = flexion response to pain O 3 = localizing to pain O 4 = thumbs-up, fist, or peace sign
Q11		Corneal Reflexes	O Absent bilaterally O Absent unilaterally O Present bilaterally O Not assessed

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Q12	*If Q01 is 'Yes'*	Cough reflex	O Absent O Present O Not assessed
Q13		Breathing	O Not intubated with regular breathing O Not intubated with Cheyne-Stokes type of breathing O Not intubated with irregular breathing O Intubated with breathing above ventilator rate O Intubated with breathing at ventilator rate or apnea O Not assessed
Q14		EEG used for neuro prognostication and impact on neuro prognostication	O Not used O Used, favorable O Used, unfavorable O Used, neutral
Q15		Somatosensory evoked potential used for neuro prognostication and impact on neuro prognostication	O Not used O Used, favorable O Used, unfavorable O Used, neutral
Q16		Brain CT used for neuro prognostication and impact on neuro prognostication	O Not used O Used, favorable O Used, unfavorable O Used, neutral
Q17		Brain MRI used for neuro prognostication and impact on neuro prognostication	O Not used O Used, favorable O Used, unfavorable O Used, neutral
Q18		Brain specific serum biomarker used for neuro prognostication and impact on neuro prognostication	O Not used O Used, favorable O Used, unfavorable O Used, neutral

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Q19	*If Q01 is 'Yes'*	Performer of neuro prognostication	O Non intensivist neurologist O Neuro intensivist O Medical intensivist/Surgical intensivist O Other
Q20		Neuro prognosis	O Favorable O Unfavorable O Neutral
Q21	*If Q20 is 'Unfavorable'*	Met brain death criteria	O No O Yes O Brain death exam not performed
Q22	*If Q21 is 'No' or 'Yes'*	Brain death exam include apnea test	O No O Yes
Q23		Neuro prognosticator also performed the brain death exam	O No O Yes
Q24	*If Q23 is 'No'*	Performer of brain death criteria	O Non intensivist neurologist O Neuro intensivist O Medical intensivist/Surgical intensivist O Other

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 505: Daily Seizure Monitoring Version 1 (12-Mar-2020)

Indicate on this form seizure-like clinical findings, EEG findings, and anticonvulsant treatments, all from the current day.

Qa		Data collected	O No O Yes
Qb		Date of assessment	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q01		Clinically evident generalized or focal seizures observed on this day *Other than myoclonus.*	O No O Generalized O Focal O Generalized and Focal
Q02		Clinically evident generalized or focal myoclonus observed on this day	O No O Generalized O Focal O Generalized and Focal
Q03		EEG conducted today	O No O Yes
Q04	*If Q03 is 'Yes'*	Duration of EEG monitoring on this day	___ ___ *1-24 hours*
Q05		EEG findings on the ictal inter-ictal continuum	O No O Yes
Q06		Electrographic seizures on EEG	O No O Yes
Q07	*If Q06 is 'Yes'*	Electrographic status epilepticus	O No O Yes
Q08		Clinical correlate for electrographic seizure	O No O Yes
Q09		Anticonvulsants for treatment or prevention of seizure or myoclonus given on this day	O No O Yes
Q10	*If Q09 is 'Yes'*	Reason for anticonvulsants	O Clinical findings O EEG findings O Both clinical and EEG findings O Prophylactic

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 506: ED Code Review and Treatment Version 1 (12-Mar-2020)

Qa		Data collected	O No O Yes
Q01		Date of ED arrival according to hospital record	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q02		Time of ED arrival according to hospital record	___ ___ : ___ ___ 24 hour clock hh:mm
Q03		ROSC sustained throughout the ED course	O No O Yes
Q04	*If Q03 is 'No'*	Use of active mechanical CPR device in the ED	O No O Yes, LUCAS O Yes, Autopulse
Q05		Number of shocks delivered in the ED	___ ___
Q06		Cumulative dose of epinephrine in the ED	___ ___ mg
Q07		Date of sustained ROSC	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q08		Time of sustained ROSC	___ ___ : ___ ___ 24 hour clock hh:mm
Q09		Type of definitive temperature control device initiated	O Arctic Sun (Medivance—Bard—BD) O Thermogard (Zoll—Previously Alsius—Previously Coolgard) O Blanketrol (Cincinnati Sub-Zero— Gentherm—Zoll STx) O Medi-Therm (Gaymar—Stryker) O Altrix (Stryker) O Other
Q10	*If Q09 is 'Thermogard'*	Type of catheter placed	O Quattro O Icy O Cool Line O Solex 7
Q11	*If Q09 is 'Blanketrol'*	Model used	O Blanketrol II O Blanketrol III O Zoll STx
Q12	*If Q09 is 'Medi-Therm'*	Medi-Therm model used	O Medi-Therm II O Medi-Therm III
Q13	*If Q09 is 'Blanketrol, Medi-Therm, or Altrix'*	Type of cooling	O Surface Pads O EnsoETM esophageal device(Attune) O Both

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Q14	*If Q09 is 'Other'*	Other device	
Q15	Other cooling induction adjuncts used *Includes cold saline, ice packs, ThermoSuit, or other.*		O No O Yes
Q16	First temperature recorded		___ ___ ___.___ °C
Q17	Temperature source		O Oral O Tympanic O Rectal O Bladder O Esophageal O Intravascular
Q18	Date first temperature recorded		___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q19	Time first temperature recorded		___ ___ : ___ ___ 24 hour clock hh:mm
Q20	ST-elevation Myocardial Infarction (MI) on ECG obtained in the ED		O No O Yes
Q21	Location of subject directly from the ED		O ICU O Coronary Catheterization Lab
Q22	*If Q21 is 'Coronary Catheterization Lab'*	Culprit obstruction found	O No O Yes
Q23		Revascularization successful	O No O Yes
Q24	Date subject went to ICU or Catherization Lab directly from the ED		___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q25	Time subject went to ICU or Catherization Lab directly from the ED		___ ___ : ___ ___ 24 hour clock hh:mm
Q26	ICU that subject was admitted to directly from the ED or after going to the Catherization Lab		O Cardiology ICU O Medical ICU O Neurological ICU O Combined or other ICU

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 507: Daily Electrolyte Log Version 1 (12-Mar-2020)

All electrolytes that are collected for the day should be recorded below. Exclude blood gas results.

Qa	Data collected	0 No 0 Yes
Qb	Date	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy
Q01	Hypertonic saline used on this day	0 No 0 Yes
Q02	Magnesium administered to treat shivering on this day	0 No 0 Yes

	QA Time of blood collection *24 hour clock hh:mm*	QB Magnesium *mEq/L*	QC Sodium *mEq/L*	QD Potassium *mEq/L*	QE Calcium *mg/dl*
Q03-1	__ __ : __ __	_____	_____	_____	_____
Q03-2	__ __ : __ __	_____	_____	_____	_____
Q03-3	__ __ : __ __	_____	_____	_____	_____
Q03-4	__ __ : __ __	_____	_____	_____	_____
Q03-5	__ __ : __ __	_____	_____	_____	_____

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 508: Daily Glucose Transgressions

Version 1 (12-Mar-2020)

Qb	Date	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q01	Any abnormal glucose observed during this day *Abnormal here indicates outside of the range described in the MoP.*	O No O Yes O Not measured

Use this form to report glucose transgressions on the current day.

1. Enter all values where glucose is outside the ranges described in the MoP.

2. Enter the first normal value following an abnormal glucose.

	QA Time *24 hour clock hh:mm*	QB Glucose *mg/dl*
Q02-1	___ ___ : ___ ___	_____
Q02-2	___ ___ : ___ ___	_____
Q02-3	___ ___ : ___ ___	_____
Q02-4	___ ___ : ___ ___	_____
Q02-5	___ ___ : ___ ___	_____
Q02-6	___ ___ : ___ ___	_____
Q02-7	___ ___ : ___ ___	_____
Q02-8	___ ___ : ___ ___	_____

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 509: Brain Imaging Version 1 (12-Mar-2020)

This form is optional and should only be completed for each brain imaging study performed during the acute hospitalization.

Qb		Date brain imaging performed	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy
Qc		Time brain imaging performed	___ ___ : ___ ___ 24 hour clock hh:mm
Q01		Type of brain imaging	0 CT 0 MRI 0 Radionuclide brain perfusion 0 Catheter angiography
Q02	*If Q01 is 'Radionuclide brain perfusion' or 'Catheter angiography'*	Findings consistent with brain death *Absence of cerebral blood flow.*	0 No 0 Yes
Q03	*If Q01 is 'CT or MRI'*	Findings suggestive of brain injury resulting from cardiac arrest	0 No 0 Yes
Q04	*If Q03 is 'Yes'*	Findings suggestive of cerebral edema *Loss of grey white differentiation on CT, diffusion abnormality on MRI, cortical effacement, decreased ventricular or cistern size, etc.*	0 No 0 Yes
Q05	*If Q03 is 'Yes'*	Mass effect or brain herniation findings	0 None 0 Mass effect without herniation 0 Subfalcine herniation without other herniation 0 Transtentorial, central or uncal herniation
Q06	*If Q01 is 'CT or MRI'*	Imaging identifies a pathology likely to have caused cardiac arrest	0 No 0 Yes, new finding 0 Yes, but reported on previous brain image CRF
Q07	*If Q06 is 'Yes, new finding'*	Pathology identified as the likely cause of cardiac arrest	0 Intraparenchymal hemorrhage 0 Subarachnoid hemorrhage 0 Ischemic stroke 0 Traumatic brain injury 0 Other

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

ICECAP	Subject:

Form 510: Daily Selected Medications Version 1 (12-Mar-2020)

For each of the selected medications listed below, if the medication was administered on the current day provide the cumulative dose administered on the current day. If the medication was not administered on the current day, enter 0.

Qa	Data collected	O No O Yes
Qb	Date	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
Q01	propofol	__ __ __ __ mg
Q02	midazolam	__ __ __ __ mg
Q03	diazepam	__ __ __ __ mg
Q04	lorazepam	__ __ __ __ mg
Q05	pentobarbital	__ __ __ __ mg
Q06	dexmedetomidine	__ __ __ __ mg
Q07	ketamine	__ __ __ __ mg
Q08	buspirone	__ __ __ __ mg
Q09	fentanyl	__ __ __ __ mg
Q10	morphine	__ __ __ __ mg
Q11	meperidine	__ __ __ __ mg
Q12	remifentanil	__ __ __ __ mg
Q13	Neuromuscular blocking agent administered on the current day	O rocuronium O cisatracurium O vecuronium O pancuronium O succinylcholine O None

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Form 511: NIH Toolbox - Central Data Entry Version 1 (12-Mar-2020)

Qa	Data collected	0 No 0 Yes
Q01	CSV data – descriptors	
Q02	CSV-Items scores	

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Screen Failure

Enter all adult patients successfully resuscitated from out of hospital cardiac arrest.

A01	Screen failure ID *Assigned by WebDCU.*	
A02	Site *Assigned by WebDCU.*	
A03	Screening date *Date of arrest.*	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
A04	Sex	O Male O Female
A05	Ethnicity	O Hispanic or Latino O Not Hispanic or Latino O Unknown
A06	Race *Check all that apply.*	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown
A07	Age	_____

Inclusion criteria

Q02	Age greater than or equal to 18 years	O No	O Yes	O Unknown
Q03	Coma after resuscitation from out of hospital cardiac arrest *Coma is operationally defined as when patient is intubated and is unable to follow commands.*	O No	O Yes	O Unknown
Q04	Cooled to less than 34 degrees Celsius within 240 minutes of cardiac arrest *Time of cardiac arrest is defined as time of the 911 call or EMS witnessed first arrest.*	O No	O Yes	O Unknown
Q05	Definitive temperature control device initiated	O No	O Yes	O Unknown
Q06	Enrollment within 6 hours of initiation of cooling *Enrollment is defined as the time of randomization. Initiation of cooling is defined as the time of initiation of a definitive temperature control device.*	O No	O Yes	O Unknown
Q07	Informed consent from LAR including intent to maintain life support for 96 hours	O No	O Yes	O Unknown

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Exclusion Criteria			
Q08	Hemodynamic instability *Defined as systolic blood pressure less than 80 mm Hg refractory to aggressive management.*		O No O Yes O Unknown
Q09	Pre-existing neurological disability or condition that confounds outcome determination		O No O Yes O Unknown
Q10	Pre-existing terminal illness, unlikely to survive to outcome determination		O No O Yes O Unknown
Q11	Planned early withdrawal of life support		O No O Yes O Unknown
Q12	Presumed sepsis as etiology of arrest		O No O Yes O Unknown
Q13	Prisoner		O No O Yes O Unknown
Screened patient clinical parameters			
B01	Subject alive at hospital discharge		O No O Yes
B02	*If B01 is 'Yes'*	Discharge location	O Home O Rehabilitation facility O Assisted living facility O Skilled nursing facility O Long term acute care O Hospice O Unknown
B03		Date of hospital discharge	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
B04	*If B01 is 'No'*	Date of death	___ ___ - ___ ___ ___ - ___ ___ ___ ___ dd-mmm-yyyy
B05		Met brain death criteria	O No O Yes O Unknown
B06	*If B05 is 'No'*	Withdrawal of life sustaining treatments	O No O Yes O Unknown
B07	Initial rhythm for the patient's first out of hospital cardiac arrest		O Shockable O Non-Shockable O Unknown
B08	*If Q05 is 'Yes'*	Target temperature used	O 33°C O 36°C O Other O Unknown
General comments			

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*

Subject Enrollment

Q01	Site	
Q02	Subject ID *Assigned by WebDCU.*	
Q03	Sex *Derived from Demographics form question 01.*	0 Male 0 Female
Q04	Ethnicity *Derived from Demographics form question 02.*	0 Hispanic or Latino 0 Not Hispanic or Latino 0 Unknown
Q05	Race *Check all that apply* *Derived from Demographics form question 03.*	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown
Q06	Age *Derived from Demographics form question 04.*	___ ___ years
Q08	Date of informed consent	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy
Q09	Date of initiation of a definitive temperature control device	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy
Q10	Time of initiation of a definitive temperature control device	___ ___ : ___ ___ 24 hour clock hh:mm

General comments

If this is a source document, sign and date:	_____ *Print name*	_____ *Signature*	__ __-__ __ __ - __ __ __ __ *dd-mmm-yyyy*