May 22, 2018 UPDATE:

This is the Method of Operations (MOO) that is applicable to the ROC Trauma Epistry. This was the original version of the Epistry MOO and contains both traumatic injury and cardiac arrest sections. An updated MOO (v5) is available for the ROC Cardiac Arrest Epistry.

EPISTRY

MANUAL OF OPERATIONS

September 17, 2007

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EPISTRY*

Overview

The burdens of out-of-hospital cardiac arrest and life-threatening traumatic injury are, at best, only crudely known. Whether and how EMS process, geographic, socioeconomic and periodic variations are associated with differences in outcome is unknown. This can be largely attributed to the absence of any internationally-representative epidemiologic database that includes outcome. Since patients at higher risk of poor outcomes are often excluded from clinical trials, estimation of the burden of illness based on those enrolled in ROC trials is subject to bias. Knowledge of factors related to specific episodes, together with regional factors including EMS system factors and outcome is a first step toward the development, implementation and evaluation of interventions to improve outcomes associated with these illnesses.

Specific aims of the ROC Epistry are to:

1. Establish a comprehensive ongoing data infrastructure to facilitate the design, implementation and interpretation of ROC trials.
2. Define the incidence and outcome of out-of-hospital cardiac arrest and life-threatening traumatic injury.
3. Describe the relationships between resuscitation performance and EMS structure, adjusting for episode-specific factors.
4. Evaluate the relationships between outcome and patient, EMS, regional, and periodic factors.

Please refer to the Epistry Protocol for further study details.

Patient Enrollment

Patients will be enrolled in Epistry December 1, 2005 through April 2009. The Epistry is designed to satisfy the requirements for minimal risk research and is intended to include all patients meeting the inclusion criteria regardless of age, gender, race or ethnic origin. It is planned that the Epistry will have sufficient enrollment of persons of both genders and diverse racial/ethnic backgrounds to insure that the benefits and burdens of research participation are distributed in an equitable manner. Subject to permission by local Institutional Review (IRB) or Research Ethics (REB) boards, a waiver of consent will be used to collect patient data. Also subject to relevant IRB and REB permission, pregnant women and prisoners will be included and age-based eligibility will not be used.

Pregnant women and prisoners will be included where permitted by local Institutional Review (IRB) or Research Ethics (REB) boards because: a) there is no scientific justification for excluding these patients, b) they represent a unique population rarely studied in resuscitation studies, and c) there is minimal risk associated with the study.

Where permitted, age-based eligibility will not be used because: a) serious injury in infants or children is a particularly devastating public health problem with many potential life-years lost, b) cardiac arrest has devastating consequences in children even though it is less common than in adults, c) pediatric injury and cardiac arrest have been greatly under researched, d) children incurring serious injuries or cardiac arrest may be more amenable to new therapies than adults, and e) there is minimal risk associated with the study.

Sudden Cardiac Arrest Inclusion Criteria

Included will be all individuals who experience cardiac arrest outside the hospital (see 'Capture' section to review Epistry geographic catchment footprint), are evaluated by organized ROC EMS personnel and:

a. receive attempts at external defibrillation (by lay responders or emergency personnel), or receive chest compressions by organized ROC EMS personnel; or

b. are pulseless but do not receive attempts to defibrillate or CPR by ROC EMS personnel. This group will include patients with do not attempt resuscitation directives signed and dated by a physician, extensive history of terminal illness or intractable disease, or request from the patient’s family.

Traumatic Injury Inclusion Criteria

Included will be individuals who experience injury outside the hospital who are evaluated by organized EMS personnel and have any of the following:

a. Systolic blood pressure $\leq$ 90 mmHg
b. Respiratory rate < 10 or >29
c. Glasgow Coma Scale score $\leq$ 12
d. Intubated in field
e. Died in field

HUMAN SUBJECTS

Population

This prospective cohort study of individuals with out-of-hospital cardiac arrest or traumatic injury will be conducted in a manner consistent with federal regulations and local standards in Canada and the United States. It is intended that all patients with cardiac arrest or traumatic injury in the participating study communities will be enrolled.

Inclusion of Children and Vulnerable Populations

In the United States, research involving children is subject to additional protections beyond the general provisions of the Common Rule. For detailed information on the regulations associated with inclusion of children in research studies, refer to the Revised Registry-Epistry Protocol (050930 Registry_Epistry_Protocol.doc) page 145-6. Posted at https://roc.uwctc.org/tiki/tiki-list_file_gallery.php?galleryId=13 .

The circumstances surrounding the ROC Epistry are not directly addressed in these regulations, but principles reflected in the regulations provide a strong basis for the ethical acceptability of enrolling children in the proposed Registry: (a) the collection of data itself poses minimal risk to the children enrolled in the Registry; (b) any risks that might follow from the inappropriate use, or inadequate protection of children's personal health information, have been thoroughly addressed in our proposed protocol for the safeguarding of privacy and confidentiality ; (c) there are strong arguments in favor of including children in research, and in specific epidemiological studies such as the one proposed here, and these arguments have been accepted as important and valid by the Food and Drug Administration and the Secretary of Health and Human Services. For example, the following argument from the American Academy of Pediatrics was included in the publication of the Final Rule: "it is important that children be included in research protocols, including those on emergency treatments, so that the safety and efficacy of various treatment methods can be determined in a scientific manner."(Protection of Human Subject; Informed Consent. Federal Register Sept 26-Oct 2, 1996. Department of Health and Human Services. Food and Drug Administration [Docket No. 95N - 0158]. Final Rule.)

In Canada, the inclusion of children in research is covered by more general provisions of the Tri-Council Policy Statement. For detailed information on the regulations associated with inclusion of children in research studies, refer to the Revised Registry-Epistry Protocol (050930 Registry_Epistry_Protocol.doc) page 145. Posted at https://roc.uwctc.org/tiki/tiki-list_file_gallery.php?galleryId=13 .

Given the minimal nature of the risks posed to children by participation in the Epistry, and given the potential value of the data collected for improvements that might benefit children, it is believed that the inclusion of children in the Epistry database is adequately justified ethically and appropriately grounded in prevailing regulations and policies.

Where permitted by local IRBs, prisoners and other vulnerable populations will be enrolled in the Epistry. Regulations suggest that prisoners may be enrolled "provided that the study

presents no more than minimal risk and no more than an inconvenience to the subjects." However their legal status will not be recorded, they will not be contacted by research staff, they will not receive any interventions related to the Epistry, and they will be given all privacy and confidentiality safeguards that are applied to other patients. For detailed information on the regulations associated with inclusion of prisoners and other vulnerable populations, refer to the Revised Registry-Epistry Protocol (050930 Registry_Epistry_Protocol.doc) page 146. Posted at https://roc.uwctc.org/tiki/tiki-list_file_gallery.php?galleryId=13 .

Source of Information

Patient-related data will be obtained from out-of-hospital records that have already been previously collected during routine clinical care. Vital status and date of discharge will be obtained from hospital records, either by phone or review. Any other hospital data will come from existing records. Patients will not be contacted.

Regulatory

Institutional Review and Research Ethics Boards

The Epistry protocol must be reviewed by the coordinating center University of Washington Institutional Review Board (IRB), the IRB or Review of Ethics Board (REB) at each site and it is up to the local IRB/REB to decide what actions must be taken by the site in order to protect the subjects of the study. Each clinical site must have IRB approval prior to the beginning of data collection. The CTC will maintain copies of IRB approvals from each participating site.

Waiver of Informed Consent for Participation

A relevant Institutional Review Board in the United States (or Research Ethics Board in Canada) can approve a waiver of the usual requirements of informed consent, provided that it finds and documents that the research:

- Involves no more than minimal risk to subjects
- Does not adversely affect the rights and welfare of the subjects
- Could not be practicably carried out without waiver of consent
- Whenever appropriate, subjects will be provided with additional pertinent information after participation
- Does not involve a therapeutic intervention

It is the assessment of Epistry primary investigators that the study has been designed to meet the requirements for waiver of informed consent.

For detailed information on Epistry justification for use of waiver of informed consent, refer to the Revised Registry-Epistry Protocol (050930 Registry_Epistry_Protocol.doc) page 143. Posted at https://roc.uwctc.org/tiki/tiki-list_file_gallery.php?galleryId=13 .

Data Overview

The goals of the data management system are to maintain data accuracy, security, and quality; and to allow efficient access to the data for monitoring and analysis. The system is meant to adhere to recommendations and guidelines from Federal agencies and academic medical center Institutional Review Boards (IRBs) on confidentiality and research data protection in light of the “Privacy Rule” under HIPAA.

Linkage

Linkage of various data sources to an episode will be accomplished at the site through use of the date and time the call was received at the dispatching center, the EMS responding agency identity, a site-determined incident number and personal identifiers. For this purpose, the date and time based on the call to dispatch is considered of fundamental importance and is required as part of any data transfer to the CTC.

A unique record identifier will be assigned by the CTC to each record, whether web-entered or batch-uploaded, when it is successfully stored in the CTC database. This CTC Episode ID provides the coordinating center with a unique file database number that does not include patient identifiers or link the CTC with RCC patient care records. The CTC Episode ID will be included in all CTC to RCC communications, site reports, data exports, and reports to outside agencies and other consortium members.

Coded patient identifiers for other related registries will be obtained if available (e.g. hospital-based trauma registry, NEISS and American College of Cardiology National Cardiovascular Data Registry [CathPCI Registry and ICD Registry components]).

Multiple Episodes

Although knowledge of multiple episodes for a given patient is not important for the stated purposes of Epistry, such information could provide a rich and unique data set which may prove helpful for some research questions. While there will not be many such multiple episode patients in any given year, the proportion of patients that may have had a previous episode in 4 years might be as high as 10 or 20%, especially for trauma patients. It will be impossible to capture all multiple episodes for a given patient with absolute certainty. However, individual sites may be able to link probabilistically on locally-retained patient identifiers, and, when able can include the link to any previous episode in the data base.

Capture

Generally, episodes will be identified by multiple strategies. Out-of-hospital data can be extracted from existing databases if possible. In most cases these will be reviewed locally and augmented with targeted review of the EMS run report to complete the required data elements and check for data errors. Where no appropriate database currently exists, processes will be put in place to funnel primary source materials to the Epistry site coordinator.

It is intended that all episodes attended by an organized ROC EMS response, and meeting Epistry inclusion criteria, will be entered in Epistry. Entered cases must originate from within the geographic boundary determined by service areas of ROC ground EMS response. Cases that originate outside the ROC ground boundary (such as might occur when air ALS or transport is called to a distant location) and then transported to a ROC ED/hospital are *not entered* in Epistry. Cases originating within the ROC ground boundary and attended first by a non-ROC EMS agency, then a ROC EMS agency, *are entered* in Epistry.

Quality Assurance

Ultimate responsibility for the quality of data will reside with each site's Primary Investigator (PI). All sites will focus efforts on education to improve the quality of data collected in the field. In addition, range and consistency checks as data are being entered on the web, and similar checks on data sets transferred to the CTC, will provide immediate feedback which is known to substantially reduce errors. The CTC will perform additional consistency checks within and across data fields as the data accumulate. These checks will produce routine reports that will be distributed to the sites requiring correction and/or verification.

Site Audit

CTC staff will visit each site annually to evaluate the process for data collection. This will include an audit of randomly selected charts including primary data sources and supporting documentation. If the audit process identifies that the data do not conform to good clinical practice (GCP), a formal process will be followed for corrective action. Furthermore, non-conforming data submitted by the site will be withheld from the ROC Registry database until such data is brought up to standard and re-submitted to the CTC by the Site.

Security

All patient and site-specific data will be kept strictly confidential. No individual patient or site identifiers will be made public outside ROC. No individually identifiable health information will be stored at the coordinating center. Security of data files and primary data materials at the site will be reviewed at each yearly site visit.

General Policy Statement on Privacy and Confidentiality

The ROC CTC complies with and follows the principles of the privacy of health information act outlined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA Public Law 104-191). Security of the databases is maintained by the procedures outlined in HIPAA. These same procedures are applied voluntarily by the CTC for the data that are not individually identifiable. These procedures are as follows:

- Administrative procedures to guard data integrity, confidentiality, and availability;
- Physical safeguards to guard data integrity, confidentiality, and availability, including protection of physical computer systems and related equipment from natural hazards as well as intrusion;
- Technical security services to guard data integrity, confidentiality, and availability, including processes to protect, control, and monitor information; and
- Technical security mechanisms to prevent unauthorized access to data transmitted over the communications network.

List of Abbreviations

AED	Automated External Defibrillator
ACLS	Advanced Cardiac Life Support
ALI	Acute Lung Injury
ALS	Advanced Life Support
AMA	Against Medical Advice
ARDS	Acute Respiratory Distress Syndrome
ATLS	Advance Trauma Life Support
BLS	Basic Life Support
CA	Cardiac Arrest
CABG	Coronary Artery Bypass Graft
CAD	Coronary Artery Disease
CHF	Congestive Heart Failure
CHI	Closed Head Injury
CPAP	Continuous Positive Airway Pressure
CPC	Cerebral Performance Category
CPR	Cardiopulmonary Resuscitation
CT	Computerized Tomography
CTC	Clinical Trial Center
CVA	Cerebral Vascular Accident
CVP	Central Venous Pressure
DBP	Diastolic Blood Pressure
DNAR	Do Not Attempt Resuscitation (order)
DOA	Dead On Arrival
DSMB	Data Safety Monitoring Board
DVT	Deep Venous Thrombosis
ED	Emergency Department
EOA	Esophageal Obturator Airway
EtCO2	End-tidal CO2
ETT	Endotracheal Tube
FiO2	Percent inhaled oxygen
GCS	Glasgow Coma Scale
HTN	Hypertension
ICD	Implantable Cardioverter Defibrillator
IO	Intraosseous
ISS	Injury Severity Score
IV	Intravenous
LMA	Laryngeal Mask Airway
LVAD	Left Ventricular Assist Device
LVEF	Left Ventricular Ejection Fraction
MI	Myocardial Infarction
MODS	Multiple Organ Dysfunction Score
MRI	Magnetic Resonance Imaging

MVC	Motor Vehicle Collision
OD	Overdose
OOH-CA	Out-of-Hospital Cardiac Arrest
PAD	Public Access Defibrillation
PaO2	Partial pressure of oxygen in the plasma phase of arterial blood
PCR	Patient Care Report (also known as “run report”, “incident report”)
PE	Pulmonary Embolus
PEA	Pulseless Electrical Activity
PEEP	Positive End Expiratory Pressure
QOL	Quality of Life
ROSC	Return of Spontaneous Circulation
RTS	Revised Trauma Score
RSI	Rapid Sequence Intubation
SaO2	Oxygen saturation
SBP	Systolic blood pressure
SCA	Sudden cardiac arrest
SOB	Shortness of Breath
TBI	Traumatic Brain Injury
TRISS	Trauma Injury Severity Score
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia

DATA COLECTION FORMS

Data are received by the CTC directly over a secure internet connection through web-based entry system. Sites log-on through a user name an password verification process. All persons who plan to enter data must complete and electronic signature agreement (see Attachment A). Password protected access is granted by the CTC database manager in consultation with each RCC PI and the CTC PI or designees. File and specific page access is controlled by software protocols. Regular data verification is performed by the CTC database manager and the data are also monitored for and protected against any suspicious or inappropriate use. Schedule of case report forms collections

Name of Form	Both cardiac & trauma	Cardiac patients only	Trauma patients only
Patient Enrollment	X		
Pre-hospital Time Record-trauma			X
Pre-hospital Time Record-cardiac		X	
Pre-hospital data-both	X		
Pre-hospital data-cardiac		X	
Pre-hospital data-trauma			X
ED/hospital Admit--both	X		
CPR Process		X	
ED/hospital records	As requested by CTC		
EMS records	As requested by CTC		
ECG records		As requested by CTC	

Cases Entered into Interventional Trials and/or Epistry

Episodes entered into ROC PRIMED or the HS interventional studies must be also considered for Epistry eligibility and data entry. A different strategy is used for Epistry data for each the ROC PRIMED and HS studies.

Epistry and ROC PRIMED:

For ROC PRIMED participating agencies, a ROC PRIMED Patient Enrollment form is completed for all cardiac arrest cases treated by EMS (defined in ROC PRIMED as being EMS chest compressions or EMS defibrillation). Separate Epistry data entry is not performed for cardiac arrest cases treated by EMS and for which ROC PRIMED requires that *further* forms (beyond just the Patient Enrollment form) be completed. See the below table. Data for an episode that qualifies for both ROC PRIMED and Epistry will be entered only in the ROC PRIMED data set. The CTC will coordinate population of ROC PRIMED data into the Epistry data set (though no associated data forms will reside on the Epistry Episode List). Data is entered separately and only in Epistry up until the time an agency enters the ROC PRIMED study and is there subject to serial case enrollment.

Cardiac Arrest	All ROC PRIMED forms	ROC PRIMED Patient Enrollment form	All Epistry forms
I. Treated by EMS (received EMS chest compressions or EMS defibrillation) and the completed ROC PRIMED patient enrollment form indicates either a) the ITD was opened (item 1) and/or b) the arrest was witnessed by ROC EMS (item 2c, exclusion criteria for this line item is marked 'yes'), or The ROC PRIMED web will indicate that further forms beyond Patient Enrollment are required.	X		
II. Treated by EMS (received EMS chest compressions or EMS defibrillation) and the ROC PRIMED web indicates that NO further forms beyond Patient Enrollment are required. This group of cases may include 'vulnerable patients' such as known prisoners, pregnant women, and children. Where permitted by the local IRB, complete all Epistry forms when the ROC PRIMED web indicates that NO further interventional trial forms are required beyond Patient Enrollment.		X	X
Treated with external defibrillation by lay responders/bystanders, but no EMS chest compressions or defibrillation provided (includes patient with ROSC at time of EMS arrival).			X
Not treated by EMS-are pulseless and do not receive attempts to defibrillate or CPR by EMS personnel. Includes those with DNR.			X

Epistry and HS Study**:**

Any patient entered into the HS Study must be separately considered for eligibility in Epistry. Whereas data for dual ROC PRIMED and Epistry eligible patients need be entered only once, it is required that data for the HS Study and for Epistry be separately entered. This is because there is little overlap in required data elements. To facilitate Epistry data entry for HS Study patients, a data transfer strategy, a 'Preload', has been developed.

Each Epistry form provides for the ability to transfer data that has previously been entered onto ROC-web HS Study forms. This function allows the coordinator to 'Preload' an Epistry form with a specified case set of HS Study data, to view that data, and to choose whether or not to 'add' the preloaded data to the Epistry dataset. You may 'preload' (or 'pull' data from the interventional database) and view the status or completeness of HS data to an Epistry form as many times as desired. Only empty Epistry forms (and not previously saved with or without errors) may be preloaded with HS data. You may 'Add' a preloaded Epistry form only once—all subsequent data entries or edits to the added Epistry form must be done in the standard data entry manner.

HS Study data is distributed differently across forms, than is Epistry. In general, the HS Study has a greater number of forms and the sequence of events and time line for data completion may be different than for Epistry. When viewing an Epistry form with preloaded data, a message will indicate the complete or incomplete status of each of the sourced HS forms. Data is preloaded to Epistry only from HS forms that are completed ('C). Data is not preloaded to an Epistry form when the all the related source HS forms are empty.

Linking Epistry case to an HS case: The Epistry patient enrollment form must be completed and saved without errors to allow 'preload' of subsequent Epistry forms. To link an Epistry case with an HS case, three Epistry Patient Enrollment form conditions must exist:

1. Epistry episode date and time (including seconds, where provided) must be identical to that entered on the HS patient enrollment form.
2. Appropriate cohort (Traumatic injury or Cardiac arrest) must be marked for Item 2-Episode Characteristics
3. 'Yes, ROC trial,' 'Trauma Study,' and the exact and valid HS study ID number (including leading zeros and single check digit) must be entered

Valid HS study ID: A study ID number is determined to be valid based on the following criteria:

1. Assigned to the same site as the coordinator logged onto the ROC-web.
2. Interventional episode/case is active (has not been deleted at the request of the site).
3. Check digit (single character at the end of case ID number) is correct.
4. Date and time match for Epistry and HS patient enrollment forms.

Unlinking Epistry case from an HS case: There may be circumstances where Epistry forms have been linked with an HS case and the site wishes to change the link. Where *only* the Epistry patient enrollment form has been completed (as above) and saved with or without errors ('C' or 'E' status), the site may edit any enrollment form field and re-establish a different (or no) link with an HS case. Where *any other* Epistry case associated forms (such as the prehospital data, time record, or ED/hospital forms) have been 'preloaded' and 'added' to the Epistry database and saved with or without errors ('C' or 'E' status), the site *cannot* change the case linking criteria—the site must request the Epistry case to be deleted to unlink it from the H case.

Case Deletions and Changes to Date of Episode or Patient Cohort

Sites may identify cases that need to be deleted from Epistry (such as those that did not meet entry criteria or duplicate entries). Contact the CTC by using the 'Request Case Deletion' button located on the Patient Enrollment form. Provide the complete reason for the requested change. When reporting a duplicate entry, also provide the complete CTC Episode ID for the case that has been duplicated. The CTC will confirm when case deletion is complete and

update the history file. The deleted case will be removed from the site Episode List.

Date of episode and patient cohort are entered into the Patient Enrollment form. These data may be changed by the site when the Patient Enrollment form has been saved with or without errors ('C' or 'E') AND no other case report forms have been opened and data entered. Once data has been entered into forms *other* than the Patient Enrollment form, the site must use the "Request Date/Cohort Change" button on that form to submit a request for the CTC to make changes. When requesting the CTC to make a change, provide the complete reason for the requested change. The CTC will confirm when the change request has been completed and update the history file for the affected case. The site may track the status of requested changes (new, pending, approved, closed or rejected) on the Requests Home page.

Closing a Case Where Final Vital Status is Unknown

Occasionally, sites may be unable to obtain the final vital status from the ED/hospital records. When alternate sources for final vital status (the death registry, social security index, or newspaper obituaries) are used, the date of the obtained outcome must be within a proscribed period in order to be considered associated with the Epistry episode. For cardiac arrest, a date of death less than 14 days from the date of the Epistry episode will be attributed to the episode. For trauma, a date of death less than 31 days from the date of Epistry episode will be attributed to the Epistry episode.

Where a date for final vital status cannot be attributed to the Epistry episode, use the 'Request Vital Status Closeout' button on the ED/hospital form to request the CTC to close the case and put it in final ('F') status. Select the reason for never knowing the final vital status—reserve 'other' for cases that clearly do not meet the listed response options.

Patient Enrollment Form –Cardiac Arrest or Trauma

Complete this form for any out-of-hospital cardiac arrest or traumatic injury patient eligible for enrollment as defined by the episode characteristics in Item 2 below.

Each eligible out-of-hospital cardiac arrest or traumatic injury is considered an episode. *Episode information* includes the date of episode and the time the call was received at dispatch (24 hours clock). For web-entry: US sites enter date as mm/dd/yyyy and Canadian sites enter date as dd/mm/yyyy. For batch upload: Sites choose the date format when specifying batch up-load configurations.

Time call received at dispatch:

The *time call received at dispatch* is the time of the earliest call received at the emergency communication center (or public safety answering point—PSAP) responsible for dispatching a vehicle as part of the EMS organized response (and includes all organized EMS respondents, i.e. fire and paramedics). For some sites, the time of the earliest call received at dispatch will be different from the time a call was received at the 911 call center. EMS and fire response may be dispatched from the same center or from different dispatch centers. A dispatch center downstream from the 911 call center is often referred

to as a secondary PSAP. Indicate the time that the earliest call was recorded at the dispatch center whether it serves as a primary or secondary public safety answering point. The time a call is received at dispatch is defined in the ROC EMS structures database and indicates if a call time is recorded at 1st ring, call answered, 1st key stroke, or other. The time of call data should be obtained from dispatch records and not from EMS records unless they are automatically downloaded from dispatch. Handwritten dispatch time information should only be used as a last resort.

For the *time call received at dispatch*, indicate if the time is *From PCR/other, from dispatch,* or *unable to obtain (non-ROC agency first arrival). Time call received at dispatch* is anticipated to be provided as hh:mm:ss (24 hour clock). Where a provided time is expressed as only as hh:mm leave the 'seconds' field blank (do not enter '0' or '00'). It is expected that most times provided *from dispatch* will have seconds. The *time call received at dispatch* will be considered "time zero" in many later analyses and precision of time, where available, is highly desirable. *Unable to obtain* is reserved for those episodes where a *Non-ROC* agency was first on scene and the origin of the data to complete *time call received at dispatch* is not accessible. Sites are encouraged to establish relationships with *non-ROC* agencies that are commonly first on scene and harbor dispatch data.

Incident Number:

For web-entry, the *incident number* is an **optional** field defined by the site and intended as an aid to link records to the Site Linking ID or to the CTC Episode ID. If an *incident number* is provided on web-entered data forms, it will appear on the first printed Patient Enrollment form but will not be stored in the CTC database. Typically, this data field will contain the Incident Number that is an alphanumeric combination generated by the 911 dispatch system within each RCC. It can be used to identify an EMS call for which an EMS vehicle was dispatched and an EMS responder made patient contact. The incident number can be used to track a specific EMS run and EMS patient care record. In cases where multiple patients were evaluated at the same scene, this number may be applied to more than one patient included in the Epistry (i.e., the 911 dispatch Incident Number may not a unique patient identifier). The *incident number* response field is not applicable for batch-upload of data.

Site Linking ID:

The *Site Linking ID* number is an alphanumeric value assigned by the sites and is a specific identifier for each episode reported in the Epistry. This data field is required for all batch up-loads and is optional for web-entry. The *Site Linking ID* must be unique across all of the site's patient records, but must not contain unique patient identifiers (e.g. name, date of birth, social security number). The *Site Linking ID* for a patient episode may be used across all ROC protocols for which the data is applicable (i.e. Epistry and HS, or Epistry and ROC PRIMED) to facilitate record keeping and data retrieval.

It is the responsibility of each RCC to maintain the link between the *Site Linking ID* (unique identifier) and patient identifiable data including patient care records. The CTC can provide algorithms or a set of pre-generated numbers upon request. Where transmitted to

the CTC, the *Site Linking ID* is stored in the CTC main database. This ID will be included along with the CTC Episode ID in all CTC to RCC communications, site reports, and data exports. Reports to outside agencies and other consortium members will not include the *Site Linking ID.*

CTC Episode ID:

The *CTC Episode ID* is a unique record identifier assigned by the CTC to each patient episode record—whether web-entered or batch-uploaded—when it is successfully stored in the CTC database. The *CTC Episode ID* provides the CTCS with a unique file database number that does not disclose patient identification or link the CTC with RCC patient care records. The *CTC Episode ID*, along with the *Site Linking* ID (where provided), will be included in selected CTC to RCC communications, site reports, and data exports. Reports to outside agencies and other consortium members will include the *CTC Episode ID.*

Item 1 –*EMS Response:*

Agency name: Provide the name of the agency for each of the first four responding EMS units (vehicles). For web-entry: Select the responding agency from the pull down menu. The pull down menu lists all agency names entered into the EMS Structures database. The pull down menu also lists ”Non-ROC agency”, ”Not on List*”*, and ”*Unknown”*. ”*Non-ROC agency*” is selected when an agency that is part of the organized EMS response is not a participant in ROC. While Non-ROC agencies may attend the episode, at least one ROC agency must be identified as one of the responding vehicles in order to save the form without errors. Where an agency name is not listed in the pull down menu, select ”Not on list” and save the form with errors. Return to the EMS Structures database and update its information to include the newly identified ROC agency – this will update Epistry pull down menus. Resume Epistry data entry. ”Unknown” agency may be selected as a placeholder when sorting out the response scenario. Selection of “Unknown” agency will allow the form to only be saved with errors. ‘No Additional Responder’ is selected to fill the otherwise blank field for Agency Name after all responding units have been listed—a response option must be provided for each of the four fields provided for ‘Agency name.’

For batch up-load: Provide the CTC-assigned EMS agency ID for each of the first four responding ROC units and for ‘no additional responder’ where appropriate. Refer to Table 1 for specific batch upload codes for *Agency Name* response options.

Table 1: Summary of *Agency* and *Vehicle Name* response options and conditions for saving the Patient Enrollment form with and without errors.

Agency pull down menu (error condition)	Batch code	Vehicle pull down menu (error condition)	Batch code
ROC agency picklist (OK)	CTC assigned	ROC vehicle name picklist (OK)	CTC assigned
		Non-ROC (OK)	-1
		No Vehicle (OK)	-7
		Not in List (save with errors)	-8
		Unknown (can override, save w/o errors)	-9
Non ROC agency (OK)	-1	Non-ROC (OK)	-1
Not on List (save with errors)	-8	Not on List (no error message)	-8
Unknown (save with errors)	-9	Unknown (no error message)	-9
No additional responder (save without errors)	-2	No additional responders (save without errors)	-2

To save a Patient Enrollment form without errors, a valid response (see Table 1) must be selected for each of the four lines provided for 'Agency Name' AND at least one of the following agency/vehicle combinations MUST be provided: ROC agency/ROC vehicle or ROC agency/unknown vehicle.

Vehicle name:

Indicate the agency-specific vehicle name/identification numbers for each of the first four responding units (vehicles). Where more than four vehicles arrive (as might occur with a trauma incident), provide information for the first arriving vehicle and for those vehicles with evidence of providing care to this case patient. Web-entry: Select the vehicle identifiers from the pull-down menu. The pull down menu lists all vehicle identifiers entered into the EMS Structures database that are associated with the previously selected *Agency Name*. Where a "ROC Agency" has been previously selected, the pull down menu also allows for selection of "Non-ROC", "No Vehicle", "Not in List" and "Unknown" vehicles. The "Non-ROC" option allows for the situation where not all tiers or portions of the selected agency are participating in the ROC. "No Vehicle" is reserved for those situations where an EMS provider is not assigned a vehicle, but is either stationed at an event or arena (such as a marathon or a football game) or whose means of transportation is not assigned an identification number (such as a bicycle). "Not in List" is reserved for

those vehicles associated with ROC, but not yet entered in the EMS Structures database – when selected, the form can only be saved with errors, until EMS Structures is updated and the vehicle is re-identified on this form as a ROC listed vehicle. "Unknown" is reserved for those vehicles that the site has no means of otherwise identifying – when selected, the form can be saved without errors after overriding the resulting error message.

Where a "Non-ROC" agency has been previously selected, the pull down menu only provides for a "*Non-ROC* vehicle – when selected, the form can be saved without errors.

Where a "Not on List" agency has been previously selected, the pull down menu only provides for a "Not on List" vehicle – when selected, the form can only be saved with errors, until the EMS Structures database is updated and the Agency is re-identified as a ROC or Non-ROC agency and the associated vehicle identified.

Where "Unknown" Agency has been previously selected, the pull down menu only provides for "Unknown" vehicle – when selected, the form can only be saved with errors, until the Agency is re-identified as a ROC or Non-ROC agency and the associated vehicle identified.

To save the Patient Enrollment form without errors, at least one of the first four EMS responding agencies and vehicles MUST provide one of these combinations: ROC agency/ROC vehicle or ROC agency/unknown vehicle.

For batch up-load: Provide the CTC-assigned vehicle ID for each of the first four responding units. Refer to the below table for specific batch upload codes for *Vehicle Name* response options and conditions for saving the Patient Enrollment form.

Number of Personnel: Indicate the number of crew members for each of the first four responding EMS units (vehicle). Where *Vehicle Name* is "No Vehicle", the *Number of Personnel* is two (2). Where a "Non-ROC" agency/vehicle name has been indicated and no documentation is available, leave the field blank (sites are encouraged to provide Non-ROC responder data where available).

Service Level: Indicate the highest level of service provided by each of the first four responding EMS units (vehicles). Where *Vehicle Name* is "No Vehicle", indicate the level of service for the individual EMS provider that was present or responded to the episode. Where a "Non-ROC" agency/vehicle has been indicated and no documentation is available, leave the field blank (sites are encouraged to provide Non-ROC responder data where available).

BLS: Noninvasive emergency lifesaving care that is used to treat airway obstruction, respiratory arrest, or cardiac arrest. For example, cardiopulmonary resuscitation, but no AED capability.

BLS-D: In addition to cardiopulmonary resuscitation, includes defibrillation using an AED. Fire in Canada may be categorized as BLS-D if the responding unit is equipped with an AED.

BLS-+: In addition to BLS, and BLS-D, can administer symptom relief medication or start an IV or maintain or perform advanced airways, such as combitubes, laryngeal

mask airways (LMA), or esophageal obturator airway (EOA).

ALS: Advanced lifesaving procedures, such as cardiac monitoring, administration of IV fluids and medications, and use of advanced airway adjuncts, such as oral or nasal endotracheal intubation, cricothyrotomy, ventilator, and continuous positive airway pressure (CPAP).

Time of Arrival: Indicate what time each vehicle arrived (meaning wheels stopped moving). Where a "Non-ROC*"* agency/vehicle has been indicated and no documentation is available, leave the field blank (sites are encouraged to provide Non-ROC responder data where available). *Time of Arrival* should be provided hh:mm:ss when available. Where only hh:mm are available, leave the seconds field blank (do not enter '0' or '00').

Source: For the *Time of Arrival,* indicate if the provided time is from the "Watch" (as written on the patient care record by an EMS responder), "Dispatch" (as provided by a dispatch log; where directly provided by dispatch records to an electronic PCR; or where local protocol is for EMS provider to call dispatch to obtain official time to be documented on the PCR), or "No Time" (to indicate the absence of a documented time of arrival for the responding agencies/vehicles). "No Time" should be reserved for "Non-ROC" *a*gencies or "Non-ROC" vehicles*.*

Item 2 –*Episode characteristics:*

Indicate if the patient meets the below definitions for inclusion in the *Cardiac Arrest* or the *Traumatic Injury* cohort. For patients that suffer a cardiac arrest (also called "traumatic arrest" or "vital signs absent") that is associated with blunt, penetrating, or burn trauma (or any condition listed in Table 2), select *Traumatic Injury*—only Trauma cohort data is required and no Cardiac Arrest data is requested (including CPR Process measures). For patients that suffer a cardiac arrest associated with injuries NOT deemed to be blunt, penetrating, or burn trauma (or any condition listed in the below table) select *Cardiac Arrest*—only Cardiac Arrest cohort data is required and no Trauma data is requested. Patients with injuries other than blunt, penetrating or burn trauma (or any condition listed in Table 2) that do NOT suffer cardiac arrest during the course of EMS care are excluded from Epistry (they qualify for neither the *Traumatic injury or Cardiac arrest* cohorts).

Cardiac arrest:

Select *Cardiac arrest* if patient meets the following criteria and indicate if the patient was treated or not treated by ROC EMS:

Out of hospital cardiac arrest (not associated with burn, blunt or penetrating trauma, or with any cause or mechanism of injury listed in the below table), were evaluated by EMS personnel that are part of an organized response and the patient was either:

a. Treated by EMS — receives attempts at external defibrillation (by lay responders or emergency personnel), or receives chest compressions by organized EMS personnel. External defibrillation does not include attempted cardioversion. Attempted defibrillation does not include cases where an AED or defibrillator is applied, no shock is advised, and the patient is determined to not be in cardiac arrest (such as a drug

overdose, or presents with a very low GCS). Chest compressions does not include precordial thump. Chest compressions do not include those provided by lay responders, EMS, or healthcare providers not part of the organized EMS response.

b. Not treated by EMS — are pulseless but do not receive attempts to defibrillate or chest compressions by EMS personnel. This group will include patients with do not attempt resuscitative directive signed and dated by a physician, extensive history of terminal illness or intractable disease, or request from the patient's family. This group will also include patients to whom a monitor/defibrillator or AED was applied to determine asystole ("no shock advised") to confirm death and/or patients who may have received CPR by lay responders prior to arrival of the organized EMS response.

Patients that are attended in the field by an organized ROC EMS response, before or during which he or she arrests, are enrolled in Epistry. This applies to patients coming from inside the ROC footprint (i.e., when transported by air from a remote ROC setting). If the patient arrests while being transferred from one health care facility (to which they have been admitted) to another (i.e.,, an interfacility transfer), the patient is NOT enrolled in Epistry.

Patients that suffer a cardiac arrest associated with injury conditions other than those listed in the below table (and meet the above inclusion criteria) are enrolled in the *Cardiac Arrest* cohort. See the below for a list of injury conditions eligible for the *Cardiac Arrest* cohort.

Table 3: Cardiac Arrest cohort—Injury conditions of the following nature, or with listed e-codes/NEMSIS codes that also meet the above definitions for 'Treated by EMS' or 'not treated by EMS', are enrolled in the *Cardiac arrest* cohort:

Cause of injury and cardiac arrest etiology	**E-code**	**NEMSIS E10_01**	**NEMSIS E11_02**
Chemical poisoning (includes carbon monoxide, toxic gases)	E86X.0	9515	
Drowning	E910.0	9525	2260
Drug poisoning	E85X.0	9530	
Electrocution (non-lightning)	E925.0	9535	2270
Excessive cold	E901.0	9540	
Excessive heat	E900.0	9545	
Lightning	E907.0	9575	
Mechanical suffocation	E913.0	9585	
Radiation exposure	E926.0	9615	
Respiratory			2265
Smoke inhalation	E89X.0	9625	
Venomous stings	E905.0	9645	
Other injury types (with no designated e-code/NEMSIS code): anaphylaxis, foreign body obstruction, hanging, non-traumatic exsanguination, sudden infant death syndrome (SIDS), strangulation,			

Source: NEMSIS v2.2, p265 of 463, variable E10_01 "Cause of Injury" and p 278 of 463, variable E11_02 "Cardiac Arrest Etiology.

Traumatic injury:

Select *Traumatic injury* if a patient (irrespective of whether they have a pulse) experienced an out-of-hospital injury, characterized as blunt, penetrating, or burn trauma (including persons with type or mechanism of injuries or corresponding e-codes/NEMSIS codes as in Table 2), is evaluated by ROC EMS personnel (dispatched as part of an organized EMS response) and meets one of three conditions: If trauma is the primary patient problem, for whatever reason, and Epistry inclusion criteria are met, enroll the patient in Epistry, regardless of their baseline status. An example of this is a comatose patient that falls out of bed and hits his head, presenting with a GCS ≤ 12.

a. Meets one or more of four physiologic criteria, as documented on the pre-hospital patient care record—indicate all physiologic criteria that qualify the patient for the Epistry *Trauma* cohort: Systolic blood pressure ≤ 90 (documented at any time during the pre-hospital course of care); Respiratory rate < 10 or > 29 breaths per minute (pediatric or adult; unassisted; documented at any time during the prehospital course of care); Advanced airway (presumed to be successful placement of oral or nasal endotracheal tube, cricothyrotomy/other surgical approach, or supraglottic airways such as laryngeal mask airway, or combitube); and/or total Glasgow Coma Scale score ≤12.

b. Dead in field with EMS treatment and no physiologic criteria documented—patient died despite EMS treatment, either at the scene or enroute to ED/hospital AND no physiologic criteria were documented during the course of prehospital EMS care. This category does not include those patients that died at the scene or enroute AND had one or more physiologic criteria documented in the patient care record (these patients are qualified by the first option, 'Meets one or more....' as above).

c. Dead at scene without EMS treatment—this includes patients to which a monitor/defibrillator/AED has been applied to determine asystole/death upon EMS arrival, where no further EMS care is provided. This also includes patients for whom only a set of confirmatory '0' vital signs have been obtained/documented to confirm death and no treatments have been provided

Table 2: Blunt, penetrating, or burn trauma—mapping of NEMSIS codes to the Epistry Trauma cohort. Injured persons with the following e-codes/NEMSIS codes AND that meet stated physioloigic criteria (SPB≤ 90, RR < 10, RR > 29, intubated, GCS ≤ 12) are enrolled in the Epistry trauma cohort:

Type or Mechanism of Injury	E-code	NEMSIS
Blunt		2035
Penetrating		2050
Burn		2040
Aircraft related accident	E84X.0	9500
Bicycle accident	E826.0	9505
Bites	E906.0	9510
Child battering	E967.0	9520
Falls	E88X.0	9550
Fire and Flames	E89X.0	9555
Firearm assault	E965.0	9560
Firearm injury (accidental)	E985.0	9565
Firearm self inflicted	E955.0	9570
Machinery accidents	E919.0	9580
Motor vehicle non-traffic accident	E82X.0	9590
Motor vehicle traffic accident	E81X.0	9595
Motorcycle accident	E81X.1	9600
Non-motorized vehicle accident	E848.0	9605
Pedestrian traffic accident	E814.0	9610
Rape	E960.1	9620
Stabbing/cutting accidental	E986.0	9630
Stabbing/cutting assault	E966.0	9635
Struck by blunt/thrown object	E968.2	9640
Water transport accident	E83X.0	9650

Source: NEMSIS v2.2, p265 of 463, variable E10_01 “Cause of Injury” and p.268 of 463, variable E10_03 “Mechanism of Injury.”

Patients injured by other than blunt, penetrating or burn trauma (or any condition listed in Table 2) are excluded from Epistry *unless* they experience a cardiac arrest prior to or after the arrival of the organized EMS response. If a cardiac arrest occurs in such patients (and the patient meets all other *Cardiac Arrest* inclusion criteria), the patient is enrolled only in the *Cardiac Arrest* cohort.

For this traumatic episode, indicate how many patients were at the scene, including the patient that is the subject of this enrollment form. 'One' indicates that only the subject of this enrollment form was a patient at the scene; 'Multiple' indicates that more than the subject of this form was a patient at the scene. Indicate 'not recorded' if the prehospital record makes no mention of multiple patients at the scene.

Item 3 –*Any indication that the patient was enrolled in another clinical trial?:*

Report if there is any indication that the patient was or was not enrolled in a pre-hospital clinical intervention trial—either a ROC or non-ROC trial—prior to admission to the ED/Hospital. If the patient was enrolled in a ROC clinical trial, indicate whether it was a Cardiac or a Trauma study and provide that study's CTC assigned ID number. For web-entry, the 3 character site name (i.e. DAL for Dallas, PGH for Pittsburgh) is autofilled—provide the 5 digit ID (including any leading zeroes, '0'). Separately provide the 1 digit that follows the PR (PRIMED) or HS (hypertonic saline) abbreviation. If the patient was enrolled in a non-ROC clinical trial during the course of pre-hospital care, specify the name or briefly describe the type of pre-hospital clinical trial (maximum 60 characters). This data element allows cross reference with the ROC clinical trial database to confirm the complete capture of Epistry or ROC clinical trial candidates.

Name of person responsible for data on this form:

Name of the individual that logged into the electronic data transmission system for clinical study forms or to execute batch up-load of files. This individual will have registered as a member with the CTC for the purpose of participating as a coordinator or investigator in a ROC clinical trial and has designated a user name and password as their "Electronic Signature." The individual has agreed to consider their electronic signature as equivalent to their handwritten signature, to maintain the confidentiality of their user name and password, and to not let others use it. Refer to the "Electronic Signature Agreement" (accessed after logging on to the ROC website) posted at https://roc.uwctc.org/tiki/roc-data-entry.

After verifying the entered data and electronic signature are correct, print the web-forms for your files, or convert the web-forms to pdf format and store electronically. Edits made later to the original web-entered forms or batch up-loaded data posted to forms are associated with the electronic signature of the individual making the changes and are documented in the file's edit history.

Pre-Hospital Time Record-Cardiac Arrest

The purpose of the Pre-Hospital Time Record is to determine the correct times and sequence of events. The items listed in the time record are the typical events that would occur when a call is received at dispatch for an eligible cardiac arrest. Complete this form for all patients assigned to the Cardiac Arrest cohort, treated or not by EMS.

Event Order: For each listed event that occurred during the course of prehospital care, provide the event order (1-16), the Watch (PCR) time and/or the Dispatch/Defib time (on 24 hour clock, hh:mm:ss) If an event did not occur during the course of prehospital care, enter '0' for that event order (e.g. If the patient survived to ED, then 'Resus. Stopped due to death" should have an event order of '0'). Enter the event order as '0' for '911 call received at primary PSAP' if no documented time exists. If more than one event is documented as having occurred at the same time, provide the same event order for the two or more events. Where local practice is to provide identical times for known serial events, distinguish those with true identical times and provide data; for the remaining events provide plausible event orders based on recorded narrative, leave related time fields blank, and mark 'no doc time.' Where an event order is determined to be the same for two or more events *and* the watch times for each is different (such as might occur if more than one wristwatch were used on the scene), you are asked to confirm this condition and override the error message. Where an event order is determined to be the same for two or more events and provided times are sourced from the same dispatch/defib, it is expected that the provided times should be the same. The order of events can be re-sorted to the chronological order entered by pressing the 'Sort Event Order' or 'Align Times' buttons.

If you left out an item in the event order, it is not necessary to reorder all the affected lines—instead give the overlooked event a decimal number to place it between two existing numbers (such as 2.5 to place the event between the previously entered event 2 and 3). When the 'Sort Event Order' or 'Align Times' button is clicked, all events will be resorted and numbered to accommodate the decimal entry. NOTE: where the event orders have been changed, all previously 'aligned' times and intervals will be removed. Click the 'Align Times' button for recalculation of the aligned times and intervals.

Time of Event: Watch time is that time documented on the patient care record by the EMS provider, likely having been sourced from a wristwatch or clock. Dispatch/Defib time is that provided by the dispatch log; a time annotated on the defibrillator/AED record (such as an ECG, CPR process report); or where site/agency protocol requires EMS to routinely contact Dispatch to acquire the time(s) documented on the PCR. For each event with an event order of 1-16, provide either the Watch or Dispatch/Defib times when available. Where a time has been documented in the patient record as hh:mm, leave the seconds ('ss') field blank, do not enter '00'. If no documented time exists (from either the PCR or dispatch) for a specific event (with event order 1-16), check the 'No Doc Time' box and leave the associated time fields blank. For events with a '0' sort order, leave the Watch and Dispatch/Defib time columns blank and do not check 'no doc time'.

Dispatch/Defib times are generally documented as hh:mm:ss. Sites are encouraged to work with their Dispatch services to acquire 911 call times with seconds. Where no seconds are provided, leave the seconds ('ss') field blank, do not enter '00'.

For event times that appear to be affected by the crossing of a time zone or daylight savings time, enter the time documented in the PCR, dispatch log, or AED/defibrillator record. Do not adjust the times entered for the 'Time of Event.' Adjustment of times is reserved for the 'Aligned Time' column when assessing time intervals and cumulative times.

Source Disp/Defib: For each Dispatch/Defib time provided, indicate the source of that time by completing the 'Source Disp/Defib' column. If the time is from Dispatch, enter '0'. Enter '1', '2', etc for each of the series of defibrillators/AEDs that provided time of events during the course of care (i.e., '1' is the first defibrillator used, '2' is the second defibrillator used and so on).

Defib Appears Synched to Atomic Clock: Complete this column where a Dispatch/Defib time is marked as '1', '2', etc (indicating a defibrillator/AED source for time). Mark the corresponding box when documented times and your knowledge of EMS agency synchronizing protocols appear to be, in your judgment, synchronized with the atomic clock. For example: a defibrillator may provide a time that is 1 hour different than other associated times; you know the EMS agency synchronizes monthly; you know that daylight savings time just took effect; therefore you conclude that the defibrillator does NOT appear synchronized (at the time of this event) and you do NOT mark the corresponding box for 'Defib Appears Synched to atomic Clock'. Another example: a defibrillator provides a time that is 5 minutes different than a Watch time documented for the same ordered event; you know the EMS agency synchronizes monthly; you understand that wristwatch and clock times are often subject to drift and sloppy setting; therefore you conclude that the defibrillator DOES appear synchronized and you DO mark the corresponding box for 'Defib Appears Synched....'.

Aligned Time and Adj: The Aligned Time column is filled automatically when the 'Align times' button is pressed. A computer algorithm assesses times entered for 'Time of Event'. The algorithm moves Dispatch times (Source marked as '0') and Defibrillator times (when marked as 'appears synched to atomic clock') over to the 'Aligned time" column. Events with watch time only are aligned (adjusted) by the computer where adjacent events provide both a watch time and a dispatch or synchronized defibrillator time for comparisons (much like a Rosetta stone). A '?' to the right of the 'Adj' column indicates those times that have been adjusted (aligned) by the computer algorithm. Click on the '?' to learn which event(s) the 'Aligned time' is based upon. You may manually adjust the 'Aligned time' where knowledge of the EMS system or judgment of EMS documentation suggest an aligned time other than that provided by the computer algorithm. Aligned times are not filled or calculated for events where neither a Watch or Dispatch/Defib time is provided--aligned time fields are left blank. Aligned Time fields are also left blank for events where the defibrillator times are not marked as 'appears synched to atomic clock.' The site is encouraged, where reasonable surrogate information allows, to provide aligned times for blank 'aligned time' fields (such as when EMS did not document their arrival at the ED, but the site knows what time the patient was admitted to the ED/hospital).

The 'Adj' box is automatically checked when you replace an aligned time (that was automatically filled) with a time judged to better represent the episode course of prehospital care.

Use the 'Adj' column to adjust for times that appear to be affected by the crossing of a time

zone or daylight savings time—calculate the time difference imposed (such as +1 hour, -1 hour) on any of the 'Time of Event' times and adjust the time to reflect the 'true' time in the 'adj' column.

Time Interval and Cumulative time (visible on the web-form): Time intervals (the elapsed time between two adjacent events) and cumulative times (the sum of elapsed times) are calculated and filled automatically when the 'Align time' button is pressed. Review the calculated intervals to assess if they "make sense." Where calculated intervals are either negative (-) or excessively short or long, review and verify the values entered for 'Time of Event' (Watch and Dispatch times). Where entered times are transcribed accurately and calculated intervals do not make sense, the site can readjust the 'aligned' times using local knowledge of the various time sources.

Question '?' and exclamation '!' marks: A question mark '?' appears between the 'Adj' and 'time interval' columns for each aligned time that has been either adjusted or calculated by the computer algorithm. Click on the '?' to learn which event(s) were used for the computer algorithm. An exclamation '!' mark appears on a line if something obvious is missing (such as 'no 'doc time' not checked for an event with an order 1-16 and no times entered).

Buttons at the bottom of the form:

- "Sort Event Order" - Sorts events into numerical order (1-16, with 0's at end of list), but does not calculate or automatically fill aligned times.

- "Align times" - sorts events into numerical order (1-16, 0's at end of list) and moves watch time, dispatch time or a computer aligned time into the "Aligned Time" column. Pressing "Align Times" will also calculate the time intervals and cumulative time. Events with watch time only will be aligned via computer algorithm if adjacent event(s) have both a watch time and a dispatch time. When the 'Aligned Times" button is pressed, aligned times and intervals will be recalculated every time a time is modified. If this is annoying, press the 'Turn align Off' button—this will erase any previous computer aligned times and computer calculated intervals. To recalculate aligned times and intervals, again press 'Align Times'.

  A question mark ('?') between the "Adj" column and the "time interval" indicates that the time is computer aligned. Clicking on the question mark tells you which event(s) the calculated aligned time is based on.

- "Turn Align Off" – Erases any previous computer aligned times and computer calculated intervals. Intended to be used where multiple times are being modified and triggering the recalculation of aligned times and calculated intervals. This button does not erase times adjusted ('adj') by the site. To re-establish computer aligned times and computer calculated intervals (as is required to save the form without errors), again press 'Aligned Times."

- "Original Order" – this returns the rows for 'Event' and 'Event order' to the original list as displayed when the form is first opened (and on the form worksheets) and erases any

computer aligned time and calculated intervals. The most recently entered 'Event order' number(s) (0, 1-16) are not erased.

- "Reset form" – Pressing this button erases/blanks out all previously entered data on the time form so that you can start over.

Item 1 –911 Call received at primary PSAP (optional):

Time of the earliest call received at the initial public safety answering point (PSAP). This initial answering center is sometimes referred to as a primary PSAP. This center may be responsible for dispatching the EMS organized response (includes all organized EMS respondents i.e. fire and paramedics), or it may transfer 911 calls to a different (downstream) EMS or fire Dispatch location. A downstream dispatch center is often referred to as a secondary PSAP. Record the time of the earliest call received at the first public safety answering point. If no documented time is available, enter '0' for the event order, leaving time fields and 'No Doc Time' box blank.

Item 2 –1st 911 Call received at dispatch:

Time of the earliest call received at the emergency communication center responsible for dispatching a vehicle as part of the EMS organized response (includes all organized EMS respondents i.e. fire and paramedics).

For some sites, the time of earliest call received at dispatch will be different from the time the call was received at the 911 call center or primary public safety answering point (PSAP). In these cases, dispatch for EMS and fire response is downstream from the 911 call center. EMS and fire response may be dispatched from the same center or from different dispatch centers. A downstream dispatch center is often referred to as a secondary PSAP. Indicate the time the earliest call was recorded at the dispatch center, whether a primary or secondary public safety answering point.

The time a call is received at dispatch is defined in the ROC EMS Structures database and indicates if calls are recorded at 1st ring, when answered, 1st key stroke, or other. It is preferred that this time of call data be the first ring and be obtained from dispatch records and not from EMS records unless they are automatically downloaded from dispatch. Handwritten dispatch time information should only be used as a last resort.

The time a call is received at dispatch will serve as "time zero" where no time is provided for the optional field titled "911 call received at primary PSAP." Over time, "time zero" should be defined as first ring at the 911 call center.

Item 3 - 1st vehicle dispatch time:

The time recorded for when the crew of the first dispatched responding vehicle was notified. The '1st vehicle dispatch time' may or may not be associated with the vehicle that is '1st arrival at scene' .It is preferred that the requested time come from dispatch rather than handwritten EMS notes.

Item 4 –1st vehicle arrival at scene:

Autofill at web-entry: 'Time of Event' 1st vehicle arrival at scene' is filled and 'Source Disp/Defib' entered as '0' automatically IF the Patient Enrollment form has been previously completed and saved (with or without errors) with 'Time of arrival' for the 1st arriving EMS agency and the source of that time marked as 'From dispatch.' Autofilled values can be edited.

Time the first responding vehicle arrives on the scene, wheels stopped. It is preferred that this time comes from dispatch rather than handwritten EMS notes. Where the cardiac arrest is witnessed by EMS *and* the EMS provider is indicated as having 'no vehicle' (on the Patient Enrollment Form, as when an EMS provider may be stationed at the scene such as at a stadium, race, or aid station), then consider their 'arrival' as being that for the '1st vehicle arrival at scene.' The next arriving EMS responder/vehicle is handled as the 2nd arriving vehicle or the 1st ALS arrival at scene, depending on the nature of the tiered response. 1st vehicle arrival at scene may be associated with a ROC or non-ROC vehicle or 'no vehicle'.

Item 5 –1st EMS AED/defib turned on:

Autofill at web-entry: Dispatch/defib time for '1st EMS AED/defib turned on" is auto-filled IF the CPR Process form (either saved with or without errors) contains a time entered for ''Time machine turned on'. Autofilled values can be edited.

The time that the EMS responder powers on the automatic external defibrillator (AED) or monitor/defibrillator. It will be used as a surrogate for arrival of the EMS responder at patient side in cardiac arrest unwitnessed by the EMS responder.

Item 6 –1st ALS arrival at scene:

Autofill at web-entry: 'Time of Event' 1st ALS arrival at scene' is filled and 'Source Disp/Defib' entered as '0' automatically IF the Patient Enrollment form has been previously completed and saved (with or without errors) with 'Time of arrival' for the 1st arriving EMS agency with a 'Service level' marked ALS, and the source of that time marked as 'From dispatch.' Autofilled values can be edited.

Time first advanced life support (ALS) designated EMS responder arrived on scene. If arriving by vehicle, time of arrival is when the wheels stopped moving. The 1st ALS arrival at scene may be associated with a ROC or non-ROC EMS response. First ALS arrival includes those situations where ALS EMS personnel arrive by non-conventional transportation (e.g. bicycle, dog sled, golf cart) or where ALS EMS personnel are stationed/staffing a public event (e.g. marathon, football game). It is preferred that this time come from dispatch rather than handwritten EMS notes.

Item 7 –Time of arrest if EMS witnessed*:*

Auto fill at web-entry: 'Time of arrest if EMS witnessed' is filled automatically IF the Prehospital Time Record form has been previously completed and saved (with or without

errors) Auto filled values can be edited.

Time of initial cardiac arrest is used when the responding EMS or fire provider has arrived on scene prior to the onset of the cardiac arrest. For example, where EMS or fire has been called for 'chest pain' or where EMS or fire is stationed at a public even such as a marathon or football game. If a bystander began chest compressions prior to EMS or fire arrival, the patient had a pulse when EMS arrived, and the patient later arrested in front of EMS, the cardiac arrest would be considered as witnessed by EMS. If the patient was defibrillated by an AED/defibrillator used by a lay person, health care provider, police or off-duty paramedic prior to EMS arrival, the patient has ROSC upon EMS arrival, but later re-arrests in front of EMS, the cardiac arrest would not be considered EMS witnessed.

If the arrest was witnessed by the EMS or fire provider, provide a sort order (on the time record) and time (if available). If not witnessed by EMS or fire provider, leave the time blank on the CPR process form. The preferred source for this data element is voice recording (where available). The second and third preferred sources for this data element are respectively, the continuous electronic ECG and the PCR. Time AED/defib is turned on is NOT considered a surrogate for 'time of arrest if EMS witnessed.

For cases monitored with pads or electrodes: Time of arrest is the onset of ventricular fibrillation (VF) or asystole. If the potential 'arrest' rhythm is ventricular tachycardia (VT) or PEA, then, the onset of VT or PEA must be temporally associated (so as to discern a perfusing from a non-perfusing rhythm) with either voice annotation, or with chest compression or shock artifact. If VT or PEA is associated with CPR, the time of arrest is when compressions are started. If VT is associated with a shock, the time of arrest is when analysis is started.

For cases not monitored (no pads or electrodes are on patient at time of arrest; or continuous electronic recording is not available): the time of arrest is determined from the PCR (if documented time is plausible).

Item 8 –1st CA EMS rhythm:

Autofill at web-entry: Dispatch/Defib time for '1st CA EMS rhythm' is auto-filled IF the CPR Process form (either saved with or without errors) contains a time entered for " 1st CA EMS rhythm *and* the source is marked as being either continuous or snapshot ECG. Auto filled values can be edited.

Time of the FIRST interpretable cardiac arrest rhythm after confirmation of cardiac arrest and captured by an EMS responder, either ROC or non-ROC. Look for the '1st CA EMS rhythm' for up to 5 minutes after pad or electrode placement and prior to documentation of drugs given or a shock delivered by EMS or fire. EMS responder is defined as a person on duty for an organized EMS or fire agency at the time of the response. If the rhythm cannot be determined during this period, then mark 'cannot determine.' This rhythm is not one obtained by bystanders (doctors, nurses, police, off duty paramedics, off duty fire providers, and laypersons). The '1st CA EMS rhythm' cannot be a perfusing rhythm.

If the first vehicle was non-ROC EMS and you don't have access to the information, record an event order and check "no documented time".

Source of rhythm: The preferred source for capturing both the time of this event and the rhythm type is the continuous electronic ECG, but ONLY IF THIS IS THE ECG FROM THE FIRST EMS AED/DEFIB APPLIED following the cardiac arrest. The primary goal is to get the first rhythm after the arrest. The '1st CA EMS rhythm' is not necessarily obtained from the first available electronic ECG (such as when only the 2nd arriving EMS recording is available). The second preferred source is a rhythm strip recording. The third preferred source is the rhythm documented in the PCR. Use the PCR only as a last resort (such as when the first electronic download is not available). Do not use information obtained from the compression channel generated by use of a 'puck' (Philips) or from compression annotations generated by use of CPR-D pads (ZOLL, Magnified ECG or CPR Quality Calculations tabs) to determine the '1st CA EMS rhythm.

Timing of the rhythm: Look for the EARLIEST rhythm from the time the pads were placed (from the FIRST EMS defibrillator placed), within the first 10 seconds if possible. For an EMS witnessed arrest (occurring after the arrival of EMS), look for the earliest rhythm following the onset of cardiac arrest, within the first 10 seconds if possible. If the ECG during the first 10 seconds is obscured then look either during a ventilatory pause, possibly during compressions if there are QRS complexes, or at the earliest pause in CPR for rhythm analysis, then look for the '1st CA EMS rhythm' for up to 5 minutes after pad placement and prior to documentation of drugs given or a shock delivered by EMS or fire.

Length of rhythm: There is no required length of time that a rhythm must be evident (such as transitional rhythms) to be considered the '1st cardiac arrest rhythm'. Use your best judgment in determining the rhythm during even a few seconds of interpretable ECG. The objective is to capture the earliest cardiac arrest rhythm, not necessarily the rhythm that is the easiest or clearest to discern. This is recognized to be a tradeoff. Where the reviewer observes a rhythm different than that indicated by the AED analysis (shock or no-shock) or the PCR, defer to the reviewer's finding as long as careful consideration is given to which source contains the information from the first EMS or fire defibrillator placed.

EMS witnessed arrest: If pads were placed prior to the EMS witnessed arrest, determine the 1st cardiac arrest rhythm within 5 minutes (if possible, within 10 seconds) immediately following arrest and prior to documentation of drugs given or a shock delivered by EMS or fire. If pads are placed after the onset of EMS witnessed arrest, then determine the '1st CA EMS rhythm' within the 5 minutes immediately following placement of the pads or electrodes and prior to documentation of drugs given or a shock delivered.

Item 9 –1st EMS CPR:

This data element is intended to capture the time when the first chest compression was applied by a responding EMS or fire provider either non-ROC or ROC. If a non-ROC vehicle is the first EMS or fire provider and initiates CPR, but the continuous ECG recording or PCR is not available, provide the sort order for the event and indicated 'no doc time' (do not use the ROC documented time for their later provided continuation of

CPR efforts). The sort-order of the event is important even in the absence of a documented time ('watch' or 'defib/dispatch') or an inferred time ('aligned').

It is recognized that this data element is a challenge to acquire. Where possible, sites are encouraged to work with EMS agencies to standardize practices that provide accurate time documentation or surrogates for time of '1st EMS CPR'—such as employing digital timers for CPR or training them to power on the AED/defibrillator when they arrive at patient side.

Source: The preferred source for this data element is voice recording (where available, such as when the provider says "CPR was started X seconds before the machine was turned on."). The second preferred source is the continuous electronic ECG or compression channel (such as when the arrest is EMS witnessed). The third and fourth preferred sources are the PCR and inferred times (such as time '1st AED/defib turned on' plus X seconds). Provide <u>all</u> documented times and/or inferred times routinely incorporated into local practices.

<u>Watch times:</u> those written in the patient care record.

<u>Defib/dispatch times:</u> those sourced from a device time-stamped snapshot or continuous ECG. Includes times calculated from time-stamped continuous ECG with voice recording commentary—for such defib/dispatch times, enter the value with seconds left blank, with no ':00'. Defib/dispatch includes times calculated from a time-stamped compression channel (Philips) where the 'puck' is on and recording prior to onset of CPR and placement of the pads.

<u>Aligned times:</u> those derived or inferred through knowledge or assumptions made of local practice, such as presuming that CPR is started when, or 30 seconds after, the AED/defib is turned on or pads are placed.

Public Access Defibrillation: Indicate a sort order of '0' for cases where non-ROC, or ROC EMS or fire, did not initiate chest compressions (such as where a bystander AED/defibrillator successfully converted the patient to ROSC prior to EMS or fire arrival and the patient did not re-arrest requiring CPR).

EMS witnessed: For cases where the arrest is considered 'EMS witnessed' (by responding EMS or fire providers), a sort order and time (or 'no doc time') for '1st EMS CPR' is required.

Item 10 –1st EMS shock assessment:

The time when EMS or fire providers, either ROC or non-ROC, initially analyze or assess the rhythm to determine whether or not a shock is indicated. This applies even if the assessed rhythm is not VF/VT and no shock is given. For the PRIMED study, it is the intent of this data variable to determine compliance with randomization to 'analyze early' or 'analyze late' CPR assignments.

<u>AED continuous ECG:</u> The time associated with the start of the first AED analysis event, free of significant artifact and CPR. Some devices are programmed to analyze

automatically (such as when the device is powered on or pads placed) and/or initiate a shock—if the analysis is aborted (stopped) by EMS, do not consider that analysis for '1st EMS shock assessment.'

ZOLL AED Pro and E-Series in Auto Defib mode: this is the time of the first "Analysis Started" event. The AED marks when analysis starts and when the device instructs the provider as to whether a shock is needed. Use the former mark.

Medtronic AED (Lifepak 500 or 1000, and Lifepak 12 in AED mode): use 'Analysis 1' which indicates the initiation of analysis (button pushed).

Philips MRX: When in AED mode, the annotation log states "analyzing" to indicate the beginning of analysis for a shock. Use the first such notation (except where aborted by EMS) as '1st EMS shock assessment'. Where 'analyzing' is indicated (and analysis was not aborted), but the compression channel (generated by the 'puck' indicates that CPR is stopped at a later time, document the later time).

Manual defibrillator continuous ECG: The time associated with the intention of pausing CPR for the assessment of the rhythm for a determination to shock or not shock. The reviewer will have to make a judgment as to when the EMS or fire provider paused for assessment of the rhythm. This may include:

a) interruption of CPR with the intent to assess the rhythm to determine if a shock is needed (this might be a pause in the impedance tracing noting chest compressions, use of voice recordings to confirm intent, etc) or

b) Identifying the first pause in compressions > 4 or < 10 seconds in duration with no movement artifact (a pause in compressions of 4-10 seconds is "presumed ventilation pause" per the ROC PRIMED protocol), or

c) If the intent is not apparent, use a combination of the information on the PCR, EMS questionnaire, or other resource to try to determine when the first rhythm assessment occurred to assess whether or not a shock was indicated. If no times are available, determine and provide at least the order of events.

Timing of event: The time of '1st EMS shock assessment' associated with different events depending on the response scenario. The time of '1st EMS shock assessment' may:

a) be same time as the '1st CA EMS rhythm' when the initial EMS shock assessment is conducted close to the time of EMS AED pad or manual defibrillator electrode/pads placement, OR when ALS arrives first on scene with a manual defibrillator (such as a Lifepak 10 or 12).

b) Occur shortly (about 30 seconds) after CPR is started (such as 'analyze early' in the ROC PRIMED trial) or immediately after an arrest when witnessed by EMS (if pads or electrodes were placed prior to the arrest).

c) Occur several minutes (about 3 minutes) after pads are placed when a ROC vehicle is first on scene, places the initial pads, and EMS CPR is prescribed for 3 minutes (such as 'analyze late' in the ROC PRIMED clinical trial).

Source of data: The preferred source for '1st EMS shock assessment' time is the AED event report or the continuous electronic ECG. The second preferred source is documentation in the PCR of a shock advised or not advised. If no continuous electronic ECG is available the reviewer must carefully review the PCR, additional written EMS or fire provider worksheets, or even phone calls to EMS or fire (document such calls in the research file) to determine if the AED shocked or did not shock the FIRST RHYTHM during the FIRST ANALYSIS following arrival of the organized EMS response. If no times are available the site should determine and provide at least the order of events.

Cases where impedance is missing: For Medtronic and Philips manual devices the EMS or fire provider might switch to a monitoring mode (or Lead II) where impedance tracings are not collected which might make it difficult to determine when the shock assessment occurred. For Medtronic cases where the mode has been switched the reviewer cannot collect further CPR process information. For Philips the reviewer might be able to see the compression activity but there are no statistics reported so sites should just end the reporting of these measures rather trying to calculate by hand.

In sites with an all ALS response team the recommendation would be to continually educate the EMS regarding the need to have the machine in the mode necessary to capture CPR process data (Medtronic—'paddles mode', Philips—'defib mode').

Item 11 –1st EMS Shock:

The time when the first shock is delivered by EMS responder to patient with a shockable rhythm. This does not include shocks delivered by lay responders AED/defibrillators (including those at satellite healthcare facilities such as day-surgery, dialysis centers, or cruise ships) prior to arrival of the organized EMS response. The 1st EMS Shock may or may not be associated with the 1st EMS shock assessment.

Item 12 –1st ROSC:

The time when return of spontaneous circulation (ROSC) is first detected by a palpable pulse in any vessel for any length of time. This is intended to include the onset of ROSC (either transient or sustained) *prior to or after* the arrival of organized EMS response. Where time is unknown, provide 'Event Order' and leave time blank.

Item 13 –Resus. Stopped due to death:

Time when chest compressions were finally discontinued, efforts at care or resuscitation are ceased, and the patient is presumed dead. This does not include the discontinuation of chest compressions when the patient has been successfully resuscitated.

Item 14–Patient transported from scene:

The time when patient was transported from the scene (when vehicle starts moving).

Item 15 –Transferred to aero-medical:

If patient transferred to care of aero-medical unit, indicate the time.

Item 16 –ED or EMS destination arrival:

Time when vehicle transporting the patient arrived at the emergency department or hospital is the point when the wheels of the vehicle stop moving.

Name of person responsible for data on this form:

Name of the individual that logged into the electronic data transmission system for clinical study forms or to execute batch up-load of files. This individual will have registered as a member with the CTC for the purpose of participating as a coordinator or investigator in a ROC clinical trial and has designated a user name and password as their "Electronic Signature." The individual has agreed to consider their electronic signature as equivalent to their handwritten signature, to maintain the confidentiality of their user name and password, and to not let others use it. Refer to the "Electronic Signature Agreement" (accessed after logging on to the ROC website) posted at https://roc.uwctc.org/tiki/roc-data-entry.

After verifying the entered data and electronic signature are correct, print the web-forms for your files, or convert the web-forms to pdf format and store electronically. Edits made later to the original web-entered forms or batch up-loaded data posted to forms are associated with the electronic signature of the individual making the changes and are documented in the file's edit history.

Pre-Hospital Time Record –Trauma

The purpose of the Pre-hospital Time Record-Trauma form is to determine the correct times and sequence of events. The items listed in the time record are the typical events that would occur when a call is received at dispatch for a potential traumatic injury.

Event Order: For all the items below, provide the event order (1-9), Watch (PCR) time (on 24 hour clock, hh:mm:ss), and/or Dispatch time (on 24 hour clock, hh:mm:ss) for each event that occurred during the course of prehospital care. If an event did not occur during the course of prehospital care, enter '0' for that event order (e.g. If the patient survived to ED, then 'Resus. Stopped due to death" should have an event order of '0'). Enter the event order as '0' for '911 call received at primary PSAP' if no documented time exists. If more than one event is documented as having occurred at the same time, provide the same event order for the two or more events. Where local practice is to provide identical times for known serial events, distinguish those with true identical times and provide data; for the remaining events provide plausible event orders based on recorded narrative, leave related time fields blank, and mark 'no doc time.' Where an event order is determined to be the same for two or more events *and* the watch times for each is different (such as might occur if more than one wristwatch were used on the scene), you are asked to confirm this condition and override the error message. Where an event order is determined to be the same for two or more events and provided times are sourced from the same dispatch/defib, it is expected that the provided times should be the same. The order of events can be re-sorted to the chronological order entered by pressing the 'Sort Event Order' or 'Align Times' buttons.

If you left out an item in the event order, it is not necessary to reorder all the affected lines—instead give the overlooked event a decimal number to place it between two existing numbers (such as 2.5 to place the event between the previously entered event 2 and 3). When the 'Sort Event Order' or 'Align Times' button is clicked, all events will be resorted and numbered to accommodate the decimal entry. NOTE: where the event orders have been changed, all previously 'aligned' times and intervals will be removed. Click the 'Align Times' button for recalculation of the aligned times and intervals.

Time of Event: Watch time is that documented on the patient care record by the EMS provider, likely having been sourced from a wristwatch or clock. Dispatch time is that provided by the dispatch log or where site/agency protocol requires EMS to routinely contact Dispatch to acquire the time(s) documented on the PCR. For each event with an event order of 1-9, provide either the Watch or Dispatch times when available. Where a time has been documented in the patient record as hh:mm, leave the seconds ('ss') field blank, do not enter '00'. If no documented time exists (from either the PCR or dispatch) for a specific event (with event order 1-9), check the 'No Doc Time' box and leave the associated time fields blank. For events with a '0' sort order, leave the Watch and Dispatch time columns blank and do not check 'no doc time'.

Dispatch times are generally documented as hh:mm:ss. Sites are encouraged to work with their Dispatch services to acquire 911 call times with seconds. Where no seconds are provided, leave the seconds ('ss') field blank, do not enter '00'.

For event times that appear to be affected by the crossing of a time zone or daylight savings time, enter the time documented in the PCR or dispatch log. Do not adjust the times entered for the 'Time of Event.' Adjustment of times is reserved for the 'Aligned Time' column when assessing time intervals and cumulative times.

Aligned Time and Adj: This column is filled automatically when the 'Align times' button is pressed. A computer algorithm assesses times entered for 'Time of Event'. The algorithm moves Dispatch times (Source marked as '0') over to the 'Aligned time" column. Events with watch time only are aligned (adjusted) where adjacent events provide both a watch time and a dispatch time for comparisons (much like a Rosetta stone). A '?' to the right of the 'Adj' column indicates those times that have been adjusted (aligned) by the computer algorithm. Click on the '?' to learn which event(s) the 'Aligned time' is based upon. You may manually adjust the 'Aligned time' where knowledge of the EMS system or judgment of EMS documentation suggest an aligned time other than that provided by the computer algorithm. Aligned times are not filled or calculated for events where neither a Watch or Dispatch time is provided—aligned time fields are left blank. The site is encouraged, where reasonable surrogate information allows, to provide aligned times for blank fields (such as when EMS did not document their arrival at the ED, but the site knows what time the patient was admitted to the ED/hospital).

The 'Adj' box is automatically checked when you replace an aligned time (that was automatically filled) with a time judged to better represent the episode course of prehospital care.

Use the 'Adj' column to adjust for times that appear to be affected by the crossing of a time zone or daylight savings time—calculate the time difference imposed (such as +1 hour, -1 hour) on any of the 'Time of Event' times and adjust the time to reflect the 'true' time in the 'adj' column.

Time Interval and Cumulative time: Time interval and cumulative times are calculated and filled automatically when the 'Align time' button is pressed. Review the calculated time intervals to assess if they 'make sense'. Where calculated time intervals are either negative (-) or excessively short or long, review and verify the values entered for 'Time of Event' (Watch and Dispatch times).

Question '?' and exclamation '!' marks: A question mark '?' appears between the 'Adj' and 'time interval' columns for each aligned time that has been either adjusted by the data entry person or calculated by the computer algorithm. Click on the '?' to learn which event(s) were used for the computer algorithm and/or if the aligned time was replaced. An exclamation '!' mark appears when an 'Event Order' is marked '0' (NA), but a time of event has been entered.

Buttons at the bottom of the form:

- "Sort Event Order" - Sorts events into numerical order (1-16, with 0's at end of list), but does not calculate or automatically fill aligned times.

- "Align times" - sorts events into numerical order (1-9, 0's at end of list) and moves watch time, dispatch time or a computer aligned time into the "Aligned Time" column. Pressing

"Align Times" will also calculate the time intervals and cumulative time. Events with watch time only will be aligned via computer algorithm if adjacent event(s) have both a watch time and a dispatch time. When the 'Aligned Times" button is pressed, aligned times and intervals will be recalculated every time a time is modified. If this is annoying, press the 'Turn align Off' button—this will erase any previous computer aligned times and computer calculated intervals. To recalculate aligned times and intervals, again press 'Align Times'.

A question mark ('?') between the "Adj" column and the "time interval" indicates that the time is computer aligned. Clicking on the question mark tells you which event(s) the calculated aligned time is based on.

- "Turn Align Off" – Erases any previous computer aligned times and computer calculated intervals. Intended to be used where multiple times are being modified and triggering the recalculation of aligned times and calculated intervals. This button does not erase times adjusted ('adj') by the site. To re-establish computer aligned times and computer calculated intervals (as is required to save the form without errors), again press 'Aligned Times."

- "Original Order" – this returns the rows for 'Event' and 'Event order' to the original list as displayed when the form is first opened (and on the form worksheets) and erases any computer aligned time and calculated intervals. The most recently entered 'Event order' number(s) (0, 1-9) are not erased.
- "Reset form" – Pressing this button erases/blanks out all previously entered data on the time form so that you can start over.

Item 1 –911 Call received at primary PSAP (optional):

Time of the earliest call received at the initial public safety answering point (PSAP). This initial answering center is sometimes referred to as a primary PSAP. This center may be responsible for dispatching the EMS organized response (including all organized EMS respondents i.e. fire and paramedics), or it may transfer 911 calls to a different (downstream) EMS or fire Dispatch location. A downstream dispatch center is often referred to as a secondary PSAP. Record the time of the earliest call received at the first public safety answering point.

Item 2 –1st 911 Call received at EMS dispatch:

Time of the earliest call received at the emergency communication center responsible for dispatching a vehicle as part of the EMS organized response (including all organized EMS respondents i.e. fire and paramedics). For some sites, the time of earliest call received at dispatch will be different from the time the call was received at the 911 call center or primary PSAP. In these cases, dispatch for EMS and fire response is downstream from the 911 call center. EMS and fire response may be dispatched from the same center or from different dispatch centers. A downstream dispatch center is often referred to as a secondary PSAP. Indicate the time the earliest call was recorded at the dispatch center, whether a primary or secondary public safety answering point.

The time a call is received at dispatch is defined in the ROC EMS Structures database and indicates if calls are recorded at 1st ring, when answered, 1st key stroke, or other. It is preferred that this time of call data be the first ring and be obtained from dispatch records and not from EMS records unless they are automatically downloaded from dispatch. Handwritten dispatch time information should only be used as a last resort.

The time a call is received at dispatch will serve as “time zero” where no time is provided for the optional field titled “911 call received at primary PSAP.” Over time, “time zero” should be defined as first ring at the 911 call center.

Item 3 - 1st vehicle dispatch:

The time recorded for when the first responding vehicle was notified by dispatch. It is preferred that this time comes from dispatch rather than handwritten EMS notes.

Item 4 –1st vehicle arrival at scene:

Autofill at web-entry: 'Time of Event' 1st vehicle arrival at scene' is filled automatically IF the Patient Enrollment form has been previously completed and saved (with or without errors) with 'Time of arrival' for the 1st arriving EMS agency and the source of that time marked as 'From dispatch.' Autofilled values can be edited.

Time the first responding vehicle arrives on the scene, wheels stopped. It is preferred that this time comes from dispatch rather than handwritten EMS notes.

Item 5–1st ALS vehicle arrival at scene:

Autofill at web-entry: 'Time of Event' 1st ALS arrival at scene' is filled automatically IF the Patient Enrollment form has been previously completed and saved (with or without errors) with 'Time of arrival' for the 1st arriving EMS agency with a 'Service level' marked ALS, and the source of that time marked as 'From dispatch.' Autofilled values can be edited.

Time first advanced life support (ALS) designated EMS responder arrived on scene. If a arriving by vehicle, time of arrival is when the wheels stopped moving. The 1st ALS arrival at scene may be associated with a ROC or non-ROC EMS response. First ALS arrival includes those situations where ALS EMS personnel arrive by non-conventional transportation (e.g. bicycle, golf cart) or where ALS EMS personnel are stationed/staffing a public event (e.g. marathon, football game). It is preferred that this time come from dispatch rather than handwritten EMS notes.

Item 6 –Transferred to aero-medical:

If patient transferred to care of aero medical unit, indicate the time.

Item 7 –Resuscitation terminated:

Time when the patient is presumed dead and chest compressions or efforts at care or resuscitation were finally discontinued. This does not include the discontinuation of

resuscitative efforts when the patient has been successfully resuscitated.

Item 8 –Patient transported from scene:

Time when patient was transported from the scene, vehicle starts moving.

Item 9 –EMS Destination (ED) arrival:

Time when vehicle transporting the patient arrived at the emergency department or hospital is the point when the wheels of the vehicle stops moving.

Name of person responsible for data on this form:

Name of the individual that logged into the electronic data transmission system for clinical study forms or to execute batch up-load of files. This individual will have registered as a member with the CTC for the purpose of participating as a coordinator or investigator in a ROC clinical trial and has designated a user name and password as their "Electronic Signature." The individual has agreed to consider their electronic signature as equivalent to their handwritten signature, to maintain the confidentiality of their user name and password, and to not let others use it. Refer to the "Electronic Signature Agreement" (accessed after logging on to the ROC website) posted at https://roc.uwctc.org/tiki/roc-data-entry.

After verifying the entered data and electronic signature are correct, print the web-forms for your files, or convert the web-forms to pdf format and store electronically. Edits made later to the original web-entered forms or batch up-loaded data posted to forms are associated with the electronic signature of the individual making the changes and are documented in the file's edit history.

Pre-Hospital Data –Cardiac Arrest and Trauma

The purpose of the Pre-Hospital Data-Cardiac Arrest & Trauma form is to collect information from the time the patient was seen in the field through the time that the patient either died or arrived at the emergency department or was admitted to the hospital. The information for the form will come from the pre-hospital PCR and dispatch, with the possibility of other information from family members or witnesses, depending on the episode and site.

The episode date/time and episode ID will be pre-filled by the web data entry program and will be consistent with the date and time recorded earlier on the Patient Enrollment form. Pre-filled data should be reviewed for accuracy.

Item 1 - Location of episode:

a. Location: Identify location of the episode using census tract, latitude/longitude (lat/long), or Universal Transverse Mercator (UTM) location types. Select one location type for an episode and provide the related coordinates. A site may use different location types for different episodes. Mark unknown/not noted when no location of episode can be identified, despite concerted efforts. It is the responsibility of each ROC site to comply with local and governing privacy requirements and to report location of episode only to the limit allowed.

Census tract: For the United States, go to http://www.ffiec.gov/geocode/default.htm. Select 'year' as 2006. For each episode enter the street address along with the city and state or the zip code. If the episode occurred at an intersection and you do not have the exact address, enter the name of the intersection (N.E. 45th and 11th Ave. N.E.) where it asks for the street address on the 'ffiec geocoding system web-page.'. Once the information has been entered, click the 'Search' button. This connects to the 'Geocode Search Result' page where state code, county code, and tract code numbers are identified in red. The web-site provided MSA/MD code is not entered into Epistry. For state code, enter 2 digits (01-99). For county code, enter 3 digits (001-999, including leading and trailing zeros). For tract code, enter 6 digits including decimal (1234.56, including leading and trailing zeros). Mark unknown/not noted if state-county-tract codes are not found despite efforts to provide complete address or intersection information and alternate location of episode location types (lat/long, UTM) are not available.

For Toronto: CTName and CTUID are each an expression of census tract location in Canada and can be derived by conversion of local postal codes using specialized software. 'CTName' data format is restricted for location of episodes that occur within metropolitan Toronto. 'CTUID' data format can be used for any location within Canada, including metropolitan Toronto.

CTName—use of this number format is restricted to metropolitan Toronto. Just as a telephone number is unique only when preceded by an area code, CTName is a unique locator only when preceded by a Census Metropolitan Area/Census Agglomeration (CMA/CA) number. Thus, the CTName data format is *restricted* to use for a known area (that of metropolitan Toronto) because of the absence of a preceding CMA/CA number (see below CTUID description). For metropolitan Toronto CTName,

enter 6 digits (1234.56) including decimal point and all leading and trailing zeros. Note: Toronto CTName is provided at local request, and is not intended to limit Toronto from using other formats for providing location of episode (CTUID, lat/long, or UTM location).

CTUID—This is a unique combination of CMA/CA and CTName numbers and is available when converting a Canadian postal code to census tract format. For CTUID, enter 9 digits (1234567.89) including decimal point and all leading and trailing zeros. The first 3 digits of the of the CTUID indicate the unique CMA/CA location—for example, Toronto CMA/CA is 535, Hamilton CMA/CA is 537. So, a Hamilton CTUID would be formatted as 537XXXX.XX

Lat/long (latitude/longitude:

Latitude/longitude is a coordinate system to locate a position on the earth, expressed in degrees (relative to a full circle). Latitude runs north/south. Longitude runs east/west. Select which of three (3) data formats the lat/long coordinates are being provided: decimal degrees (DD), DM (degrees:minutes), or DMS (degrees:minutes:seconds or 12:12:12). The most common format is decimal degrees (example: 123.1234) and is recommended for ROC data entry. The latitude and longitude for an episode must be reported in the same format. No directional designate (north, south, east, west, or '-' sign) is required as all ROC sites are within North America.

Decimal degrees—the most common format for lat/long. In its most precise form, decimal degrees is expressed as 123.123456. For privacy purposes, decimal degrees are rounded (up or down) and reported for ROC to a maximum of four decimals (123.1 to 123.1234, including all leading zeros). No directional designate or '-' sign are to be included. Where local rules to protect privacy restrict lat/long to be reported to less than 4 decimals (as in British Columbia).

DM or Degrees:minutes—for latitude, enter 5 characters including colon and no spaces (such as 49:30 or 49:03, designating 30 minutes and 3 minutes respectively). Do not provide decimal place values (such as 49:30.24 is reported as 49:30). For longitude, enter 5-6 characters including colon and no spaces (such as 122:20, 79:24, 114:01 or 96:46 designating 20, 24, 1, and 46 minutes respectively).

DMS or Degrees:minutes:seconds—it is rare that this lat/long format would be used. Contact the CTC to discuss if this report format is contemplated or preferred over the decimal degrees format.

Datum (or map datum)--this is the topographic map standard to which the lat/long coordinates are applied. There are three map datums used in the western hemisphere: NAD27 (North American Datum 1927), NAD83 (North American Datum 1983), and WGS84 (World Geodetic System 1984, based on satellite measurements). There is a measurable difference between the map datums, and thus important to know the source for measurements for later geographic analyses.

UTM (Universal Transverse Mercator):

The UTM coordinate system is a grid-based method to identify a location on the earth. Unlike lat/long coordinates, the UTM coordinate system divides the surface of the earth into zones, or uniform grid squares, each identified by a number (North America is assigned numbers 7 through 21) and a letter. The location of a position within a zone is expressed by using both 'easting' and 'northing' values, and are expressed in either meters or kilometers units of measure.

Easting—this is the projected distance within the zone. Provide the first 3 (kilometers) or 6 (meters) digits of the 'easting' coordinate. Do not round. Instead, truncate the number to the required field length (e.g. 821.8 km is entered as 821, *not* 822). Indicate the units of measure. Where local privacy guidance restricts coordinates to less than 3 (kilometers) or 6 (meters) digits, truncate the number and replace with '0's' (e.g. 828 km is entered as 820 or 800).

Northing—this is the projected distance from the equator and can be expressed in meters or kilometers (most common) units of measure. Provide the first 4 (kilometers) or 7 (meters) digits of the 'northing' coordinate. Do not round. Instead, truncate the number to the required field length (e.g. 8218.68 km is entered as 8218, *not* 8219). Indicate the units of measure. Where local privacy guidance restricts coordinates to less than 4(kilometers) or 7 (meters) digits, truncate the number and replace with '0's' (e.g. 8218 km is entered as 8210 or 8200).

Zone—the UTM designated grid area associated with the provided 'easting' value. Provide the one or two digit zone number (it is anticipated that ROC sites would provide a number ranging 10 to 18) *without* the associated letter (e.g. Zone 17N is entered as 17; the 'N' is not required for the ROC footprint).

b. Public or non-public: Indicate whether or not the location of the episode occurred in a public or non public setting. For either public or non-public, select one description from the lists provided that best describes the location of the episode.

Public (check one only)

Street/highway: includes highway, alley, road, public thoroughfare, and NEMSIS 1160.

Public building: includes schools and their playground/athletic fields, government offices and NEMSIS 1165.

Place of recreation: includes park, stadium, lake and NEMSIS 1155 place of recreation or sport.

Industrial place: includes factory, warehouse, construction site, and NEMSIS 1150 industrial place and premises, and NEMSIS 1145 mine and quarry.

Other public property: includes sidewalk, store, church, restaurant, bar, hotel, and NEMSIS 1170 trade or service. Also includes train tracks.

Non public (check one only)

Home residence: includes inside or immediately surrounding the apartment, home/mobile home/farmhouse, garage, yard, garden and NEMSIS 1135 home/residence. Also includes adult family home and shelters for the homeless.

Farm/ranch: includes farm land, pasture, barn or other outbuilding and NEMSIS 1140.

Healthcare facility: includes hospital, medical clinic, and NEMSIS 1175. Does not include nursing home (note that NEMSIS includes this in both 1175 and 1180)

Residential institution: includes assisted living, nursing home, jail, and NEMSIS 1180 residential institution.

Other private: those private locations not included above.

Item 2 –Demographics:

a. Age:

Provide patient's age. Indicate if calculated from date of birth or estimated by EMS. Enter a whole (integer) number and indicate if expressed in years, months, or days. Use "years" for subjects ≥ 3 years of age; use "months" for subjects ≥ 1 month of age and up to 35 months (< 3 years) old, rounded to the nearest whole month; and use "days" for subjects < 1 month of age. For subjects less than 1 day old, enter "0".

If age is not estimated or calculated, provide the approximate age of the patient using the list provided: Infant (if < 1 year); Child (1-11 years); Adolescent (12-19 years); Adult (20-39 years); Middle age (40-60 years); Older (61-75 years), or Elderly (> 75 years); or unknown/not noted

b. Gender:

Indicate "male," "female," or unknown/not noted.

c. Race/Ethnicity:

Check all that apply from the list provided. Where self-identification is not feasible or appropriate, attempt to determine ethnicity and race or multiple races.

Definitions:

Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin. The term, "Spanish origin," can be used in addition to "Hispanic or Latino." Includes NEMSIS 690.

White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa. Includes NEMSIS 680.

African-American/Black: A person having origins in any of the black racial groups of Africa.

Terms such as “Haitian” or “Negro” can be used in addition to “Black or African American.” Includes NEMSIS 670.

American-Indian/Alaska Native: A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. Includes NEMSIS 660.

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. Includes NEMSIS 665.

Native Hawaiian/Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. Includes NEMSIS 675.

Other: Identifiable race/ethnicity not described above. Includes NEMSIS 685.

Unknown/Nothing noted: EMS provider is not able to determine the patient’s race and ethnicity and notes it in the patient care record, or information has not been recorded. Includes NEMSIS -10, -5, -15.

Item 3 –Pre-hospital intervention:

Mark 'No EMS prehospital interventions from the list below were recorded' where no one item in the provided list has been documented or interpreted as having occurred as part of the EMS response protocol. Mark this option only when full documentation for the organized EMS response is available to the ROC coordinator (such as both the BLS and ALS record).

For each listed intervention, mark 'done' if the procedure was 'attempted (performed) by EMS responders during the pre-hospital course of care. Indicate 'NA/NR' (not available or not recorded) if the procedure was not recorded in the patient care record or was not part of the EMS response protocol.

Where only partial documentation is available to the ROC coordinator (as where a non-ROC BLS or ALS was first on scene or where the ALS or the BLS record is missing), mark those prehospital interventions that available documentation indicates were 'done.' Mark 'NA/NR' for interventions that available and skill-related documentation (e.g. BLS record missing, but ALS record available and indicates no IV/IO line was started) is available. Leave both 'NA/NR' and 'done' blank for a prehospital intervention for which the skill-related documentation (e.g. BLS record is available, but ALS record is missing so 'IV/IO line' and 'airway, advanced' might be left blank)–then, override the error message and indicate which documentation is missing. Where only partial documentation is available, do not mark 'no prehospital interventions recorded'.

<u>Definitions for pre-hospital interventions:</u>

Airway, bag-mask: patient ventilation is assisted with a face mask and anesthesia bag (with or without oxygen)

Airway, advanced: If airway advanced: check all methods that were attempted or used:

Combitube/LMA/EAO (or other supraglottic airway) includes combitube (NEMSIS 96.051), laryngeal mask airway (NEMSIS 96.052), EOA/EGTA (NEMSIS 96.030).

Oral ET: oral endotracheal tube (NEMSIS 96.040).

Cricothyrotomy: includes needle cricothyrotomy (NEMSIS 31.110) and surgical cricothyrotomy (NEMSIS 31.120).

Ventilator: airway ventilator (NEMSIS 96.700).

Nasal ET: nasal endotracheal tube (NEMSIS 96.041).

CPAP: continuous positive airway pressure (NEMSIS 93.900).

RSI: rapid sequence intubation (NEMSIS 96.042). RSI is indicated if the PCR includes charted evidence of step-wise series of three drugs (sedative, analgesic, and paralytic) coupled with an attempt to intubate.

CPR: Attempted cardiopulmonary resuscitation (NEMSIS 99.600).

Hemorrhage control: Includes direct pressure, pressure dressings, tourniquets, MAST (medical/military anti-shock trousers, NEMSIS 93.580).

Hypothermia: marked when one or both of the listed Hypothermia procedures is attempted by EMS*Optional*: indicate the method(s) of hypothermia therapy that were attempted in the pre-hospital setting. External includes ice packs, ice on head. Internal includes cold IV fluids.

IV/IO line: marked when one or both of the listed Intravascular line procedures is attempted by EMS—IO (intra-osseous NEMSIS 41.920, 41.921) or IV (intravenous NEMSIS 38.991, 38.992, 39.995, 39.996, 38.993, 38.994, 89.620). Indicate if fluid was given (hung) via the attempted IV/IO routes—select either no, unknown/not noted, TKO (to keep open), or yes (where measurable volumes of fluid types are recorded).

Optional: if yes, IV/IO fluid was given, indicate which type of fluid was hung and the total volume (expressed in milliliters) of each that was infused.

Monitor, advanced: Marked when one or more of the listed advanced monitoring procedures is attempted by EMS—12-lead ECG (NEMSIS 89.820); EtCO2 (end-tidal CO2, includes NEMSIS 96.991), and pacing (external cardiac pacing, NEMSIS 99.624).

Item 4 –Disposition:

Indicate the patient's status at the conclusion of the pre-hospital course of care, whether died at scene or enroute; was transported by EMS to the ED/hospital; or was alive and not transported by EMS to the ED/hospital. If "Died at scene or enroute" indicate whether or not the patient was treated by EMS as part of an organized response. For either 'treated by EMS' or 'not treated by EMS' indicate why treatment was withheld or halted, either: considered futile; a written or verbal do not resuscitate directive (DNR) was presented; or

the patient was obviously dead.

If 'transported by EMS to ED/hospital with ROSC or ongoing resuscitation', indicate the method of transport and the status of the patient upon ED arrival. Where a patient is transported by both land and air, mark 'air'. Indicate the patient status at ED arrival, either: presence of ROSC (patient is alive with no CPR in progress); resuscitation efforts (CPR) are ongoing; or the patient status is unknown/not noted. 'ROSC present' is intended to include any patient with a pulse at ED arrival/wheels stopped. For trauma patients who did not have a loss of pulse during the course of care, mark 'ROSC present' to indicate the presence of a pulse at ED/hospital arrival. This data element is not intended to capture the recovery of ROSC between the ED/arrival/wheels stopped and the ED door (such as might occur on the ramp to the ED).

Definitions relating to Disposition response options:

Died at scene or enroute: includes NEMSIS 4820.

Considered futile: Withholding or termination of care at discretion or with judgment by the responder and/or medical control. May include a “10-99 called in field”. May include patients with end stage disease (such as cancer, advanced liver failure) and/or poor prognosis.

DNR (written or verbal): Directive to not resuscitate the patient, either verbal or in writing, by the patient, family, or guardian. Includes NEMSIS 2650, 2660, 2655, 2645.

Obviously dead: Includes patients with rigormortis, lividity, or decapitation. Where applicable, includes 'Legally Dead as per local legislation' as defined by local or state legislation.

Transported By EMS to ED/Hospital with ROSC or ongoing resuscitation: Transported alive or with resuscitative efforts in progress, includes NEMSIS 4850. Indicate if patient was transported by land or air. Where a patient has been transported by both land and air, select Air.

Alive and not transported by EMS to ED /Hospital: The patient either remained at scene or was transported by non-EMS means, such as by law enforcement or private vehicle. Includes NEMSIS 4855, 4860, 4840.

Name of person responsible for data on this form:

Name of the individual that logged into the electronic data transmission system for clinical study forms or to execute batch up-load of files. This individual will have registered as a member with the CTC for the purpose of participating as a coordinator or investigator in a ROC clinical trial and has designated a user name and password as their "Electronic Signature." The individual has agreed to consider their electronic signature as equivalent to their handwritten signature, to maintain the confidentiality of their user name and password, and to not let others use it. Refer to the "Electronic Signature Agreement" (accessed after logging on to the ROC website) posted at https://roc.uwctc.org/tiki/roc-data-entry.

After verifying the entered data and electronic signature are correct, print the web-forms for your files, or convert the web-forms to pdf format and store electronically. Edits made later to the original web-entered forms or batch up-loaded data posted to forms are associated with the electronic signature of the individual making the changes and are documented in the file's edit history.

Pre-Hospital Data –Cardiac Arrest

Item C1 –Cardiac Arrest occurred:

Indicate if the cardiac arrest or collapse occurred before or after (includes witnessed by EMS) the arrival of the organized EMS response (includes fire BLS response). Organized EMS response includes those EMS responders that are stationed at an arena or public event (such as a marathon, football game, parade). If the cardiac arrest occurred before arrival of the organized EMS response, indicate if the arrest was either: witnessed (either seen or heard) by non-EMS responders (e.g. Family, lay persons, or police); not witnessed (either seen or heard); or unknown/not noted. A witnessed arrest is known to be a key element associated with cardiac arrest outcome.

Definitions for witnessed cardiac arrest:

After EMS (includes fire) arrival/witnessed by EMS: limited to a cardiac arrest or collapse that is witnessed by an EMS responder that is part of an organized EMS response to this episode. Includes cardiac arrest after EMS arrival (NEMSIS 2245). Does not include police.

Witnessed (seen or heard) by someone other than EMS – includes those instances where a cardiac arrest or collapse is witnessed by a lay person, a healthcare provider, or EMS or Fire provider who are off duty and not part of the organized EMS response to this episode. Includes police, off-duty EMS, and healthcare provider prior to EMS arrival (NEMSIS 2310), and Lay person (NEMSIS 2315), and cardiac arrest prior to EMS arrival (NEMSIS 2240).

Not witnessed –not witnessed prior to EMS arrival (NEMSIS 2320).

Unknown/not noted—includes not known NEMSIS -10.

Item C2 –EMS Chest Compressions:

Indicate if member(s) of the organized EMS response (including fire) performed chest compressions. If yes, indicate what method(s) chest compressions were used during the course of patient care, either or both manual and mechanical (i.e. thumper, AutoPulse).

Item C3 –Was resuscitation attempted by bystanders?

Indicate if attempts at CPR (chest compressions and/or ventilations) or AED/defibrillator was applied by a bystander prior to arrival of the organized EMS response. A bystander is defined as any person who responds and is NOT on duty with an EMS agency at the time of the arrest. Bystanders include doctors, nurses, police, off duty paramedics, off duty fire providers, and laypersons. This also includes healthcare providers at satellite healthcare facilities such as day surgery, dialysis centers, nursing homes, assisted living and cruise ships.

Where resuscitation was attempted, indicate if CPR was attempted and if a bystander (such as lay or public access) AED was applied. Where shock was delivered, characterize the bystander that applied the AED/defibrillator (lay person, police, healthcare, other, or unknown). Indicate if the bystander applied AED delivered shocks to the patient (yes, no, unknown).

Item C4 –Drug therapies noted:

Indicate which of the listed drugs were administered at any time during the pre-hospital EMS course of care. Suspected extravasation of a drug is considered to have been administered. Check all listed drugs that apply. Where only partial EMS documentation is available to the ROC coordinator (as where the ALS or BLS record is missing), mark 'yes' or 'NA/NR' for those drug therapies for which skill-related (such as the ALS patient care record) documentation is available. Leave 'NA/NR' and 'yes' blank for a prehospital drug therapy for which the skill-related documentation is missing—then override the error message and indicate which documentation is missing. It is not intended that medications administered prior to arrival of the organized EMS response be listed (e.g. Where a cardiac arrest occurs at a day-surgery facility or on a cruise ship, attending medical staff might administer epinephrine prior to arrival of the organized EMS response—this epinephrine would not be listed as Epistry pre-hospital data; epinephrine later administered by EMS would be listed).

For each drug given (note required or optional data elements) provide the total dose administered and all routes used.

Total Dose is the sum of all doses of a drug administered during the course of pre-hospital care, regardless or the route of administration. Doses are expressed in milligrams (mg) for epinephrine, amiodarone, atropine, lidocaine, naloxone, calcium, magnesium, and procainamide; milliequivalents (mEq) for sodium bicarbonate; grams (g) for dextrose; and international units (IU) for vasopressin.

Route of administration: Check all that apply for a given drug-- intravenous (IV) (NEMSIS 4205); endotracheal tube (ETT) (NEMSIS 4175); intra-osseous (IO) (NEMSIS 4191), or drip (as for a titration)

Reporting requirements for Drug therapies are divided into four categories:

I. *Drug/dose/route required*: Indicate if Epinephrine was administered at any time during course of pre-hospital care. If so, provide the total dose administered (mg) and the route(s) it was given.

II. *Drug required and dose/route optional:* Amiodarone, Atropine, Sodium bicarbonate, Lidocaine.

III. *Drug/dose/route optional:* Calcium, Dextrose, Magnesium, Naloxone, Procainamide, Vasopressin.

IV. *Drug class optional:* Inotropes (includes dopamine, dobutamine, isoproterenol), paralytics (includes succinylcholine, pancuronium, vecuronium).

Item C5 –Etiology of arrest: Field Classification:

Where EMS responders are provided a dedicated location on the PCR to record their impression of the etiology of arrest, indicate their recording as either 'no obvious cause' (includes presumed cardiac NEMSIS 2250) or 'obvious cause'. If a cause of arrest is recorded by EMS in the PCR's dedicated location (not in the narrative) as presumed to be other than cardiac etiology, go to column A ('Field classification') and select the one recorded 'obvious cause' of arrest. It is intended that the EMS designation for etiology of arrest be taken at face value and is not to be translated by the obvious cause definitions provided for later site classification of etiology of arrest. If the recorded cause of arrest is not listed in Column A, mark 'other obvious cause' and specify (60 characters). It is not intended that contributing factors or circumstances be here recorded.

Where the PCR does not provide a dedicated location to record the field EMS impression of the etiology of arrest, mark 'No field classification, do not complete column A ('Field classification') and move to question C6, 'Etiology of arrest: Site classification'.

Item C6 –Etiology of arrest: Site Classification:

Indicate the apparent cause of arrest, either 'obvious' or 'no obvious', based only on information documented in the pre-hospital care record. It is anticipated that the majority of arrests will fall into the 'no obvious cause' category and will include those cases that are presumed cardiac (NEMSIS 2250) or do not clearly fit in any of the 'obvious cause' categories listed in column B (site classification) and defined below. The selected site classification for etiology of arrest may differ from that documented for the 'field classification.' The field classification will have been documented based upon local provider protocol, definitions, and/or habit. The site classification will be based upon interpretation of the complete pre-hospital record and conformance to the below definitions. Mark 'obvious cause' only when the cause of out of hospital cardiac arrest clearly meets the defined criteria. The Epistry PIs expect that 'obvious cause' may be rarely selected in the data set. Arrest patients with an 'obvious cause' become a unique subgroup that may have different treatments and outcomes.

Definitions for obvious cause of arrest:

Anaphylaxis: Cases of sudden collapse with other clear signs of anaphylaxis including urticaria, facial and tongue swelling, respiratory distress, and clear exposure to an allergen (e.g., bee sting or ingested food with known allergy) that triggered the event. In addition to these physical and historical findings, an Epipen (intramuscular injectable source of epinephrine) may have been used. However, a used Epipen without physical signs of anaphylaxis (or witnessed by bystanders) is not diagnostic for this etiology option.

Chemical poisoning (intentional or unintentional, includes carbon monoxide, toxic gases): This category does NOT include prescribed medications, recreational drugs, or ethanol (see “Drug Poisoning”). However, isopropyl alcohol, ethylene glycol and methanol are included as “chemical poisoning”. This category will include all cases where there is high likelihood that the cardiac arrest would not have occurred in the absence of a poison. Chemical poisons are considered substances that would not normally be ingested, inhaled or consumed and may be environmental or industrial, including such items as insecticides, herbicides, industrial

gases, cleaning solutions, carbon monoxide sources (e.g., automobile exhaust or space heaters), or similar compounds. The cardiac arrest timing and clinical scenario should be consistent with the presumed chemical poisoning. This etiology includes both intentional chemical poisoning (i.e., cases where ingestion, inhalation or contact with a chemical poison for the purposes of suicide is clear - suicide note, witnesses confirm discussion of suicidal intent or witnessed clear impulsive intentional ingestion temporarily related to the collapse), and unintentional chemical poisoning (cases where witnessed chemical exposure precedes the collapse by 3-5 minutes). This category would include cases where witnesses confirm contact with a chemical poison just prior to collapse. (may include chemical poisoning NEMSIS 9515)

Drowning: victim is found by provider or bystanders submersed in water without an alternative causation (May include drowning NEMSIS 9525 and NEMSIS 2260).

Examples of cases that fit this definition include; young and presumably healthy person found floating in the water with no evidence of overdose or drug ingestion; in the absence of other contributing factors, any patient who was witnessed to be choking or coughing before going under water.

Examples of cases that do NOT fit this definition include; patients who suffer trauma immediately prior to falling in the water (the case should be entered in the trauma, not the cardiac, patient cohort; for patients presumed to be older than 39 years of age one cannot be certain whether the submersion or some medical event was the cause of death so 'no obvious cause' would generally be selected; person who was inebriated or toxic on a drug who then drowned (the case should be classified as 'no obvious cause').

References: *S*alomez F, Vincent JL. Drowning: a review of epidemiology, pathophysiology, treatment and prevention. *Resuscitation.* 2004 Dec;63(3):261-8.

Idris AH, Berg J, Bierens L, et al. Recommended guidelines for uniform reporting of data from drowning: the 'Utstein style'. *Circulation.* 2003 Sept; 108:2565-2574.

Drug poisoning (intentional or unintentional, includes ethanol): This category includes prescribed medications, recreational drugs, and ethanol. Intentional drug overdose may include cases where ingestion of a drug (i.e., prescribed or over the counter medication, recreational drugs including alcohol) for the purposes of suicide is clear (suicide note, witnesses confirm discussion of suicidal intent or witnessed clear impulsive intentional ingestion temporarily related to the collapse). Unintentional drug overdose may include cases where witnessed inhaled or intravenous or oral recreational drug use immediately precedes the collapse. The Drug Poisoning category includes cases where witnesses confirm the situation, for example an injection of heroin just prior to collapse or where the evidence strongly suggests immediate use prior to arrest (e.g., tourniquet on arm and empty syringe at side). (may include drug poisoning NEMSIS 9530)

Examples of cases that fit this definition; a victim collapses and there are empty pill bottles or ethanol containers at the scene without clear evidence of suicidal intent.

Examples of cases that DO NOT fit this definition; patient with a history of recreational drug use within 24 hours of the event (e.g., adolescent found collapsed at a party or

the known alcoholic found dead the morning after heavily imbibing); classify these types of cases as 'no obvious cause' (presumed cardiac).

Electrocution (non-lightning): This category includes all cases where the patient has an electrical cutaneous burn in the setting of contact with a high voltage source. Electrocution would be also the obvious choice if the victim was found attached or nearly so, to a high-tension source of current. This category also includes all cases where the patient has been removed from the source of high tension current but the event was witnessed. (may include electrocution non-lightning NEMSIS 9535 or electrocution NEMSIS 2270)

Excessive cold: Low ambient temperature (below 40F or 0C) where an obviously healthy individual is inappropriately clothed for the ambient temperature. (may include excessive cold NEMSIS 9540)

Excessive heat: Situations in which an obviously healthy person experiences a cardiac arrest and the most significant contributing factor is increased ambient temperature i.e. exercise on a hot day or confined in a locked car or lost hiking in the desert. (may include excessive heat NEMSIS 9545)

Examples of cases that fit this definition; the inebriated patient found outside for a prolonged period of time exposed to extreme heat or cold.

Foreign body obstruction: Cases of sudden airway obstruction leading to cardiac arrest due to ingestion of a foreign body identified by history or by direct visualization within the airway. Some of these cases may be preceded by choking. (may include airway obstruction NEMSIS 9585)

Examples of cases that fit this definition include; small child (age 4 or less) choking after a balloon popped in front of their face or after eating a hot dog and succumbs to cardiac arrest; or man observed to be eating and suddenly begins to choke and hold his throat prior to collapsing; or on intubation a foreign body is visualized +/- removed.

Examples of cases that DO NOT fit this definition include: paramedics report inability to ventilate the patient and presume airway obstruction without finding the source of the obstruction;

Hanging: Cases of sudden airway obstruction leading to cardiac arrest secondary to hanging. Requires either the presence of ligature present around the neck, found hanging, or marks on the neck compatible with a previous ligature in the setting that suggests this was the obvious cause of death.

Examples of cases that fit this definition; case in which the victim is found with a rope around the neck after fire or police have cut them down from a gallows equivalent

Examples of cases that would NOT fit this definition: victim has a ligature around the neck without any evidence at the scene of any attempt to hang himself; a victim who has been strangled by an assailant’s hands during an altercation (this case would be classified as 'obvious cause' Strangulation).

Lightning: cases of cardiac arrest where the event was directly attributed to lightning strike or blast effect from lightning temporally related to the event i.e. immediately following the strike,

burn marks on the ground or nearby objects, melting of metal objects, or documented classic signs of electrocution by lightning. (may include lightning NEMSIS 9575)

> Examples of cases that fit this definition: witnessed lightning strike on golf course where members of a foursome documented direct hit to one of their group and called 911; or unwitnessed cases where there are visible signs of lightning strike including cutaneous burns described as Lichtenburg figures, flash burns, punctuate burns, contact burns, or linear burns in the skin folds.
>
> Example of a case that does NOT fit this definition: man found outside in the rain without witnesses to verify direct strike or blast effect or any signs or symptoms of lightning related electrocution.

Mechanical suffocation: Mechanical suffocation causing arrest is distinct from hanging, strangulation, choking, respiratory, anaphylaxis, or SIDS etiologies. This category will rarely be coded. It is included for a unique and very specific group of patients who arrest because of suffocation due to an external physical barrier. (may include mechanical suffocation NEMSIS 9585)

> Examples of cases that fit this definition: someone with the plastic bag over the head; a pillow or another object was used to suffocate the patient; or a child or adult with tracheostomy site who develops an obstruction.

Non-traumatic exsanguination: This category includes the rare situation where it is highly likely that the patient "bled to death" in a short period of time and there is strong evidence that acute and catastrophic loss of blood was the direct cause of the arrest.

> Examples of cases that fit this definition: hemodialysis line disconnected with obvious large loss of blood; vomiting of blood with EMS witnessed and documented large loss of blood; blood in stool (lower GI bleed) with EMS witnessed and documented large loss of blood.
>
> Examples of cases that DO NOT fit this definition: vomiting blood with unknown amount or small amount on face or clothes; possible or suspected ruptured aortic aneurysm (this can never be proved without autopsy or diagnostic imaging); epistaxis; hemoptysis

Radiation: This etiology will be rarely coded. Cardiac arrest due to radiation requires an acute and massive radiation exposure that temporally (typically within seconds to minutes) produces a cardiac arrest. (may include radiation exposure NEMSIS 9615)

> Examples of cases that fit this definition: industrial exposure or terrorist event with presumed high radiation levels.

Respiratory: Adult cardiac arrest due to primary respiratory cause requires that the patient have 1) an established medical history of asthma and 2) a witnessed reported clinical course prior to arrest implicating asthma. Although there are no absolutes, death due to asthma (as a respiratory 'obvious cause') would generally be expected to evolve over hours or even days with progressive shortness of breath as the principal symptom rules. Pediatric (patients < 16 years) cardiac arrest due to primary respiratory cause requires that the patient have 1) an

established history of an underlying disease that places the patient at higher risk for respiratory disease (see below examples) and 2) a witnessed reported clinical course of an acute respiratory problem prior to the arrest.

Examples of adult cases that fit this definition: a) 54 yo male with history of asthma, hospitalized previously, who experienced progressive shortness of breath over the past day following URI for past week. He has been using inhalers around the clock since yesterday and took an extra dose of prednisone this morning. His spouse called 9-1-1 when his respiratory symptoms made him unable to talk or answer questions. No chest pain or prior heart history. EMS arrives to find the patient unresponsive without pulse or respirations. Rationale: Several circumstances suggest a primary respiratory arrest: 1) the history suggests that he has fairly significant asthma, the clinical circumstances are highly consistent with an asthma exacerbation with similar past events, and there is information indicating that he did not have clinical heart disease. Hence the level of information sufficiently implicates a respiratory mechanism as the primary cause; b) 16 year old woman with a history of asthma witnessed by bystander or responder to have inspiratory and expiratory wheezing prior to cardiac arrest.

Examples of pediatric cases (patients < 16 years of age) that fit this definition: a) Child receiving chronic oxygen therapy or respiratory assistance, such as a premature infant at home on oxygen with an increase in oxygen requirement over the previous hours or days; b) Child with acute febrile respiratory illness in the days or hours prior to arrest, such as an otherwise healthy child with a presumed respiratory infections disease preceding the event; c) child with history of asthma and progressive acute respiratory distress (“asthma attack”) whereby witnessed respiratory distress progresses over hours until he/she cannot talk, then turns blue, and collapses.

Examples of cases that do NOT fit this definition include: a) 65 yo male with history of COPD (home oxygen dependent) and heart disease (prior bypass) was last seen at breakfast by his wife. He had no complaints at that time. When she returned home later that morning she found him unresponsive on the couch with his home nebulizer running. She called 9-1-1 and the EMS arrived to find him without pulse or respiration. Rationale: Although the patient had fairly severe chronic lung disease, he did not have clear prodromal symptoms or signs indicating progressive respiratory decline. The scene was suggestive that he experienced some symptoms prior to death since the nebulizer machine was running but this could have been due to a variety of cardiopulmonary symptoms. This patient should be classified as no obvious cause (presumed cardiac); b) 75 yo female nursing home resident develops cough for at least 1 day and then increasing shortness of breath this morning. The nursing home staff had provided oxygen and an albuterol but without relief. At the time of the 9-1-1 call she was awake but unable to speak due to extreme respiratory distress. When EMS arrives she is unresponsive without pulse or blood pressure and nursing staff have initiated CPR. Her history is notable for history of asthma for which she uses 2 different inhalers. Rationale: The patient did have some history of lung disease and some symptoms of progressive dyspnea. However the severity of lung disease is not clear and the symptoms could be consistent with other etiologies of arrest. For example, this patient could be manifesting congestive heart failure or pulmonary embolism. Although a judgment, the level of information leaves some question as to whether respiratory

disease was the primary etiology. The best etiology classification for this patient would be 'no obvious cause' (presumed cardiac).

Examples of pediatric cases (patients <16 years of age) that do NOT fit this definition: a) Developmentally disabled child without a supported airway found pulseless and apneic, such as 6 year old child with cerebral palsy and limited ambulation found pulseless and apneic in bed (this case would be coded as 'no obvious cause'); b)child with a supported airway (i.e. Tracheostomy) and found pulseless and apneic (this case would be coded as 'obvious cause' mechanical suffocation); c) prior history of congenital heart disease and no other 'obvious cause' identified—congenital heart disease is not an etiologic classification, but should be included as a 'contributing factor.' This case would be coded as 'no obvious cause' (presumed cardiac).

SIDS (sudden infant death syndrome, less than 13 months of age): Cases of death where an infant, ages 1 month to 12 months is found in their crib/bed and death was unwitnessed. All three criteria—age, crib/bed location, and unwitnessed death—must be present to be categorized as SIDS. Background of sudden infant death syndrome: The American Academy of Pediatrics—SIDS, also called crib or cot death, is the sudden death of an infant under 1 year of age that remains unexplained after thorough case investigation, including performance of a complete autopsy, examination of the death scene, and a review of the clinical history. [NOTE: Site classification of etiology of arrest for classification of SIDS as an obvious cause is to be determined solely from the prehospital patient care record. SIDS is the most common cause of death between 1 and 6 months of age. The incidence of SIDS peaks between 2 and 4 months of age. Approximately 90% of SIDS deaths occur before the age of 6 months.]

SIDS is suspected when a previously healthy infant, usually younger than 6 months, is found dead in bed, prompting an urgent call for emergency assistance. Often, the baby is fed normally just before being placed in bed to sleep, no outcry is heard, and the baby is found in the position in which he or she had been placed at bedtime or naptime. In some cases, cardiorespiratory resuscitation initiated at the scene by emergency personnel is continued without apparent beneficial effect en route to the hospital, where the baby is finally declared dead. Evidence of terminal motor activity, such as clenched fists, may be seen. There may be serosanguineous, watery, frothy, or mucoid discharge coming from the nose or mouth. Skin mottling and postmortem lividity in dependent portions of the infant's body are commonly found. Review of the medical history, scene investigation, radiographs, and autopsy are unrevealing.

The Canadian Pediatric Society refers to SIDS as the sudden and unexpected death of an apparently healthy infant usually less than one year of age, which remains unexplained even after a full investigation. On average, 3 infants a week are reported to die of SIDS in Canada. Although in Canada there has been a decrease in the number of infant deaths reported as SIDS, it still remains a significant public health concern. Aboriginal infants have a risk of SIDS that is higher than the risk to non-Aboriginal infants.

Example of pediatric case (less than 13 months of age) that are included: Although there is some controversy and a few documented cases of long QT causing what

appears to be SIDS, the evidence supports that most are related to respiratory issues. A case can be made that this is mechanical suffocation, but that can not reliably be done in the absence of a thorough review of the history and even location of the death. We need to be consistent with this as we will have many cases of this and CPR will be delivered.

Smoke inhalation: Cases of collapse in a fire setting with significant smoke exposure. This is defined as the patient who was exposed to fire in a closed space (Ryan et al N Engl J Med, 1998). May include smoke inhalation NEMSIS 9625.

Strangulation: The impression of EMS responders is that the patient's most significant condition that led to cardiopulmonary arrest is strangulation. Strangulation is a form of asphyxia (though not categorized as 'obvious cause' asphyxia) characterized by closure of the blood vessels or air passages of the neck as a result of external pressure on the neck (McClane et al J Emerg Med 2001) The paramedic usually describes crush marks around the neck.

Examples of cases that fit this definition: victim becomes non-responsive during a witnessed altercation where the assailants hands were around the neck.

Examples of cases that would NOT fit this definition: a) where the individual was involved in an altercation and becomes unresponsive without witnesses documenting strangulation just prior to collapse; b) victim has bruising around the neck without documented history of strangulation related to the collapse;

Terminal illness (includes end-stage diseases such as cancer): Death due to "terminal" condition is one in which death is expected and for which there is evidence of poor function or functional decline prior to death. Both conditions need to be met. Terminal condition will most often be considered in patients with advanced cancer. An individual whose function is declining and for whom death is expected should be classified as terminal illness (see below examples).

Examples of cases that fit this definition: a) 45 year old woman is found unresponsive and not breathing. She has advanced pancreatic cancer and is enrolled in an experimental treatment protocol. She has been sleeping mostly during the last week because of weakness and malaise and has declined to return to the hospital. She was quite difficult to arouse earlier in the day; b) 88 yo male with liver cancer who has been mostly bedridden the past month. He has been progressively more confused over the last two days to the point where his caretaker could not wake him.

Examples of cases that do NOT fit this definition: a) Patient with advanced cancer who is reasonably functional – carrying out ADLs, living independently, and collapses would be classified as "no obvious cause" (presumed cardiac); b) 68 yo male with metastatic colon cancer ("his cancer had spread to his lung and liver" per bystander son) who collapsed while walking in the park. "He had gotten a bit weaker over the past year but seemed fine today". The son is not aware of other conditions or medications. Classify this case as 'no obvious cause' (presumed cardiac); c) 71 yo female found unresponsive by her husband. She has lung cancer that has spread to her bones and a past history of a "heart attack" 2 years ago. Her husband reports that "she has been

receiving radiation treatment for the cancer and the doctors weren't sure how long she had." This morning she had no complaints and they were leaving the house to go shopping when she collapsed. Classify this case as 'no obvious cause' (presumed cardiac).

Trauma (includes blunt, penetrating or burns): Patients who have experienced a cardiac arrest directly caused by blunt, penetrating or burn injury should be enrolled in the Trauma Epistry cohort, not the cardiac arrest cohort.

Examples of cases that do NOT fit this definition: a patient scenario where it is clear from the bystander history that the patient collapsed due to some medical condition prior to experiencing the trauma (such as an elderly male that was clutching his chest, was short of breath, and fell). This patient would be entered in the cardiac arrest cohort and if the etiology of the arrest is unclear, would be marked 'no obvious cause' (presumed cardiac).

Venomous stings and venomous bites: This category will include all cases where there is visual evidence or witnessed attack of a venomous organism (e.g., animal, reptile, insect) that immediately preceded and presumably precipitated the cardiac arrest. Evidence for the sting must include visible localized skin findings (e.g., local erythema or edema at site) and/or witnessed report by bystanders of history that supports this etiology. If a venomous sting precipitated anaphylaxis, the obvious cause "Anaphylaxis" should be marked. (may include bites NEMSIS 9510 and venomous stings either plants or animals NEMSIS 9645)

Item C7 –Were contributing factors directly related to this cardiac arrest?

This section is intended to capture the variety of factors that were observed by, or reported to, the EMS responders during the course of prehospital care. The site coordinator will mark all applicable conditions that are documented in the PCR (whether narrative or check item format) that may have been related to the cardiac arrest. It is not necessary for a 'contributing factor' to meet the same burden of proof as does 'obvious cause' for Etiology of Arrest: Site Classification. Check all contributing factors that appear to be directly related to this cardiac arrest.

Definitions for contributing factors:

Anaphylaxis: Signs of anaphylaxis including urticaria, facial and tongue swelling, respiratory distress, and clear exposure to an allergen (e.g. bee sting or ingested food with known allergy) that triggered the event. An Epipen (intramuscular injectable source of epinephrine) may have been used.

Chemical poisoning (intentional or unintentional, includes carbon monoxide, toxic gases): This category does NOT include prescribed medications, recreational drugs, or ethanol (see "Drug Poisoning"). However, isopropyl alcohol, ethylene glycol and methanol are included as "chemical poisoning". Chemical poisons are considered substances that would not normally be ingested, inhaled or consumed and may be environmental or industrial, including such items as insecticides, herbicides, industrial gases, cleaning solutions, carbon monoxide

sources (e.g. automobile exhaust or space heaters), or similar compounds. May include chemical poisoning NEMSIS 9515.

Dialysis: The patient was undergoing or very recently underwent dialysis treatment (peritoneal or hemodialysis). This does not include exsanguination secondary to disconnection of dialysis shunts—see 'non-traumatic exsanguination'.

Drowning: victim is found by provider or bystanders submersed in water or witnessed to be choking or coughing before going under water (May include drowning NEMSIS 9525 and NEMSIS 2260).

Drug poisoning (intentional or unintentional, includes ethanol): Includes prescribed or over the counter medications, recreational drugs, and ethanol (alcohol). May include drug poisoning NEMSIS 9530)

Electrocution (non-lightning): This category includes all cases where the patient has an electrical cutaneous burn in the setting of contact with a high voltage source. Electrocution would be also the obvious choice if the victim was found attached or nearly so, to a high-tension source of current. This category also includes all cases where the patient has been removed from the source of high tension current but the event was witnessed. (may include electrocution non-lightning NEMSIS 9535 or electrocution NEMSIS 2270)

Excessive cold: Low ambient temperature (below 32F or 0C) where an obviously healthy individual is inappropriately clothed for the ambient temperature. May include excessive cold NEMSIS 9540.

Excessive heat: High ambient temperature i.e. exercise on a hot day or confined in a locked car or lost hiking in the desert. May include excessive heat NEMSIS 9545.

*Foreign body obstruction: S*udden airway obstruction due to ingestion of a foreign body identified by history or by direct visualization within the airway. Some of these cases may be preceded by choking. May include airway obstruction NEMSIS 9585.

Hanging: Cases of sudden airway obstruction secondary to hanging. Patient may have a ligature present around the neck, be found hanging, or have marks on the neck compatible with a previous ligature.

Lightning: cases of cardiac arrest where a lightning strike or blast effect from lightning temporally related to the event i.e. immediately following the strike, burn marks on the ground or nearby objects, melting of metal objects, or documented classic signs of electrocution by lightning. (may include lightning NEMSIS 9575)

Mechanical suffocation: Mechanical suffocation is distinct from hanging, strangulation, choking, respiratory, anaphylaxis, or SIDS etiologies. It includes suffocation due to an external physical barrier. (may include mechanical suffocation NEMSIS 9585). May include someone with a plastic bag over the head; pillow or another object used to suffocate the patient; or a child or adult with a tracheostomy site who develops an obstruction.

Non-traumatic exsanguination: There is evidence that acute and catastrophic loss of blood occurred in a short period of time. May include disconnection of a hemodialysis line; vomiting of blood; blood in stool.

Radiation: Radiation requires an acute and massive radiation exposure that temporally (typically within seconds to minutes) produces a cardiac arrest. May include radiation exposure NEMSIS 9615. May include industrial exposure or terrorist event with presumed high radiation levels.

Respiratory: Adult cardiac arrest due to a medical history of COPD or asthma or a witnessed reported clinical course prior to arrest implicating respiratory difficulties. May evolve over hours or even days with progressive shortness of breath as the principal symptom rules. May have been using inhalers with increased frequency or increased dose of prednisone. May have been at home with oxygen with an increase in oxygen requirement over the hours prior to arrest. Pediatric (patients < 16 years) cardiac arrest due to 1) an established history of an underlying disease that places the patient at higher risk for respiratory disease (see below examples) and 2) a witnessed reported clinical course of an acute respiratory problem prior to the arrest. This does not include a child with a supported airway (i.e. Tracheostomy) found pulseless and apneic--this would be 'mechanical suffocation'.

SIDS (sudden infant death syndrome, less than 13 months of age): Cases of death where an infant, ages 1 month to 12 months is found in their crib/bed and death was unwitnessed. All three criteria—age, crib/bed location, and unwitnessed death—must be present to be categorized as SIDS. See Etiology of arrest 'Obvious cause' definitions for background on SIDS.

Smoke inhalation: Cases of collapse in a fire setting with significant smoke exposure. This is defined as the patient who was exposed to fire in a closed space (Ryan et al N Engl J Med, 1998). May include smoke inhalation NEMSIS 9625.

Strangulation: Strangulation is a form of asphyxia (though not categorized as 'contributing factor' asphyxia) characterized by closure of the blood vessels or air passages of the neck as a result of external pressure on the neck (McClane et al J Emerg Med 2001) The paramedic usually describes crush marks or bruising around the neck.

Terminal illness (includes end-stage diseases such as cancer): “Terminal” illness is one in which death is expected and for which there is evidence of poor function or functional decline prior to death.

Trauma (includes blunt, penetrating or burns): Patients who have experienced a cardiac arrest directly caused by blunt, penetrating or burn injury should be enrolled in the Trauma Epistry cohort, not the cardiac arrest cohort.

Venomous stings and venomous bites: This category will include cases where there is evidence or witnessed attack of a venomous organism (e.g., animal, reptile, insect) that immediately preceded and presumably precipitated the cardiac arrest. Evidence may include visible localized skin findings (e.g., local erythema or edema at site) and/or witnessed report by bystanders of history that supports this etiology. If a venomous sting precipitated anaphylaxis, the contributing factor “Anaphylaxis” should be marked. (may include bites NEMSIS 9510 and venomous stings either plans or animals NEMSIS 9645)

Item C8 –Evidence of implantable cardioverter defibrillator (optional):

Indicate if patient appears to have or is reported by friends or family to have an

implantable cardioverter defibrillator (ICD).

Name of person responsible for data on this form:

Name of the individual that logged into the electronic data transmission system for clinical study forms or to execute batch up-load of files. This individual will have registered as a member with the CTC for the purpose of participating as a coordinator or investigator in a ROC clinical trial and has designated a user name and password as their “Electronic Signature.” The individual has agreed to consider their electronic signature as equivalent to their handwritten signature, to maintain the confidentiality of their user name and password, and to not let others use it. Refer to the “Electronic Signature Agreement” (accessed after logging on to the ROC website) posted at https://roc.uwctc.org/tiki/roc-data-entry.

After verifying the entered data and electronic signature are correct, print the web-forms for your files, or convert the web-forms to pdf format and store electronically. Edits made later to the original web-entered forms or batch up-loaded data posted to forms are associated with the electronic signature of the individual making the changes and are documented in the file’s edit history.

Pre-Hospital Data –Trauma

The purpose of the Pre-Hospital Data –Trauma form is to collect information specific to trauma patients during the pre-hospital course of care, from the time the patient was seen in the field through the time that the patient either died, arrived at the emergency department or was admitted to the hospital. The information for the form will come from the PCR and dispatch, with the possibility of other information from family members or witnesses, depending on the episode and site. Complete this form for any eligible trauma episode.

The Pre-Hospital Data—Cardiac Arrest or Trauma form separately asks for data that are common to both the cardiac arrest and trauma patient groups.

The episode date/time, source of time, and episode ID will be pre-filled for web; entry of data and will be consistent with the date and time recorded on the Patient Enrollment form. It should be reviewed here for accuracy.

Item 1 –*Vital Signs—First recorded and Second recorded sets:*

Provide the values for the first and second recorded sets of pre-hospital patient vital signs A 'set' of vital signs is the collection of recordings that appear to have been documented for approximately the same period of time. A set of vital signs may not include all the listed elements. The first and second sets of vital signs may include different combinations of data elements. (Glasgow Coma Scale (GCS), blood pressure, respiratory rate, pulse, and SpO2)

Indicate 'yes' or 'no' if the patient was in traumatic arrest or VSA (vital signs absent), during the period that a first or second set of vital signs were documented. If yes, do not indicate 'NA/NR' or 'Done' for each of the listed vital sign components. If no, indicate 'NA/NR' or 'Done' for each component. Where 'done', enter the appropriate values.

Indicate 'yes' or 'no' if more than one set of vital signs was recorded in the pre-hospital record. If 'yes', complete Second Recorded and Worst Recorded vital signs. If 'no' leave Second Recorded and Worst Recorded vital signs blank and skip to Item T2, Injury Characteristics.

GCS: For patient's who are evaluated using the Glasgow Coma Score (GCS), provide the best response score for Eye, Verbal, and Motor categories as part of the first or second recorded sets of vital signs. Total score can be entered, or will be automatically calculated if values for eye, verbal, and motor are entered. Indicate if patient had an advanced airway or was chemically paralyzed or sedated at time of assessment. Indicate "not available/not recorded" if GCS is not recorded in the pre-hospital patient care record or part of the first or second set of vital sign.

Definitions for standard and pre-verbal/pediatric for Glasgow Coma Score (GCS):
Pre-verbal/Pediatric scale are to be used when assessing children ≤ 2 years or individuals at any age with developmental delay or mental retardation. Following is a comparison of the Standard and Preverbal/Pediatric assessment scales with differences *italicized.*

GCS Scales		Standard	Preverbal/Pediatric
Eyes	4	spontaneous	spontaneous
	3	to speech	to speech
	2	to pain	to pain
	1	no response	no response
Motor	6	obedient	*spontaneous movements*
	5	localizing	*withdraw to pain*
	4	withdraw to pain	*withdraw to pain*
	3	abnormal flexion	abnormal flexion
	2	abnormal extension	abnormal extension
	1	no response	no response
Verbal	5	oriented x 4	*baseline for patient*
	4	confused	*irritable cry*
	3	inappropriate	*cries to pain*
	2	incomprehensible	*moans to pain*
	1	no response	no response

NEMSIS Glasgow Coma Scale (GCS) Qualifiers:

Initial GCS without interventions/qualifiers –NEMSIS 3210

Patient chemically sedated –NEMSIS 3215

Patient intubated –NEMSIS 3220

Patient intubated and chemically paralyzed –NEMSIS 3225

SBP/DBP (optional): Recorded values may have been obtained by either palpation, auscultation, or automated device. Where recorded pressure has only systolic component, enter that value and leave diastolic blood pressure field blank. Indicate if the systolic blood pressure was indicated in the PCR as being 'not detectable'--do not enter '0' or other value for SBP if 'not detectable' is marked. If no SBP is recorded in the pre-hospital record, indicate not available/not recorded (NA/NR).

Spontaneous respiratory rate: Unassisted and spontaneous respirations, expressed in breaths per minute. If respiratory rate is assisted (for example with bag-mask), mark “not available/not recorded.”

Pulse: Determined by palpation, auscultation, or automated device, expressed in beats per minute. Indicate “not applicable/not recorded” if pulse not recorded in the pre-hospital PCR.

SpO2: Determination of oxyhemoglobin saturation (SpO2). To be obtained from properly positioned sensor including the ear or finger. Indicate “not available/not recorded” if SpO2 not recorded in the pre-hospital patient care record. If recorded, indicate if supplemental oxygen was provided to the patient prior to and during acquisition of the documented

value.

Item 1 –Vital Signs--Worst recorded:

Provide the values for the worst vital signs recorded in the patient care record during the pre-hospital course of care. Worst recorded values may be those previously recorded in whole or part as First Recorded and/or Second Recorded, or recorded at a different period. Worst recorded values need not have been obtained at the same time or be considered a set of vital signs. Where a vital sign was recorded only once in the pre-hospital care record, enter that value as both the lowest and highest (for respiratory and pulse rates) recorded value. These data provide the range of vital signs recorded during the pre-hospital period and may be useful in later designing pre-hospital interventional trials. Vital signs are defined as for First Recorded or Second Recorded vital signs with the following qualifiers:

Lowest total score GCS: Provide the Eye, Verbal, and Motor scores for the lowest total scored GCS during the pre-hospital course of care. Indicate if an advanced airway was present or the patient was chemically paralyzed or sedated at the time of the GCS score.

Lowest SBP/DBP: Lowest recorded systolic and corresponding diastolic (optional) blood pressure. Indicate if the systolic blood pressure was noted in the PCR as being 'not detectable'--do not enter '0' or other value for SBP if 'not detectable' is marked

Highest/lowest spontaneous respiratory rate: Highest and lowest respiratory rates recorded during the pre-hospital course of care. Enter only values for respiratory rates that are unassisted and spontaneous.

Highest/lowest pulse rates: Highest and lowest pulse rates recorded during the pre-hospital course of care.

Lowest SpO2: Lowest value recorded for noninvasive determination of oxyhemogolobin. Indicate if supplemental oxygen was administered with the lowest recorded value.

Item 2 –Injury characteristics:

a. Type of injury: Select one broad classification for type of trauma. For cases where there are multiple types of injury, select the predominant type of injury most likely to result in morbidity and mortality. For example, motor vehicle crash with burns –“blunt” would be selected. Gang fight with patient that is both beaten and shot-“penetrating” would be selected. The 'other' response option should be reserved only for cases where blunt, penetrating, or burn cannot be assigned.

Blunt – Caused by an object or instrument either struck by or against. Includes amputation, crush, laceration and asphyxia with the exception of stab, spike, or missile injury which are classed as penetrating injury. (NEMSIS 2035)

Penetrating –To pass into or through a patient’s body. This may result from either an object (e.g., gun shot wound, stabbing) or patient’s own velocity (e.g., fall onto fence or

pole). (NEMSIS 2050)

Burn – Injury or damage resulting from exposure to fire, heat, caustics, electricity, or certain radiations. (NEMSIS 2040)

Not Known –NEMSIS -10

Other (specify) –Includes unspecified type of injury not caused by a category in the above list. (NEMSIS 2045). Specify type of injury (30 characters)

b. Mechanism of injury: Select one detailed classification for cause of trauma from the list provided. Select the cause of injury from the perspective of the injured person. (For example if a bicyclist runs into a pedestrian and only the bicyclist is injured—coded as bicycle). Where more than one cause for injuries may be present, select the mechanism responsible for the greatest morbidity and mortality.

Definitions for Mechanism of Injury:

Motor vehicle occupant: includes NEMSIS 9595 motor vehicle traffic accident;

Motorcyclist: includes NEMSIS 9600 Motorcycle accident;

Pedal cyclist: includes NEMSIS 9505 bicycle accident;

Pedestrian: includes NEMSIS 9610 pedestrian traffic accident;

Other transport: includes off-road vehicle crash, and NEMSIS 9590 motor vehicle non-traffic accident, 9605 non-motorized vehicle accident;

Fall: includes NEMSIS 9550 falls;

Struck by/against or crushed: includes unarmed fight and NEMSIS 9640 struck by blunt/thrown object, 9620 rape, 9520 child battering;

Cut/pierce/stab: includes NEMSIS 9630 stabbing/cutting accidental, 9635 stabbing/cutting assault;

Fire/burn: includes NEMSIS 9555 fire and flames,

Machinery: includes NEMSIS 9580 machinery accidents;

Firearm gunshot: includes BB/pellet gunshot and NEMSIS 9565 firearm injury (accidental), 9560 firearm assault, 9570 firearm self inflicted;

Natural/environmental: includes overexertion and NEMSIS 9545 9510 bites,

Not known: NEMSIS -10.

Other/specify: includes foreign body, NEMSIS 9530 drug poisoning, 9615 radiation exposure, 9515 chemical poisoning, 9650 water transport accident, 9500 aircraft related accident. Specify other mechanism of injury, 30 characters.

Item 3 – Safety Equipment:

Indicate safety equipment that was observed by or reported to the EMS responder to be in use or deployed at the time of the trauma episode, selecting all that apply. Indicate 'not applicable' where safety equipment would not be expected to be worn, such as a civilian injured by gunshot.

Definitions for Safety Equipment:

Restraint Use: Includes seatbelt, lap belt, shoulder belt, or car seat/booster seat with restraint use. (includes NEMSIS 2219, 2185, 2170, 2210);

Air bag deployment : air bag deployed in seat position of subject (e.g., driver-side air bag deployment where subject was driver) (includes NEMSIS 2230, 2225);

Helmet: Observed by or reported to emergency medical services responder. (NEMSIS 2180);

None: No safety equipment observed by or reported to EMS responder. (NEMSIS 2187);

Unknown: NEMSIS -10

Not applicable: Traumatic injury of patient not associated with environment where use of safety equipment would not be anticipated. (NEMSIS -25).

Other: If selected, provide brief description of “other” safety equipment. Includes Eye protection, Protective clothing (welding gloves), PFD (Personal Flotation Device), other protective equipment. (includes NEMSIS 2190, 2200, 2195, 2205);

Name of person responsible for data on this form:

Name of the individual that logged into the electronic data transmission system for clinical study forms or to execute batch up-load of files. This individual will have registered as a member with the CTC for the purpose of participating as a coordinator or investigator in a ROC clinical trial and has designated a user name and password as their “Electronic Signature.” The individual has agreed to consider their electronic signature as equivalent to their handwritten signature, to maintain the confidentiality of their user name and password, and to not let others use it. Refer to the “Electronic Signature Agreement” (accessed after logging on to the ROC website) posted at https://roc.uwctc.org/tiki/roc-data-entry.

After verifying the entered data and electronic signature are correct, print the web-forms for your files, or convert the web-forms to pdf format and store electronically. Edits made later to the original web-entered forms or batch up-loaded data posted to forms are associated with the electronic signature of the individual making the changes and are documented in the file’s edit history.

CPR Process –Cardiac Arrest

The purpose of this form is to document the elements of cardio-pulmonary resuscitation that may be useful for quality assurance. This will include the type of rhythm being treated, the monitoring device used, and minute-by-minute notations of the number of ventilations and compressions, the rate of compression, CPR fraction, and compression depth and release. Optional data fields are provided for sites electing to participate in the Ventilation Substudy and include peak end-tidal CO2 and capnography ventilations. This form also provides for the capability to attach electronic ECG recordings and upload them to the ROC database/library.

The episode date/time and episode ID will be pre-filled by the web data entry program and will be consistent with the date and time recorded on the Patient Enrollment form. It should be reviewed for accuracy.

Item 1 –Does a continuous ECG recording exist for the EMS resuscitative effort?

Indicate no or yes, whether a continuous electronic ECG recording of the EMS resuscitative effort (either in part or whole) was downloaded from EMS (includes fire) to the ROC site. This is not intended to include 12-lead ECG recordings, 'snap shot' recordings, or long continuous paper rhythm strips. This is also not intended to include electronic ECG recordings from lay or bystander use of AEDs (such as public access, police, health care clinic).

If yes, an electronic ECG recording was downloaded from EMS, indicate whether the available recording(s) collectively represent the 'entire' or 'part' of the EMS resuscitative effort. Some EMS systems have tiered response by fire, BLS, and ALS so that more than 1 electronic ECG recording must be separately retrieved and downloaded. Indicate the number of EMS ECG recordings that comprise the resuscitative effort.

Item 2 –Device used (check all that apply):

For up to the first three EMS defibrillation devices used (such as might occur in a tiered EMS response system where fire BLS places a device and ALS replaces it with their own upon arrival), indicate the brand (manufacturer)--either Medtronic, Philips, ZOLL, or other. If other, specify the manufacturer (30 characters maximum).

For each device used, indicate if yes or no, the audio feedback function (related to CPR performance) was 'turned on' or 'muted' (only Philip's and ZOLL devices), an electronic ECG recording exists, and whether the recording was reviewed by ROC or site quality assurance personnel.

Use the 'attach recording' section to browse the site local database to identify and attach the ECG file that corresponds to the indicated device. 'DEL' allows a selected file to be unattached.

Naming files for upload to ROC-website: An attached ECG file name *must* include the *entire* study identification number assigned by the CTC for the Epistry case. Examples of an 'entire' Epistry case ID; DAL-123456-1 or ARC-000456-3 or PGH-123450-2 (include site code, all

dashes and leading and trailing zeros, and the check digit). It is recommended that you prepend the current name of the file with the ROC case ID and device order. This will allow you to see both the original file name and the ROC case ID in the file name making it easier to determine which of your original files was used to create a given ROC upload file. For example, if you have a file called 2007-12-31.ZOL that needs to be attached to the first device listed for case CTC-000000-0 you would rename the file. CTC-000000-0-dev1-2007-12-31.ZOL.

NOTE for ZOLL recordings: The ROC website currently accepts only files with '.ZOL'. The .ZOL file format is acquired by choosing *File->Rename* Sites. The ROC website does not currently accept .CRD or .FUL file formats (obtained by choosing *File->Export->Entire Defibrillator Record, Binary (.crd/.ful))* from the menu. The CTC is evaluating the upload option for the .CRD and .FUL formats.

Another NOTE for ZOLL recordings: The .ZOL files have to de-identified following the below outlined process:

1. Create a folder that is used for containing files to be uploaded to the ROC website. This step only needs to be done once and not for every case. This cannot be the same folder that holds the original .ZOL files that your site receives from the participating agencies. Do not use this folder for storing cases that have not been de-identified.

2. Open the desired case in the RNCR software. This can be done by double clicking on the file itself or by clicking the *Open* icon and browsing for the file.

3. Select *File -> Send to -> Folder* from the menu.

4. Answer "Yes" when asked "Remove personally identifying data?"

5. When the *Browse for Folder* window appears choose the roc upload folder. This will create a file in the folder with the exact same name as the .zol file that you are currently reading.

6. If this file does not have the ROC caseid in the file name you need to rename the file.

    1. Close the file that is currently open by selecting *File -> Close* from the menu. Important: do not skip this step and go immediately to step 2 because the software messes up when you attempt to open another file when one is already open.

    2. Open the file that you created with the *Send to* command. Remember that

        1. Click the *Open* icon in the icon bar

        2. Browse to your ROC upload directory and select the file from those shown.

    3. Rename the file by selecting *File -> Rename* from the menu. It is recommended that you follow the renaming process as described above.

Only one recording is intended to be uploaded for each of the three listed devices. Where more than one recording exists for the same device (such as when a device was applied, then turned off, and later turned on) can recordings into one zip file and attach it (using the required file naming conventions, as above) for upload.

It is expected that for each device used for which a 'recording exists', a file will be attached for upload. Where multiple ECG files are merged to one (such as when the BLS and ALS device ECG files are merged to represent the entire EMS response), indicate that a recording exists for each of the devices used, leave the 'attach recording' file name field blank, and provide an explanation in the error-override message box that indicates the merge of recordings for devices x and y (specify).

Item 3 –Were any shocks delivered by EMS responders?

Indicate no or yes, if any defibrillation shocks were delivered by EMS responders (includes volunteer fire). If yes, indicate the number of shocks. Shocks are considered as “delivered” regardless of their apparent success. Do not consider defibrillation shocks that are delivered by a bystander, police, healthcare provider, or person that is not part of the organized EMS response to this episode. If shocks were delivered by EMS responders, indicate how many.

Item 4 –Sequence of events*:*

This section is intended to capture the time, rhythm, and source (of rhythm) for two early rhythms. Enter the time (hh:mm:ss on 24 hour clock) and leave seconds blank if not recorded (do not enter '0' as a placeholder). Check the one rhythm that best describes the first cardiac arrest rhythm—see below definitions for rhythms, 'NA' and 'cannot determine'. Check the one source from which the one selected rhythm was determined. Where 'NA' is marked for a rhythm event, leave the time, rhythm, and source fields blank.

1st CA rhythm with Non-EMS AED/defibrillator: A non EMS AED/defibrillator includes any use by a bystander before the EMS or fire providers arrive at the scene. A bystander is defined as any person who responds and is NOT on duty with an EMS agency at the time of the arrest. Bystanders include doctors, nurses, police, off duty paramedics, off duty fire providers, and laypersons. Non EMS AED/defibrillators also includes public access AEDs (shopping malls, airports, etc) and defibrillators at satellite healthcare facilities such as day surgery, dialysis centers, nursing homes, assisted living and cruise ships).

Often the ECG is not available for review and instead the site must rely on the PCR for information. This is usually in the form of notation as to either administering shocks or having had no shock advised. If a shock is administered, mark VT/VF (includes AED shock). If no shock was advised, mark AED-no shock, no strip. In most cases the time of the rhythm will be missing unless there is an electronic ECG. If the time is missing please leave blank and override the error.

NA-(not applicable)- Not applicable means that a bystander did not place any defib or AED pads or ECG electrodes and had no knowledge of the rhythm. NA does not apply to situations where the ECG or rhythm is missing (see cannot determine).

Cannot determine: Select this if any pads or electrodes were placed by a bystander, but the ECG recording is missing, artifact or compressions obscure the rhythm or documentation on the PCR is incomplete regarding the initial cardiac arrest rhythm. Includes rhythms for which the ECG documentation or indication of AED shock status is not available or missing from the PCR.

Timing of the rhythm: Look for the EARLIEST rhythm from the time the pads were placed (from the first non-EMS AED or defibrillator placed). If the ECG during the first 10 seconds is obscured then look either during a ventilatory pause, possibly during compressions if there are QRS complexes, or at the earliest pause in CPR for rhythm analysis, then look for the '1st CA rhythm' with non-EMS defibrillator' after pad placement and prior to documentation of the pads of the EMS AED/defibrillator being applied or drugs given or a shock delivered by EMS or fire.

Length of rhythm: There is no required length of time that a rhythm must be evident (such as transitional rhythms) to be considered the '1st cardiac arrest rhythm'. Use your best judgment in determining the rhythm during even a few seconds of interpretable ECG. The objective is to capture the earliest cardiac arrest rhythm, not necessarily the rhythm that is the easiest or clearest to discern. This is recognized to be a tradeoff. Where the reviewer observes a rhythm different than that indicated by the AED analysis (shock or no-shock) or the PCR, defer to the reviewer's finding as long as careful consideration is given to which source contains the information from the first EMS or fire defibrillator placed.

Definitions of Rhythms:

VF/VT: Ventricular fibrillation (VF)–irregular, disorganized ventricular electrical activity of variable amplitude exceeding 0.2mV, or; ventricular tachycardia (VT)—HR > 100 bpm with QRS duration greater than 110 msec (with evidence of AV dissociation where device bandwidth may allow) , or; cardiac arrest rhythm for which an AED advised a shock on the first analysis as can be best determined (need not have the ECG strip), or; cardiac arrest rhythm documented in the prehospital PCR.

PEA (Pulseless electrical activity): Electrical activity with QRS complexes of any width at an average rate of >10 beats per minute (e.g. organized ventricular electrical activity with QRS complexes that occur more than once over a 6-second period) that is not associated with a pulse. Occasionally, EMS will note a Pulseless rhythm (other that "PEA") in the PCR (such as idioventricular, wide complex rhythm, wide complex tachycardia, sinus tachycardia)—in these cases, mark the rhythm as PEA. If PEA is marked, indicate the rate in beats per minute or if 'unknown/not noted'. If less than a 6 second window is available, use your best judgment to determine asystole vs. PEA. Determination of a rhythm is preferable to reporting "cannot determine".

Asystole: Mark 'asystole' where low voltage baseline activity (< 0.2 mV) and no QRS complexes transpire for a 6 second window (this is intended to indicate a rate of ≤ 10

bpm). If less than a 6 second window is available, use your best judgment to determine asystole vs. PEA. Determination of a rhythm is preferable to reporting “cannot determine”.

AED-no shock (no strip): Notes from the patient record indicate that analysis was done and no shock was advised or delivered, but no ECG strip available.

Definitions of Rhythm Source:

Continuous ECG: An electronic recording of the initial cardiac arrest ECG and CPR process. Where the initial 'continuous ECG' is one of multiple recording sources (such as PCR documentation or an a snapshot ECG or paper strip), mark 'Continuous ECG.”

Snapshot ECG: a short paper recording (sometimes as brief as 6 seconds) or more lengthy paper printout (such as that from a defibrillator code summary print out or from a 12-lead ECG machine) that captures a portion of the cardiac arrest period.

PCR (patient care record): the first cardiac arrest rhythm is documented in the patient care record and the source recording (either snapshot or continuous) is not available for review.

1st CA EMS rhythm: Time of the FIRST interpretable cardiac arrest rhythm after confirmation of cardiac arrest and captured by an EMS responder either ROC or non-ROC. Look for the ‘1st CA EMS rhythm’ for up to 5 minutes after pad or electrode placement and prior to documentation of drugs given or a shock delivered by EMS or fire. EMS responder is defined as a person on duty for an organized EMS or fire agency at the time of the response. If the rhythm cannot be determined during this period, then mark ‘cannot determine.’ This rhythm is not one obtained by bystanders (doctors, nurses, police, off duty paramedics, off duty fire providers, and laypersons). The ‘1st CA EMS rhythm’ cannot be a perfusing rhythm.
If the first vehicle was non-ROC EMS and you don’t have access to the information, record an event order and check “no documented time”.

N*A-(not applicable)*- Not applicable means there was not an EMS cardiac arrest rhythm, as in the case where a) there was a bystander administered AED shock, but by the time the EMS arrived the rhythm was perfusing and the patient never rearrested; OR b) EMS did not place any defib or AED pads or ECG electrodes and had no knowledge of the rhythm. NA does not apply to situations where the ECG or rhythm is missing (see cannot determine).

Cannot determine: Select this if any EMS placed pads or electrodes were placed, but the ECG recording is missing, artifact or compressions obscure the rhythm or documentation on the PCR is incomplete regarding the initial cardiac arrest rhythm. Includes rhythms for which the ECG documentation or indication of AED shock status is not available or missing from the PCR.

Source of rhythm*:* The preferred source for capturing both the time of this event and the rhythm type is the continuous electronic ECG, but ONLY IF THIS IS THE ECG FROM THE FIRST EMS AED/DEFIB APPLIED following the cardiac arrest. The primary goal is to get the first rhythm after the arrest. The ‘1st CA EMS rhythm’ is not necessarily obtained

from the first available electronic ECG (such as when only the 2nd arriving EMS recording is available). The second preferred source is a rhythm strip recording. The third preferred source is the rhythm documented in the PCR. Use the PCR only as a last resort (such as when the first electronic download is not available). Do not use information obtained from the compression channel generated by use of a 'puck' (Philips) or from compression annotations generated by use of CPR-D pads (ZOLL, Magnified ECG or CPR Quality Calculations tabs) to determine the '1st CA EMS rhythm.

Timing of the rhythm: Look for the EARLIEST rhythm from the time the pads were placed (from the FIRST EMS defibrillator placed), within the first 10 seconds if possible. For an EMS witnessed arrest (occurring after the arrival of EMS), look for the earliest rhythm following the onset of cardiac arrest, within the first 10 seconds if possible. If the ECG during the first 10 seconds is obscured then look either during a ventilatory pause, possibly during compressions if there are QRS complexes, or at the earliest pause in CPR for rhythm analysis, then look for the '1st CA EMS rhythm' for up to *5 minutes* after pad placement and prior to documentation of drugs given or a shock delivered by EMS or fire.

Length of rhythm: There is no required length of time that a rhythm must be evident (such as transitional rhythms) to be considered the '1st cardiac arrest rhythm'. Use your best judgment in determining the rhythm during even a few seconds of interpretable ECG. The objective is to capture the earliest cardiac arrest rhythm, not necessarily the rhythm that is the easiest or clearest to discern. This is recognized to be a tradeoff. Where the reviewer observes a rhythm different than that indicated by the AED analysis (shock or no-shock) or the PCR, defer to the reviewer's finding as long as careful consideration is given to which source contains the information from the first EMS or fire defibrillator placed.

Definitions of Rhythms:

VF/VT: Ventricular fibrillation (VF)–irregular, disorganized ventricular electrical activity of variable amplitude exceeding 0.2mV, or; ventricular tachycardia (VT)—HR > 100 bpm with QRS duration greater than 110 msec (with evidence of AV dissociation where device bandwidth may allow) , or; cardiac arrest rhythm for which an AED advised a shock on the first analysis as can be best determined (need not have the ECG strip), or; cardiac arrest rhythm documented in the prehospital PCR.

PEA (Pulseless electrical activity): Electrical activity with QRS complexes of any width at an average rate of >10 beats per minute (e.g. organized ventricular electrical activity with QRS complexes that occur more than once over a 6-second period) that is not associated with a pulse. Occasionally, EMS will note a Pulseless rhythm (other that "PEA") in the PCR (such as idioventricular, wide complex rhythm, wide complex tachycardia, sinus tachycardia)—in these cases, mark the rhythm as PEA. If PEA is marked, indicate the rate in beats per minute or if 'unknown/not noted'. If less than a 6 second window is available, use your best judgment to determine asystole vs. PEA. Determination of a rhythm is preferable to reporting "cannot determine".

Asystole: Mark 'asystole' where low voltage baseline activity (< 0.2 mV) and no QRS complexes transpire for a 6 second window (this is intended to indicate a rate of ≤ 10

bpm). If less than a 6 second window is available, use your best judgment to determine asystole vs. PEA. Determination of a rhythm is preferable to reporting “cannot determine”.

AED-no shock (no strip): Notes from the patient record indicate that analysis was done and no shock was advised or delivered, but no ECG strip available.

Definitions of Rhythm Source:

Continuous ECG: An electronic recording of the initial cardiac arrest ECG and CPR process. Where the initial 'continuous ECG' is one of multiple recording sources (such as PCR documentation or an a snapshot ECG or paper strip), mark 'Continuous ECG.”

Snapshot ECG: a short paper recording (sometimes as brief as 6 seconds) or more lengthy paper printout (such as that from a defibrillator code summary print out or from a 12-lead ECG machine) that captures a portion of the cardiac arrest period.

PCR (patient care record): the first cardiac arrest rhythm is documented in the patient care record and the source recording (either snapshot or continuous) is not available for review.

Item 5 –ECG Analysis:

Fill in the following time points. If data has been previously entered in the Pre-hospital time record and the CPR Process form is blank, three selected ECG analysis times (time of arrest if EMS witnessed; time resuscitation stopped; and time ED arrival) will be autofilled at web-entry. These times may be edited—site is encouraged to review and edit the Prehospital Time Record to reflect any edits. Enter all times as hh:mm:ss on 24 hour clock—enter '00' for seconds only when documented, not as a placeholder:

Time first EMS AED/defibrillator turned on: Time the initial (first) EMS responder (includes fire) AED or manual defibrillator is powered on. This does not include bystander, police, or healthcare provider. Indicate if the time is 'not available'. If 'not available' and only 1 device was used during the course of EMS prehospital resuscitation, stop here (question 6 is not required).

Time first EMS pads placed: Indicate when pads (capable of defibrillation) of the FIRST EMS defibrillator/monitor of the FIRST EMS or fire provider AED or manual defibrillator were in contact with the skin, as evidenced by the commencement of ECG recording. If pads lose contact and there is more than one time to pad placement time, use the first time the pads were placed. It is expected that ‘time first EMS pads placed’ will be left blank if 'time first EMS AED/defibrillator turned on' is 'not available'. Do not use time ECG-only electrodes (sometimes called ‘pads’) are placed. The time the EMS pads are placed is auto filled as the ‘start time’ for the Item 6, CPR process measurements.

If the accelerometer (Philips device) or ‘puck’ is placed before the pads, DO NOT use this time as ‘1st EMS pads placed.’ Do NOT manually try to calculate the CPR fraction, # compressions, or compression rate prior to pads placed. Starting from the time the initial pads were placed allows consistent comparison between devices.

Time of arrest if EMS witnessed: Autofill at web-entry: 'Time of arrest if EMS witnessed' is filled automatically IF the Prehospital Time Record form has been previously completed and saved (with or without errors) Auto filled values can be edited.

Time of initial cardiac arrest is used when the responding EMS or fire provider has arrived on scene prior to the onset of the cardiac arrest. For example, where EMS or fire has been called for 'chest pain' or where EMS or fire is stationed at a public even such as a marathon or football game. If a bystander began chest compressions prior to EMS or fire arrival, the patient had a pulse when EMS arrived, and the patient later arrested in front of EMS, the cardiac arrest would be considered as witnessed by EMS. If the patient was defibrillated by an AED/defibrillator used by a lay person, health care provider, police or off-duty paramedic prior to EMS arrival, the patient has ROSC upon EMS arrival, but later re-arrests in front of EMS, the cardiac arrest would not be considered EMS witnessed.

If the arrest was witnessed by the EMS or fire provider, provide a sort order (on the time record) and time (if available). If not witnessed by EMS or fire provider, leave the time blank on the CPR process form. The preferred source for this data element is voice recording (where available). The second and third preferred sources for this data element are respectively, the continuous electronic ECG and the PCR. Time AED/defib is turned on is NOT considered a surrogate for 'time of arrest if EMS witnessed.

For cases monitored with pads or electrodes: Time of arrest is the onset of ventricular fibrillation (VF) or asystole. If the potential 'arrest' rhythm is ventricular tachycardia (VT) or PEA, then, the onset of VT or PEA must be temporally associated (so as to discern a perfusing from a non-perfusing rhythm) with either voice annotation, or with chest compression or shock artifact. If VT or PEA is associated with CPR, the time of arrest is when compressions are started. If VT is associated with a shock, the time of arrest is when analysis is started.

For cases not monitored (no pads or electrodes are on patient at time of arrest; or continuous electronic recording is not available): the time of arrest is determined from the PCR (if documented time is plausible).

Time of advanced airway placement: Advanced airway includes intubation, LMA and other supraglottal airways. Indicate if either 'no advanced airway' was placed (such as when only bag mask valve have been used) or 'unable to determine' the time of placement.

Time resuscitation stopped due to death: Autofill at web-entry: 'Time resuscitation stopped due to death' is filled automatically IF the Prehospital Time Record form has been previously completed and saved (with or without errors). Auto filled values can be edited.

Indicate when EMS resuscitation stopped due to a decision to end rescue efforts. Indicate "Not applicable" if CPR was ongoing upon ED arrival/hospital admission.

Time ED arrival: Autofill at web-entry: 'Time of ED arrival' is filled automatically IF the Prehospital Time Record form has been previously completed and saved (with or without

errors). Auto filled values can be edited.

Time when the patient transporting vehicle stops moving on arrival at the receiving hospital or ED. Indicate “Not applicable” if patient was not transported to the ED/hospital.

Item 6 –Did the ECG provide CPR process measurements?*:*

Indicate no or yes if the available ECG information provides or allows CPR process measurements. If no, stop here. If yes, provide a minimum of 5 minutes CPR process data for the resuscitative effort (5 minutes beginning with the first available ECG recordings). Where feasible, provide data for each minute of the resuscitative effort, up to 20 minutes. Optional data elements are provided for more extensive reporting and for the Ventilation Substudy.

Definitions for CPR process measurements:

Device order: More than one device may be used during the course of the resuscitative effort. '1' is auto filled for all rows IF 'Time first EMS pads placed' has been entered in the prior question (#5 ECG Analysis). When (during the course of prehospital care) CPR process data comes from a second device source, enter '2' for that row—all below rows will be autofilled with '2' (and so on for subsequent devices).

If 'Time first EMS pads placed' was not entered in the prior question, enter '1' for the first row and mark 'no ECG' (to indicate that there is no electronic ECG from which to determine CPR process measures for that device).

Where an EMS device has been used, but no CPR process measures are available for that period of time, enter 1, 2, or 3, etc to indicate the device order of use (and mark 'no ECG data'). No other data for that row is expected.

Enter '0' in the 'Device order' column immediately below the last row of CPR process data to be entered—this signifies the term of the data provided and releases error checks for subsequent rows.

Start time: The hh:mm:ss for the first and subsequent minutes are auto filled at web-entry, beginning with the 'time first EMS pads placed' entered in the prior question (#5 ECG Analysis). The autofilled time may be edited and subsequent minutes will adjust to 1 minute increments from the edited time. Where the change of devices causes a lapse in time, enter the new device number and enter the 'start time' of that device—all below rows will be autofilled with 1 minute increments from that edited 'start time'. If 'time first EMS pads placed' has been left blank (as the data was not available), leave the start time blank and mark 'no ECG'. Move to the next row and enter the next 'device order' and either mark 'no ECG' or enter the 'start time' for the recording (whichever is appropriate). Where the 'start time' for each subsequent 'device used' is entered, all below rows will be autofilled with 1 minute increments from that edited 'start time.' NOTE: each row of the 'Start time' column is numbered 1, 2, 3, etc, representing the number of rows, not necessarily the number of

minutes for which CPR process measures are provided.

No ECG: check this box for a device used for which no electronic CPR process data is available. When checked, no other data for that row is required. It is intended that the device number be entered once and 'no ECG' marked. 'No ECG' is intended for use to indicate when an entire recording is missing, not minutes within a recording—see '#seconds with no measures."

#*Ventilations:* The number of ventilations counted for a minute, or for the portion of the minute for which the continuous-recorded signal could be analyzed. A separate approach is taken for each device used:

Medtronic—BLS device (Lifepak 500) does not have a bio-impedance channel filtered for ventilations. The ALS device (Lifepak 12, in manual or AED mode) has a composite bio-impedance channel requiring manual annotation of waveforms. Such composite waveforms are complex and are difficult to annotate for ventilations during chest compressions. However, during epochs or time intervals with no compressions, recent investigative work by Dr. Ahamed Idris suggests that ventilations can be observed both before and after intubation (either spontaneous or with positive pressure ventilations). Following are Idris guidelines for recognizing and counting ventilations on the Medtronic bioimpedance channel:

Device related

1. Review files with ventilation filter OFF and compression filter OFF to review 'raw file'. Use ventilation filter as needed to filter out high frequency interference (such as 60 Hz cycle, transient spikes).
2. Count ventilations in Medtronic PCO files during epochs that are free of chest of chest compressions.
3. A ventilation waveform at the end of an epoch which becomes intruded upon by compressions may be counted in order to complete the interval if the ventilation is clean.
4. Ventilations may be counted in epochs with chest compressions if the ventilations are absolutely uniform & rhythmic.

Waveform characteristic

1. Single broad/wide parabola
2. Duration of less than or equal to 2.5 seconds
3. Amplitude equal to at least 75% of the amplitude of the majority of waves, or equal to the amplitude of a "typical" waveform for that particular file
4. Keep a "questionable" ventilation if not filtered out by software—*they reviewed with ventilation filter on and off*

Reviewer ambiguity

1. Be liberal with eliminating entire epochs if guessing becomes excessive.

If unable to discern ventilations from compressions for a given full minute (60 seconds), leave the minute's filed for '# bens' blank. If continuous capnography (a separate device) was used during the course of care, the site is encouraged to provide values

for that data element for the given minutes. Error checks will not be triggered for blank '#vents' for Medtronic devices. The approach to ventilations for Medtronic devices will be revised with evolution in understanding and technology.

Philips— look at recorded ventilation waveform, minute by minute. For each minute, assess if the ventilation signal is corrupted. If corrupted (such as 60 cycle interference or movement), leave that minute's '# vent' data field blank (do not enter '0') and override and give a reason for the related error message. Do not over-read or annotate (add or delete) ventilations, even if voice channel or continuous capnography available. For minutes with no corrupted signal (either pre-or post-intubation), enter '# vents' reported by QCPR Review. Though optional, it is strongly encouraged to enter values for 'capnography vents' for later comparison with the ventilation channel.

ZOLL—do not enter values for '# vent", leaving the field blank. Error checks will not be triggered for blank '#vents' for ZOLL devices. Ventilations will be revisited when ETCO2 is introduced by the manufacturer.

 # Compressions: The number of chest compressions actually delivered in a given minute. If part of a minute cannot be analyzed, record the number of seconds in the "number of seconds with no measures" column. A separate approach is taken for each device used:

Medtronic—Review and annotate the impedance recording to indicate compressions (adding or deleting counted compressions). Sites may use voice recording to assist with annotating the recording. Generate the report and enter values for '# comp'.

Philips—when the compression channel recording is available (as when the 'puck' and pads are placed and a waveform produced, and the device set to 'defibrillation mode'), generate the report and enter statistics values for '# compressions.' If only the force channel (as when only the 'puck' is placed) or the impedance channel (as when only the pads are placed or the device is switched to 'Monitor Mode') is available, hand count compressions for each minute.

ZOLL—Review the compression channel. The compression channel cannot be annotated by the reviewer. Instead the software uses criteria to judge whether a compression was present or not. Generate the report statistics and enter reported values for '# compressions'. ZOLL reported values for 'Comp rate' is the same as ROC '# comp'.

Compression rate: The device-calculated median rate at which chest compressions were performed for a given minute. If part of a minute cannot be analyzed record the number of seconds in the "number of seconds with no measures" column. A separate approach is taken for each device used:

Medtronic—enter the reported CodeStat values.

Philips—For minutes where the compression channel (derived from the force and impedance channels) provide the values reported by QCPR Review. For any minute where compressions have been hand counted (when the QCPR Review software does not generate statistics) for 1-60 seconds calculate the Compression Rate for a given minute using a standard approach used by the PGH site/spreadsheet:

((#compressions/(60-unanalyzed seconds-seconds no compressions))*60. Contact PGH or the CTC for an Excel spreadsheet for automatic calculations.

ZOLL— For ROC, take the ZOLL reported '# compressions' and divide by the reported CPR fraction. Compression rate for ROC data entry is not to be confused with 'compression rate' reported by ZOLL RescueNet Code Review. Be certain that the complete resuscitative effort is included in the device statistics—that is, the start time corresponds to that time entered for 'Time 1st pads placed' or 'Time of arrest if EMS witnessed' and end of resuscitative effort corresponds with 'Time resus stopped due to death', time resus stopped due to persistent ROSC, or time of ED/hospital arrival (which ever start and stop time is relevant to the case).

CPR fraction: The portion of time during which chest compressions were administered, expressed as a fraction. Report the value calculated/documented by the manufacturer software.

Medtronic—divide 'compression ratio' by 100. The 'compression ratio' should not be confused with the 'CPR ratio". The 'compression ratio' should be used for ROC because it has a default setting of 3 seconds in calculating the pause from CPR. The CPR ratio has a default setting of 10 seconds in calculating the pause from CPR and should NOT be used for ROC. Agencies might want to use this for another purpose beyond ROC. The report shows both ratios unless the administrator goes into the settings and removes the CPR ratio. Please remove the CPR ratio from the minute by minute report to avoid confusion.

Philips—use the FR (flow ratio) column. The company has recently reorganized the statistical printout to align more with ROC data points. Where compressions have been hand counted (when the QCPR Review software does not generate statistics) for a 1-60 seconds, calculate the CPR Fraction for a given minute (using a standard approach used by the PGH site/spreadsheet): (60-unanalyzed seconds-seconds no compression)/(60-unanalyzed seconds). Round to 2 digits (for example 0,65) Contact PGH or the CTC for an Excel spreadsheet for automatic calculations.

ZOLL—this is calculated automatically and reported on the summary. Be certain that the complete resuscitative effort is included in the device statistics—that is, the start time corresponds to that time entered for 'Time 1st pads placed' or 'Time of arrest if EMS witnessed' and end of resuscitative effort corresponds with 'Time resus stopped due to death', time resus stopped due to persistent ROSC, or time of ED/hospital arrival (which ever start and stop time is relevant to the case).

 # secs with no measures and why: The number of seconds in a minute (0-60) during which CPR measures cannot be determined. For 1-60 seconds with no measures, select the reason why from the pull down menu—reasons why are 'ROSC' (so no CPR performed) and 'unanalyzable' (such as when the patient is being moved, cable is disconnected temporarily). For Medtronic devices, the formula to derive '# seconds with no measures' is (100% minus Compr. Ratio)*0.6.

Compression depth (optional): for those machines capable of reporting compression depth. This data element is required for sites participating in the Philips Feedback Study. A

separate approach is taken for each device used:

Medtronic—does not have this feature.

Philips—unit of measure expected to be millimeters (mm). This data element is the calculated average measured depth of compression for a minute, provided on the Detailed Statistics page. Enter data only for minutes where QCPR Review software based its calculation on a full minute of data (where both the puck and pads were placed, and the device in 'defibrillation mode' for the full 60 seconds). Where a portion of the compressions were hand counted (the QCPR Review software did not count compressions for the full 60 seconds), leave the data field blank (do not enter '00') for any minute affected.

ZOLL—units of measure expected to be centimeters (cm)--be certain that the units of measure is not set to inches.

Compression release (optional): for those machines capable of reporting the number of compressions with incomplete release (as assessed by the device) on the upswing of the compression. This data element is required for sites participating in the Philips Feedback Study. A separate approach is taken for each device used:

Medtronic—does not have this feature

Philips—the number of compressions in a given minute with incomplete release (as assessed by the device) on the upswing of the compression. This data element is referred to as “Compressions Leaning” in the QCPR Review report. Enter data only for minutes where QCPR Review software based its calculation on a full minute of data (where both the puck and pads were placed, the device in 'defibrillation mode' for the full 60 seconds, and all compressions were counted by the device). Where a portion of the compressions were hand counted (the QCPR Review software did not count compressions for the full 60 seconds), leave the data field blank (do not enter '00') for any minute affected.

ZOLL—does not have this feature

*Peak ETCO2 (optional): f*or those sites that have continuous end tidal CO2 levels reported as part of the electronic download indicate the average CO2 level over 60 seconds.

Capnography ventilations and # seconds missing (optional): for those sites that have continuous end tidal CO2 levels, record the ventilations per minute as reported by the analysis software. Indicate the number of seconds in a minute (0-60) for which capnography signal was interrupted. If # seconds missing is 60, then no data (do not put '0' as a place holder) should be entered for 'capnography ventilations.'

Name of person responsible for data on this form:

Name of the individual that logged into the electronic data transmission system for clinical study forms or to execute batch up-load of files. This individual will have registered as a member with the CTC for the purpose of participating as a coordinator or investigator in a ROC clinical trial and has designated a user name and password as their “Electronic Signature.” The individual has agreed to consider their electronic signature as equivalent to

their handwritten signature, to maintain the confidentiality of their user name and password, and to not let others use it. Refer to the “Electronic Signature Agreement” (accessed after logging on to the ROC website) posted at https://roc.uwctc.org/tiki/roc-data-entry.

After verifying the entered data and electronic signature are correct, print the web-forms for your files, or convert the web-forms to pdf format and store electronically. Edits made later to the original web-entered forms or batch up-loaded data posted to forms are associated with the electronic signature of the individual making the changes and are documented in the file’s edit history.

ED/Hospital Admit - Cardiac Arrest or Trauma

The purpose of the ED/Hospital Admit-Cardiac Arrest or Trauma form is to document information occurring during the Emergency Department (ED) and/or Hospital course of care. It is to be completed for patients who were transported by EMS and were alive or for whom resuscitative efforts were ongoing. The first five information items are mandatory. Other data fields are optional.

The episode date/time and episode ID will be prefilled by the web data entry program and will be consistent with the date and time recorded on the Patient Enrollment form. It should be reviewed for accuracy.

Information items 1-5 are mandatory.

Item 1 - Name of ED/Hospital transported to:

For web-entry, select name of receiving emergency department or hospital from the pull-down menu. The name of the hospital links with the ROC EMS Structures Database to provide service characteristics including level of trauma service designation, cardiac catheterization laboratory, and cardiac electrophysiology laboratory. If a receiving ED or hospital is not listed, update the EMS Structures database and resume Epistry data entry.

For batch-upload, provide CTC-assigned Hospital ID number for the receiving ED or hospital admission, whichever occurs first.

Cardiac/Trauma designation –For web-entry, this information will be automatically filled from the ROC EMS Structures database. For US hospitals, trauma designations are Level I, Level II, Level III, and Level IV, as accredited by the American College of Surgeons. For Canadian hospitals, trauma designations are TTC (Tertiary Trauma Centre), DTC (District Trauma Centre), PTC (Primary Trauma Centre, and UMC (Urban Medical Center as designated by a state or provincial government body. For batch upload, the CTC will populate this field with data residing in the EMS Structures database.

Item 2 –Date/time of ED /Hospital admit:

Date (required, mm/dd/yyyy) and time (*optional*, 24 hour clock hh:mm) of patient arrival at the initial emergency department or admission to the hospital (which ever occurred earliest). Sourced from hospital admission or patient care records.

Item 3 –Was patient transferred to another acute care hospital?

Indicate if the patient was transferred from the initial ED/Hospital to a different acute care ED or hospital during the course of care associated with this cardiac arrest or traumatic injury episode. If yes, the patient was transferred to another acute care hospital, select the name of that facility from the pull-down menu and date of transfer to that acute care facility. This form provides for up to five hospital transfers and allows for some assessment of patient longevity/duration of acute hospital care, should final vital status later not be attainable. The pull-down menu provides names of ROC hospitals entered in

the EMS Structures database and selection options for 'non-ROC Hospital and 'unknown Hospital'. Select 'unknown Hospital' when the destination hospital will never be known. Where a ROC-hospital is known, but not listed in the pull-down menu, go to the EMS Structures database and enter the additional information. Do not provide the names of nursing home, rehabilitation, or other non-acute care facilities. Transfer to one of these three entities constitutes an 'ED/hospital discharge, reclassification, or death' and is the subject of the next question (#4).

It is important to know if a patient was discharged alive or transferred to another acute care hospital. Sites should be careful when gathering information regarding hospital discharge and confirm the true status of patient disposition.

Item 4 –Date/time of final ED/hospital discharge, reclassification, or death:

Date (required, mm/dd/yyyy) and time (*optional***,** 24 hour clock hh:mm) that the course of care was completed and the patient discharged alive or dead, or reclassified to a non-acute status and awaiting placement in a non-acute care facility. This is reported for the latest (last) ED or acute care hospital the patient was admitted to throughout the course of care associated with the related cardiac arrest or trauma episode. If the patient is discharged dead, the time and date recorded should be the official time of pronouncement.

Item 5 –Final Vital Status:

Indicate patient status—dead or alive—when the course of care associated with this cardiac arrest or traumatic injury episode was completed. Final status is reported for the latest (last) ED or acute care hospital that the patient was admitted or transferred to during the course of care. **Dead or Alive status is mandatory information**. Discharge status when alive and location of death is optional information, though sites are encouraged to provide this.

The intended and preferred source for final vital status is the hospital patient care record. When a hospital record cannot be accessed, the 'death registry' or 'social security index' is the second preferred source. Where used for cardiac arrest, a date of death less than 14 days from the date of the Epistry episode will be attributed to the episode. Where used for trauma, a date of death less than 31 days from the date of Epistry episode will be attributed to the episode. A news paper obituary may be used where a date of death cannot be obtained from other preferred sources, though it is considered the least reliable source for final vital status. Use of news paper obituaries is subject to the same time guidelines as other preferred sources. **Information items 6-17, T1- T3, and C1-C4 are optional:**

Item 6 –Trauma Registry (optional):

Indicate yes or no if a Trauma Registry ID number has been assigned to this patient. The site may choose to include the number in data transmission (either by web-entry forms or batch up-load) to the CTC. If the trauma registry number is provided, the CTC will store it

in the Epistry database and include it in data uploads to the sites to facilitate linking with later data sources.

Item 7 –Cardiac Registry (e.g.,: ICD Registry, Cath/PCI Registry) (optional):

Indicate yes or no if a Cardiac Registry (such as the American College of Cardiology's ICD or Cath/PCI Registry) identification number is assigned to this patient. The Cardiac Registry ID serves as a potential identifier for sites to link to a separate registry to access episode or hospital related data. The site may choose to include the number in data transmission (either by web-entry forms or batch up-load) to the CTC. If the cardiac registry number is provided, the CTC will store it in the Epistry database and include it in data uploads to the sites to facilitate linking with later data sources.

Item 8 –Residential status at final vital status (optional):

The type/location of patient residential status when discharged from the latest (last) ED or hospital the patient was admitted to during the course of care associated with the related cardiac arrest or trauma episode. If home, indicate if the patient returned home to live independently or with assistance, or if unknown/not recorded.

Residential status definitions;

Home: a relative term meaning that the patient was discharged to their own home or a home like situation (i.e. with a relative). Indicate whether they were independent or went home with assistance (e.g. visiting nurse, chore services or outpatient physical therapy or occupational therapy).

Rehabilitation: an adjoining rehab facility or separate rehab facility providing temporary care that would allow the patient to regain strength and function with the intent of returning home or to an assisted living facility.

Assisted living: includes discharged to an environment with services such as physical therapy, occupational therapy; or to a group home, adult day home or halfway house. Distinguished from 'home' in that 'assisted living' is generally a fee-based environment.

Nursing home: includes a location where others are fully responsible for the care of the patient on a long-term basis or a location where the patient can receive high level nursing care on a short-term basis.

Remains in acute care hospital, reclassified: Patient has been reclassified as a non-acute patient and awaits placement or chronic care. Not uncommon in Canada.

Item 9 –First recorded vital signs in ED/hospital (optional):

Indicate if the first set of vital signs were 'done' or are 'not available/not recorded' (NA/NR). A set of vital signs is comprised of those values acquired within a common period of time and are considered relevant to each other.

If 'done', note the values for the first set recorded in a common time frame (a set may not include all the listed components):

SBP: systolic blood pressure (mmHg). Indicate the time recorded for the first set of vital signs.

Pulse: beats per minute, palpated or auscultated.

Respiratory rate: spontaneous breaths per minute. Indicate if patient intubated or chemically paralyzed at time of assessment.

Temperature: indicate scale of measurement (degrees Celsius or Fahrenheit) and source for temperature (rectal, axillary, oral, tympanic, or core). Temperature is often not taken with the first set of vital signs. If taken later (such as in the ICU), do not include it with the first recorded set of vital signs.

*GCS: f*or patient's who are evaluated using the Glasgow Coma Score (GCS), provide the best response score first recorded for Eye, Verbal, and Motor categories or provide the total score for the three components. Total score will be automatically calculated. Indicate if patient had an advanced airway placed or was chemically paralyzed or sedated at time of assessment.

Definitions for standard and pre-verbal/pediatric for Glasgow Coma Score (GCS)

Pre-verbal/Pediatric scale are to be used when assessing children ≤ 2 years or individuals at any age with developmental delay or mental retardation. Following is a comparison of the Standard and Preverbal/Pediatric assessment scales with differences *italicized.*

GCS Scales		**Standard**	**Preverbal/Pediatric**
Eyes	4	spontaneous	spontaneous
	3	to speech	to speech
	2	to pain	to pain
	1	no response	no response
Motor	6	obedient	*spontaneous movements*
	5	localizing	*withdraws to pain*
	4	withdraw to pain	*withdraws to pain*
	3	abnormal flexion	abnormal flexion
	2	abnormal extension	abnormal extension
	1	no response	no response
Verbal	5	oriented x 4	*baseline for patient*
	4	confused	*irritable cry*
	3	inappropriate	*cries to pain*
	2	incomprehensible	*moans to pain*
	1	no response	no response

Item 10 –First ED/hospital labs (optional):

Indicate if the listed lab values were 'done' (and recorded) or 'not available/not done' (NA/NR) in the ED/hospital.

If done, enter the first value recorded for the listed labs and provide date (mm/dd/yyyy) and time (24 hour clock, hh:mm) of value. Note the expected units of measure for the listed labs. Indicate units of measure for blood glucose and hemoglobin.

SaO2: Give the first SaO2 percent as either recorded by a plethysmograph or calculated from arterial blood gas.

For the first recorded ED/hospital arterial blood gas report components for a single arterial blood gas sample. Indicate if patient had an advanced airway placed or had mask/nasal prongs and provide the associated supplemental oxygen.

Item 11 –Demographics (optional):

a. Age:

Provide patient's age as calculated from the date of birth, rounded to the nearest whole number and indicate if expressed in years, months, or days.

Definitions for recorded calculated age:

Years: use for subjects = 3 years, round to nearest whole year

Months: use for subjects = 1 month of age and up to 35 months (< 3 years) old, rounded to nearest whole month

Days: use for subjects < 1 month of age. For subjects less than 1 day old, enter "0."

b. Race:

Check all that apply from the list provided. It is anticipated that race will be either self-reported or indicated by the patient's friends or family during the ED/hospital course of care.

American-Indian/Alaska Native: A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. Included NEMSIS 660

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. Includes NEMSIS 665 Black/African-American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." Includes NEMSIS 670

Native Hawaiian/Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. Includes NEMSIS 675

White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa. Includes NEMSIS 680

Unknown/Not noted: Health care provider is not able to determine the patient's race and notes it in the patient care record, or information has not been recorded. Includes NEMSIS -10, -5, -15.

b. Ethnicity:

Check one from the list provided. It is anticipated that ethnicity will be either self-reported or indicated by the patient's friends or family during the ED/hospital course of care. Indicate if the patient is reported to be Hispanic/Latino or non-Hispanic/Latino.

Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin. The term, "Spanish origin," can be used in addition to "Hispanic or Latino." Includes NEMSIS 690

Non Hispanic or Latino: A person does not indicate their Hispanic or Latino ethnicity or they do not meet the definition for Hispanic or Latino.

Unknown/Not noted: Health care provider is not able to determine the patient's ethnicity and notes it in the patient care record, or information has not been recorded. Includes NEMSIS -10, -5, -15.

Item 12 –Residential status prior to event (optional):

The type/location of patient residence <u>prior</u> to Epistry enrollment for cardiac arrest or trauma. Definitions include:

Home: Patient was living in their own home or a home like situation (maybe with a relative). Indicate whether they were *independent* or living at home *with assistance* (e.g. visiting nurse, chore services or outpatient physical therapy or occupational therapy).

Rehabilitation: Defined as a facility with the purpose of providing temporary care that allows the patient to regain strength and function with the intent of returning home or to an assisted living facility.

Assisted living: includes an environment with services such as physical therapy, occupational therapy; or a group home, adult day home or halfway house. Distinguished from 'home' in that 'assisted living' is generally a fee-based environment.

Nursing home: includes a location where others are fully responsible for the care of the patient on a long-term basis or a location where the patient receives high level nursing care on a short-term basis.

Unknown/not noted: type of residence prior to epistry enrollment is not known or is not noted in the patient care record.

Item 13 –Location of residential status prior to event (optional):

Identify location of the patient's residence (prior to the episode) using census tract, latitude/longitude (lat/long), or Universal Transverse Mercator (UTM) location types. Where the location of residence is known to be outside the US or Canada, select

'unknown/not noted'. Where location of residential status is within the US or Canada, select one location type and provide the related coordinates. A site may use different location types for different cases. It is the responsibility of each ROC site to comply with local and governing privacy requirements and to report location of residence only to the limit allowed.

Census tract: For the United States, go to http://www.ffiec.gov/geocode/default.htm. Select 'year' as 2006. For each residential status enter the street address along with the city and state or the zip code. If you do not have the exact address, enter the name of the intersection (N.E. 45th and 11th Ave. N.E.) where it asks for the street address on the 'ffiec geocoding system web-page.' Once the information has been entered, click the 'Search' button. This connects to the 'Geocode Search Result' page where state code, county code, and tract code numbers are identified in red. The web-site provided MSA/MD code is not entered into Epistry. For state code, enter 2 digits (01-99). For county code, enter 3 digits (001-999, including leading and trailing zeros). For tract code, enter 6 digit number including decimal (1234.56, including leading and trailing zeros).

For Toronto: CTName/CTUID

CTName and CTUID are each an expression of census tract location in Canada and can be derived by conversion of local postal codes using specialized software. 'CTName' data format is restricted for location of residential status within metropolitan Toronto. 'CTUID' data format can be used for any location within Canada, including metropolitan Toronto.

CTName—use of this number format is restricted to metropolitan Toronto. Just as a telephone number is unique only when preceded by an area code, CTName is a unique locator only when preceded by a Census Metropolitan Area/Census Agglomeration (CMA/CA) number. Thus, the CTName data format is *restricted* to use for a known area (that of metropolitan Toronto) because of the absence of a preceding CMA/CA number (see below CTUID description). For metropolitan Toronto CTName, enter 6 digits (1234.56) including decimal point and all leading and trailing zeros. Note: Toronto CTName is provided at local request, and is not intended to limit Toronto from using other formats for providing location of residential status (CTUID, lat/long, or UTM location).

CTUID—This is a unique combination of CMA/CA and CTName numbers and is available when converting a Canadian postal code to census tract format. For CTUID, enter 9 digits (1234567.89) including decimal point and all leading and trailing zeros. The first 3 digits of the CTUID indicate the unique CMA/CA location—for example, Toronto CMA/CA is 535, Hamilton CMA/CA is 537. So, a Hamilton CTUID would be formatted as 537XXXX.XX

Lat/long (latitude/longitude:

Latitude/longitude is a coordinate system to locate a position on the earth, expressed in degrees (relative to a full circle). Latitude runs north/south. Longitude runs east/west. Select which of three (3) data formats the lat/long coordinates are being provided: decimal degrees (DD), DM (degrees:minutes), or DMS (degrees:minutes:seconds or 12:12:12). The most common format is decimal degrees (example: 123.1234) and is recommended

for ROC data entry. The latitude and longitude for a location of residential status must be reported in the same format. No directional designate (north, south, east, west, or '-' sign) is required as all ROC sites are within North America.

Decimal degrees—the most common format for lat/long. In its most precise form, decimal degrees is expressed as 123.123456. For privacy purposes, decimal degrees are rounded (up or down) and reported for ROC to a maximum of four decimals (123.1 to 123.1234, including all leading zeros). No directional designate or '-' sign are to be included.

DM or Degrees:minutes—for latitude, enter 5 characters including colon and no spaces (such as 49:30 or 49:03, designating 30 minutes and 3 minutes respectively). Do not provide decimal place values (such as 49:30.24 is reported as 49:30). For longitude, enter 5-6 characters including colon and no spaces (such as 122:20, 79:24, 114:01 or 96:46 designating 20, 24, 1, and 46 minutes respectively).

DMS or Degrees:minutes:seconds—it is rare that this lat/long format would be used. Contact the CTC to discuss if this report format is contemplated or preferred over the decimal degrees format.

Datum (or map datum)--this is the topographic map standard to which the lat/long coordinates are applied. There are three map datums used in the western hemisphere: NAD27 (North American Datum 1927), NAD83 (North American Datum 1983), and WGS84 (World Geodetic System 1984, based on satellite measurements). There is a measurable difference between the map datums, and thus important to know the source for measurements for later geographic analyses.

UTM (Universal Transverse Mercator):

The UTM coordinate system is a grid-based method to identify a location on the earth. Unlike lat/long coordinates, the UTM coordinate system divides the surface of the earth into zones, or uniform grid squares, each identified by a number (North America is assigned numbers 7 through 21) and a letter. The location of a position within a zone is expressed by using both 'easting' and 'northing' values, and are expressed in either meters or kilometers units of measure.

Easting—this is the projected distance within the zone. Provide the first 3 (kilometers) or 6 (meters) digits of the 'easting' coordinate. Do not round. Instead, truncate the number to the required field length (e.g. 821.8 km is entered as 821, *not* 822). Indicate the units of measure. Where local privacy guidance restricts coordinates to less than 3 (kilometers) or 6 (meters) digits, truncate the number and replace with '0's' (e.g. 828 km is entered as 820 or 800).

Northing—this is the projected distance from the equator and can be expressed in meters or kilometers (most common) units of measure. Provide the first 4 (kilometers) or 7 (meters) digits of the 'northing' coordinate. Do not round. Instead, truncate the number to the required field length (e.g. 8218.68 km is entered as 8218, *not* 8219). Indicate the units of measure. Where local privacy guidance restricts coordinates to less than 4(kilometers) or 7 (meters) digits, truncate the number and replace with '0's' (e.g. 8218 km is entered as 8210 or 8200).

Zone—the UTM designated grid area associated with the provided 'easting' value. Provide the one or two digit zone number (it is anticipated that ROC sites would provide a number ranging 10 to 18) *without* the associated letter (e.g. Zone 17N is entered as 17; the 'N' is not required for the ROC footprint).

Unknown/not noted: Where location of residential status prior to the event is not available. Also mark this option where the location of residence is known to be outside the United States or Canada (such as when a tourist from another country experiences trauma or cardiac arrest while visiting the US or Canada).

Item 14 –Total days in the ICU (optional):

Indicate the number of calendar days the patient was in an intensive care setting (includes CCU, ICU, CCC, SICU, TICU etc). Any portion of 24-hour period is considered one day. If using web-entry for data, a prompt will indicate the total number of days the patient was in the ED/Hospital (including all acute care stays) to serve as a double-check.

Item 15 –Was patient made DNR or care limited or withdrawn in the ED/Hospital?(optional):

Choose “yes” or “no” to indicate if a decision was made in the *ED or hospital to actively withdraw life support or limit treatment for the patient. (This may include a DNR or do not resuscitate order, extubation, withdrawal of pressors, etc.).*

Item 16 –Major procedures while in ED and/or Hospital (optional):

For patients admitted to the ED/Hospital provide up to 15 ICD-9-CM or ICD-10-PCS **procedure** codes recorded at the time of final patient disposition OR indicate which major procedures were performed during the patient’s course of ED and hospital care. If no major procedures were noted during the ED/hospital course of care, mark the provided box. If providing up to 15 procedure codes, indicate which version of ICD codes are provided.

Definitions of Major Procedure types—Cardiac arrest:

Fibrinolytics: includes TPA (tissue plasminogen activator), Streptokinase, Alteplase, Reteplase, Tenecteplase, Activase and other fibrinolytic agents. Does not include antiplatelet or antithrombin agents such as heparins, clopidogrel, 2B3A inhibitors, or aspirin.

Hypothermia therapy: methods to reduce patient temperature. If hypothermia therapy was performed, indicate the number of hours of therapy. External cooling includes cutaneous contact with chilled surfaces including ice packs or ice on head, cooling blankets; Internal cooling includes intravenous infusion of fluids chilled to below room temperature and invasive and central catheter lines intended for internal cooling and thermal regulation (such as those provided by Alsius and Medivance).

Definitions of Major Procedure types—Trauma:

Abdominal surgery: includes laparotomy with or without therapeutic intervention, percutaneous drainage of intra-abdominal abscess.

Thoracic surgery: includes cardiac, pulmonary, thoracotomy, sternotomy, VATS, percutaneous drainage of empyema or lung abscess.

Neurosurgery: includes intracranial pressure, ventriculostomy, craniotomy, spine surgery.

Vascular surgery: includes angiographic control of hemorrhage, peripheral vascular repair.

Interventional angiography: including stent insertion, embolization, dilatation, angiographic control of hemorrhage.

Major Orthopedic surgery: including open fixation repair, repair of femur fracture, fasciotomy for extremity compartment syndrome.

Neck surgery: includes neck exploration, pharynx/larynx surgery

Airway management: includes cricothyrotomy or emergent tracheostomy.

Blood transfusion: limited to the infusion of whole blood or packed cells. Does not include infusion of other blood products, including platelets, fresh frozen plasma, albumin. Indicate the number of units of whole blood or packed red blood cells that were given during the first 24 hours of ED/Hospital admission.

Item 17 –Optional patient identification information:

Identifying information would be critical in long-term follow-up beyond hospital discharge using the National Death Index. Collecting identifying information was suggested by the Protocol Review Committee September 18, 2005. This information would also help to identify repeat episodes. Sites are expected to work within local regulatory and legal frameworks. This identifying information is intended only for site use and is not transmitted to or stored in the database at, the CTC. If entered on the web-form, it is retained when printing hard-copy or saving as pdf.

For Trauma patients only (items #T1-T3)

Item T1, –Anatomic Injuries (optional):

List the abbreviated injury score (AIS) for the 3 worst injuries in each of six anatomic regions, if no injury is to be entered for any one of the anatomic regions (such as face or chest) or any one of the three injuries, enter “0” to the left of the decimal point provided (do not enter the '0' to the right of the decimal point). The AIS is an anatomical scoring system for ranking and comparing severity of injury in trauma patients. The AIS is the foundation for the Injury Severity Score (ISS). Indicate if the anatomic injury scores are based on autopsy results.

ItemT2 –Trauma Scores (optional):

'Calculated' scores are automatically provided for each of the three trauma scores where the underlying data elements have been previously web-entered (see below definitions). 'Calculated' scores are blank if underlying data elements are not complete. 'Calculated' scores cannot be edited.

'Provided' scores are those separately calculated (or documented in the patient record) and entered by the site. It is encouraged that trauma scores be 'provided' where ED/hospital records differ from those scores 'calculated' with web-entered data.

Injury Severity Score (ISS) is calculated from the worst injuries from each of three different anatomic regions. The ISS anatomic scoring system correlates with mortality, morbidity, hospital stay, and other measures of severity.

Revised Trauma Score (RTS) is calculated from the first vital signs data obtained on the patient for GCS, systolic blood pressure and respiratory rate. RTS is a physiologic scoring system with demonstrated accuracy in predicting death. RTS is an element for calculating TRISS.

Trauma Score Injury Severity Score (TRISS) is calculated using RTS, ISS, and patient age to estimate probability of survival.

Item T3 –Diagnosis codes while in ED/hospital (optional):

Provide up to fifteen (15) ICD-9-CM or ICD-10-CM **diagnosis** codes obtained from the discharge summary (used to calculate an ICISS). Indicate which version of diagnosis codes are provided.

For Cardiac patients only (items #C1-C4):

Item C1 –Etiology of arrest: Data guardian classification (optional):

This data element is intended to be completed by the site data guardian using all available information, including prehospital and ED/hospital records (including lab values, toxicology screens, and autopsy) and public records (including death certificates, news, and coroner reports). The data guardian is to report if the etiology of arrest (that qualified this case for Epistry enrollment) is 'obvious' or 'not obvious' (presumed cardiac). The data guardian's classification may differ from that documented for the 'field' or 'site' classifications for the case—this is anticipated and may be due to the broader set of records with which the data guardian is allowed to use when classifying etiology of arrest.

It is anticipated that the majority of arrests will fall into the 'no obvious cause' category and will include those cases that are presumed cardiac (NEMSIS 2250) or do not clearly fit in any of the 'obvious cause' categories listed and defined below. Also mark 'no obvious cause' (presumed cardiac) where the ED/hospital course of care confirms a cardiac cause of arrest (such as 12-lead ECG findings or enzyme lab results). Mark 'obvious cause' only when the cause of out of hospital arrest is clearly other than cardiac and meets the defined criteria.

Definitions for obvious cause of arrest:

Anaphylaxis: Cases of sudden collapse with other clear signs of anaphylaxis including urticaria, facial and tongue swelling, respiratory distress, and clear exposure to an allergen (e.g., bee sting or ingested food with known allergy) that triggered the event. In addition to these physical and historical findings, an Epipen (intramuscular injectable source of epinephrine) may have been used. However, a used Epipen without physical signs of anaphylaxis (or witnessed by bystanders) is not diagnostic for this etiology option.

Chemical poisoning (intentional or unintentional, includes carbon monoxide, toxic gases): This category does NOT include prescribed medications, recreational drugs, or ethanol (see “Drug Poisoning”). However, isopropyl alcohol, ethylene glycol and methanol are included as “chemical poisoning”. This category will include all cases where there is high likelihood that the cardiac arrest would not have occurred in the absence of a poison. Chemical poisons are considered substances that would not normally be ingested, inhaled or consumed and may be environmental or industrial, including such items as insecticides, herbicides, industrial gases, cleaning solutions, carbon monoxide sources (e.g., automobile exhaust or space heaters), or similar compounds. The cardiac arrest timing and clinical scenario should be consistent with the presumed chemical poisoning. This etiology includes both intentional chemical poisoning (i.e., cases where ingestion, inhalation or contact with a chemical poison for the purposes of suicide is clear - suicide note, witnesses confirm discussion of suicidal intent or witnessed clear impulsive intentional ingestion temporarily related to the collapse), and unintentional chemical poisoning (cases where witnessed chemical exposure precedes the collapse by 3-5 minutes). This category would include cases where witnesses confirm contact with a chemical poison just prior to collapse or hospital work-up later confirms. (may include chemical poisoning NEMSIS 9515)

Drowning: victim is found by provider or bystanders submersed in water without an alternative

causation (May include drowning NEMSIS 9525 and NEMSIS 2260).

Examples of cases that fit this definition include; young and presumably healthy person found floating in the water with no evidence of overdose or drug ingestion; in the absence of other contributing factors, any patient who was witnessed to be choking or coughing before going under water; water in lungs found at autopsy.

Examples of cases that do NOT fit this definition include; patients who suffer trauma immediately prior to falling in the water (the case should be entered in the trauma, not the cardiac, patient cohort; for patients presumed to be older than 39 years of age one cannot be certain whether the submersion or some medical event was the cause of death so 'no obvious cause' would generally be selected; person who was inebriated or toxic on a drug who then drowned (the case should be classified as 'no obvious cause').

References: *S*alomez F, Vincent JL. Drowning: a review of epidemiology, pathophysiology, treatment and prevention. *Resuscitation.* 2004 Dec;63(3):261-8.

Idris AH, Berg J, Bierens L, et al. Recommended guidelines for uniform reporting of data from drowning: the 'Utstein style'. *Circulation.* 2003 Sept; 108:2565-2574.

Drug poisoning (intentional or unintentional, includes ethanol): This category includes prescribed medications, recreational drugs, and ethanol. Intentional drug overdose may include cases where ingestion of a drug (i.e., prescribed or over the counter medication, recreational drugs including alcohol) for the purposes of suicide is clear (suicide note, witnesses confirm discussion of suicidal intent or witnessed clear impulsive intentional ingestion temporarily related to the collapse). Unintentional drug overdose may include cases where witnessed inhaled or intravenous or oral recreational drug use immediately precedes the collapse. The Drug Poisoning category includes cases where witnesses confirm the situation, for example an injection of heroin just prior to collapse or where the evidence strongly suggests immediate use prior to arrest (e.g., tourniquet on arm and empty syringe at side). May include drug poisoning NEMSIS 9530.

Examples of cases that fit this definition; a victim collapses and there are empty pill bottles or ethanol containers at the scene without clear evidence of suicidal intent.

Examples of cases that DO NOT fit this definition; patient with a history of recreational drug use within 24 hours of the event (e.g., adolescent found collapsed at a party or the known alcoholic found dead the morning after heavily imbibing); classify these types of cases as 'no obvious cause' (presumed cardiac).

Electrocution (non-lightning): This category includes all cases where the patient has an electrical cutaneous burn in the setting of contact with a high voltage source. Electrocution would also be the obvious choice if the victim was found attached or nearly so, to a high-tension source of current. This category also includes all cases where the patient has been removed from the source of high tension current but the event was witnessed. (may include electrocution non-lightning NEMSIS 9535 or electrocution NEMSIS 2270)

Excessive cold: Low ambient temperature (below 32F or 0C) where an obviously healthy individual is inappropriately clothed for the ambient temperature. (may include excessive cold

NEMSIS 9540)

Excessive heat: Situations in which an obviously healthy person experiences a cardiac arrest and the most significant contributing factor is increased ambient temperature i.e. exercise on a hot day or confined in a locked car or lost hiking in the desert. (may include excessive heat NEMSIS 9545)

> Examples of cases that fit this definition; the inebriated patient found outside for a prolonged period of time exposed to extreme heat.

Foreign body obstruction: Cases of sudden airway obstruction leading to cardiac arrest due to ingestion of a foreign body identified by history or by direct visualization within the airway. Some of these cases may be preceded by choking. (may include airway obstruction NEMSIS 9585)

> Examples of cases that fit this definition include; small child (age 4 or less) choking after a balloon popped in front of their face or after eating a hot dog and succumbs to cardiac arrest; or man observed to be eating and suddenly begins to choke and hold his throat prior to collapsing; or on intubation a foreign body is visualized +/- removed.
>
> Examples of cases that DO NOT fit this definition include: paramedics report inability to ventilate the patient and presume airway obstruction without finding the source of the obstruction;

Hanging: Cases of sudden airway obstruction leading to cardiac arrest secondary to hanging. Requires either the presence of ligature present around the neck, found hanging, or marks on the neck compatible with a previous ligature in the setting that suggests this was the obvious cause of death.

> Examples of cases that fit this definition; case in which the victim is found with a rope around the neck after fire or police have cut them down from a gallows equivalent
>
> Examples of cases that would NOT fit this definition: victim has a ligature around the neck without any evidence at the scene of any attempt to hang himself; a victim who has been strangled by an assailant's hands during an altercation (this case would be classified as 'obvious cause' Strangulation).

Lightning: cases of cardiac arrest where the event was directly attributed to lightning strike or blast effect from lightning temporally related to the event i.e. immediately following the strike, burn marks on the ground or nearby objects, melting of metal objects, or documented classic signs of electrocution by lightning. (may include lightning NEMSIS 9575)

> Examples of cases that fit this definition: witnessed lightning strike on golf course where members of a foursome documented direct hit to one of their group and called 911; or unwitnessed cases where there are visible signs of lightning strike including cutaneous burns described as Lichtenburg figures, flash burns, punctuate burns, contact burns, or linear burns in the skin folds.
>
> Example of a case that does NOT fit this definition: man found outside in the rain without witnesses to verify direct strike or blast effect or any signs or symptoms of lightning related electrocution.

Mechanical suffocation: Mechanical suffocation causing arrest is distinct from hanging, strangulation, choking, respiratory, anaphylaxis, or SIDS etiologies. This category will rarely be coded. It is included for a unique and very specific group of patients who arrest because of suffocation due to an external physical barrier. (may include mechanical suffocation NEMSIS 9585)

> Examples of cases that fit this definition: someone with the plastic bag over the head; a pillow or another object was used to suffocate the patient; or a child or adult with tracheostomy site who develops an obstruction.

Non-traumatic exsanguination: This category includes the rare situation where it is highly likely that the patient "bled to death" in a short period of time and there is strong evidence that acute and catastrophic loss of blood was the direct cause of the arrest.

> Examples of cases that fit this definition: hemodialysis line disconnected with obvious large loss of blood; vomiting of blood with EMS witnessed and documented large loss of blood; blood in stool (lower GI bleed) with EMS witnessed and documented large loss of blood.
>
> Examples of cases that DO NOT fit this definition: vomiting blood with unknown amount or small amount on face or clothes; possible or suspected ruptured aortic aneurysm (this can never be proven without autopsy or diagnostic imaging); epistaxis; hemoptysis

Radiation: This etiology will be rarely coded. Cardiac arrest due to radiation requires an acute and massive radiation exposure that temporally (typically within seconds to minutes) produces a cardiac arrest. (may include radiation exposure NEMSIS 9615)

> Examples of cases that fit this definition: industrial exposure or terrorist event with presumed high radiation levels.

Respiratory: Adult cardiac arrest due to primary respiratory cause requires that the patient have 1) an established medical history of asthma and 2) a witnessed reported clinical course prior to arrest implicating asthma. Although there are no absolutes, death due to asthma (as a respiratory 'obvious cause') would generally be expected to evolve over hours or even days with progressive shortness of breath as the principal symptom rules. Pediatric (patients < 16 years) cardiac arrest due to primary respiratory cause requires that the patient have 1) an established history of an underlying disease that places the patient at higher risk for respiratory disease (see below examples) and 2) a witnessed reported clinical course of an acute respiratory problem prior to the arrest.

> Examples of adult cases that fit this definition: a) 54 yo male with history of asthma, hospitalized previously, who experienced progressive shortness of breath over the past day following URI for past week. He has been using inhalers around the clock since yesterday and took an extra dose of prednisone this morning. His spouse called 9-1-1 when his respiratory symptoms made him unable to talk or answer questions. No chest pain or prior heart history. EMS arrives to find the patient unresponsive without pulse or respirations. Rationale: Several circumstances suggest a primary respiratory arrest: 1) the history suggests that he has fairly significant asthma, the clinical circumstances are highly consistent with an asthma exacerbation with similar past

events, and there is information indicating that he did not have clinical heart disease. Hence the level of information sufficiently implicates a respiratory mechanism as the primary cause; b) 16 year old woman with a history of asthma witnessed by bystander or responder to have inspiratory and expiratory wheezing prior to in cardiac arrest.

Examples of pediatric cases (patients < 16 years of age) that fit this definition: a) Child receiving chronic oxygen therapy or respiratory assistance, such as a premature infant at home on oxygen with an increase in oxygen requirement over the previous hours or days; b) Child with acute febrile respiratory illness in the days or hours prior to arrest, such as an otherwise healthy child with a presumed respiratory infections disease preceding the event; c) child with history of asthma and progressive acute respiratory distress ("asthma attack") whereby witnessed respiratory distress progresses over hours until he/she cannot talk, then turns blue, and collapses.

Examples of cases that do NOT fit this definition include: a) 65 yo male with history of COPD (home oxygen dependent) and heart disease (prior bypass) was last seen at breakfast by his wife. He had no complaints at that time. When she returned home later that morning she found him unresponsive on the couch with his home nebulizer running. She called 9-1-1 and the EMS arrived to find him without pulse or respiration. Rationale: Although the patient had fairly severe chronic lung disease, he did not have clear prodromal symptoms or signs indicating progressive respiratory decline. The scene was suggestive that he experienced some symptoms prior to death since the nebulizer machine was running but this could have been due to a variety of cardiopulmonary symptoms. This patient should be classified as no obvious cause (presumed cardiac); b) 75 yo female nursing home resident develops cough for at least 1 day and then increasing shortness of breath this morning. The nursing home staff had provided oxygen and an albuterol but without relief. At the time of the 9-1-1 call she was awake but unable to speak due to extreme respiratory distress. When EMS arrives she is unresponsive without pulse or blood pressure and nursing staff have initiated CPR. Her history is notable for history of asthma for which she uses 2 different inhalers. Rationale: The patient did have some history of lung disease and some symptoms of progressive dyspnea. However the severity of lung disease is not clear and the symptoms could be consistent with other etiologies of arrest. For example, this patient could be manifesting congestive heart failure or pulmonary embolism. Although a judgment, the level of information leaves some question as to whether respiratory disease was the primary etiology. The best etiology classification for this patient would be 'no obvious cause' (presumed cardiac).

Examples of pediatric cases (patients <16 years of age) that do NOT fit this definition: a) Developmentally disabled child without a supported airway found pulseless and apneic, such as 6 year old child with cerebral palsy and limited ambulation found pulseless and apneic in bed (this case would be coded as 'no obvious cause'); b)child with a supported airway (i.e. Tracheostomy) and found pulseless and apneic (this case would be coded as 'obvious cause' mechanical suffocation); c) prior history of congenital heart disease and no other 'obvious cause' identified—congenital heart disease is not an etiologic classification, but should be included as a 'contributing factor.' This case would be coded as 'no obvious cause' (presumed cardiac).

SIDS (sudden infant death syndrome, less than 13 months of age): Cases of death where an infant, ages 1 month to 12 months is found in their crib/bed and death was unwitnessed. All three criteria—age, crib/bed location, and unwitnessed death—must be present to be categorized as SIDS. Background of sudden infant death syndrome: The American Academy of Pediatrics—SIDS, also called crib or cot death, is the sudden death of an infant under 1 year of age that remains unexplained after thorough case investigation, including performance of a complete autopsy, examination of the death scene, and a review of the clinical history. [NOTE: Site classification of etiology of arrest for classification of SIDS as an obvious cause is to be determined solely from the prehospital patient care record. SIDS is the most common cause of death between 1 and 6 months of age. The incidence of SIDS peaks between 2 and 4 months of age. Approximately 90% of SIDS deaths occur before the age of 6 months.]

SIDS is suspected when a previously healthy infant, usually younger than 6 months, is found dead in bed, prompting an urgent call for emergency assistance. Often, the baby is fed normally just before being placed in bed to sleep, no outcry is heard, and the baby is found in the position in which he or she had been placed at bedtime or naptime. In some cases, cardiorespiratory resuscitation initiated at the scene by emergency personnel is continued without apparent beneficial effect en route to the hospital, where the baby is finally declared dead. Evidence of terminal motor activity, such as clenched fists, may be seen. There may be serosanguineous, watery, frothy, or mucoid discharge coming from the nose or mouth. Skin mottling and postmortem lividity in dependent portions of the infant's body are commonly found. Review of the medical history, scene investigation, radiographs, and autopsy are unrevealing.

The Canadian Pediatric Society refers to SIDS as the sudden and unexpected death of an apparently healthy infant usually less than one year of age, which remains unexplained even after a full investigation. On average, 3 infants a week are reported to die of SIDS in Canada. Although in Canada there has been a decrease in the number of infant deaths reported as SIDS, it still remains a significant public health concern. Aboriginal infants have a risk of SIDS that is higher than the risk to non-Aboriginal infants.

> Example of pediatric cases (less than 13 months of age) that are included: Although there is some controversy and a few documented cases of long QT causing what appears to be SIDS, the evidence supports that most are related to respiratory issues. A case can be made that this is mechanical suffocation, but that can not reliably be done in the absence of a thorough review of the history and even location of the death. We need to be consistent with this as we will have many cases of this and CPR will be delivered.

Smoke inhalation: Cases of collapse in a fire setting with significant smoke exposure. This is defined as the patient who was exposed to fire in a closed space (Ryan et al N Engl J Med, 1998). May include smoke inhalation NEMSIS 9625.

Strangulation: The impression of EMS responders is that the patient’s most significant condition that led to cardiopulmonary arrest is strangulation. Strangulation is a form of asphyxia (though not categorized as 'obvious cause' asphyxia) characterized by closure of the blood vessels or air passages of the neck as a result of external pressure on the neck

(McClane et al J Emerg Med 2001) The paramedic usually describes crush marks around the neck.

Examples of cases that fit this definition: victim becomes non-responsive during a witnessed altercation where the assailants hands were around the neck.

Examples of cases that would NOT fit this definition: a) where the individual was involved in an altercation and becomes unresponsive without witnesses documenting strangulation just prior to collapse; b) victim has bruising around the neck without documented history of strangulation related to the collapse;

Terminal illness (includes end-stage diseases such as cancer): Death due to "terminal" condition is one in which death is expected and for which there is evidence of poor function or functional decline prior to death. Both conditions need to be met. Terminal condition will most often be considered in patients with advanced cancer. An individual whose function is declining and for whom death is expected should be classified as terminal illness (see below examples).

Examples of cases that fit this definition: a) 45 year old woman is found unresponsive and not breathing. She has advanced pancreatic cancer and is enrolled in an experimental treatment protocol. She has been sleeping mostly during the last week because of weakness and malaise and has declined to return to the hospital. She was quite difficult to arouse earlier in the day; b) 88 yo male with liver cancer who has been mostly bedridden the past month. He has been progressively more confused over the last two days to the point where his caretaker could not wake him.

Examples of cases that do NOT fit this definition: a) Patient with advanced cancer who is reasonably functional – carrying out ADLs, living independently, and collapses would be classified as "no obvious cause" (presumed cardiac); b) 68 yo male with metastatic colon cancer ("his cancer had spread to his lung and liver" per bystander son) who collapsed while walking in the park. "He had gotten a bit weaker over the past year but seemed fine today". The son is not aware of other conditions or medications. Classify this case as 'no obvious cause' (presumed cardiac); c) 71 yo female found unresponsive by her husband. She has lung cancer that has spread to her bones and a past history of a "heart attack" 2 years ago. Her husband reports that "she has been receiving radiation treatment for the cancer and the doctors weren't sure how long she had." This morning she had no complaints and they were leaving the house to go shopping when she collapsed. Classify this case as 'no obvious cause' (presumed cardiac).

Trauma (includes blunt, penetrating or burns): Patients who have experienced a cardiac arrest directly caused by blunt, penetrating or burn injury should be enrolled in the Trauma Epistry cohort, not the cardiac arrest cohort.

Examples of cases that do NOT fit this definition: a patient scenario where it is clear from the bystander history that the patient collapsed due to some medical condition prior to experiencing the trauma. This patient would be entered in the cardiac arrest cohort and if the etiology of the arrest is unclear, would be marked 'no obvious cause' (presumed cardiac).

Venomous stings and venomous bites: This category will include all cases where there is visual evidence or witnessed attack of a venomous organism (e.g., animal, reptile, insect) that immediately preceded and presumably precipitated the cardiac arrest. Evidence for the sting must include visible localized skin findings (e.g., local erythema or edema at site) and/or witnessed report by bystanders of history that supports this etiology. If a venomous sting precipitated anaphylaxis, the obvious cause "Anaphylaxis" should be marked. (may include bites NEMSIS 9510 and venomous stings, either plants or animals NEMSIS 9645)

Item C2–Were there contributing factors directly related to this cardiac arrest? (optional):

This section is intended to capture the variety of factors that were observed or reported during the course of prehospital and hospital course of care. The data guardian will mark all applicable conditions that are documented in the prehospital PCR (whether narrative or check item format) and hospital record that may have been related to the cardiac arrest. It is not necessary for a 'contributing factor' to meet the same burden of proof as does 'obvious cause' for either Site classification or Data guardian classification. Check all contributing factors that appear to be directly related to this cardiac arrest.

Definitions for contributing factors:

Anaphylaxis: Signs of anaphylaxis including urticaria, facial and tongue swelling, respiratory distress, and clear exposure to an allergen (e.g. bee sting or ingested food with known allergy) that triggered the event. An Epipen (intramuscular injectable source of epinephrine) may have been used.

Chemical poisoning (intentional or unintentional, includes carbon monoxide, toxic gases): This category does NOT include prescribed medications, recreational drugs, or ethanol (see "Drug Poisoning"). However, isopropyl alcohol, ethylene glycol and methanol are included as "chemical poisoning". Chemical poisons are considered substances that would not normally be ingested, inhaled or consumed and may be environmental or industrial, including such items as insecticides, herbicides, industrial gases, cleaning solutions, carbon monoxide sources (e.g. automobile exhaust or space heaters), or similar compounds. May include chemical poisoning NEMSIS 9515.

Dialysis: The patient was undergoing or very recently underwent dialysis treatment (peritoneal or hemodialysis). This does not include exsanguination secondary to disconnection of dialysis shunts—see 'non-traumatic exsanguination'.

Drowning: victim is found by provider or bystanders submersed in water or witnessed to be choking or coughing before going under water (May include drowning NEMSIS 9525 and NEMSIS 2260).

Drug poisoning (intentional or unintentional, includes ethanol): Includes prescribed or over the counter medications, recreational drugs, and ethanol (alcohol). May include drug poisoning NEMSIS 9530)

Electrocution (non-lightning): This category includes all cases where the patient has an electrical cutaneous burn in the setting of contact with a high voltage source. Electrocution would be also the obvious choice if the victim was found attached or nearly so, to a high-tension source of current. This category also includes all cases where the patient has been removed from the source of high tension current but the event was witnessed. (may include electrocution non-lightning NEMSIS 9535 or electrocution NEMSIS 2270)

Excessive cold: Low ambient temperature (below 32F or 0C) where an obviously healthy individual is inappropriately clothed for the ambient temperature. May include excessive cold NEMSIS 9540.

Excessive heat: High ambient temperature i.e. exercise on a hot day or confined in a locked car or lost hiking in the desert. May include excessive heat NEMSIS 9545.

*Foreign body obstruction: S*udden airway obstruction due to ingestion of a foreign body identified by history or by direct visualization within the airway. Some of these cases may be preceded by choking. May include airway obstruction NEMSIS 9585.

Hanging: Cases of sudden airway obstruction secondary to hanging. Patient may have a ligature present around the neck, be found hanging, or have marks on the neck compatible with a previous ligature.

Lightning: cases of cardiac arrest where a lightning strike or blast effect from lightning temporally related to the event i.e. immediately following the strike, burn marks on the ground or nearby objects, melting of metal objects, or documented classic signs of electrocution by lightning. (may include lightning NEMSIS 9575)

Mechanical suffocation: Mechanical suffocation is distinct from hanging, strangulation, choking, respiratory, anaphylaxis, or SIDS etiologies. It includes suffocation due to an external physical barrier. (may include mechanical suffocation NEMSIS 9585). May include someone with a plastic bag over the head; pillow or another object used to suffocate the patient; or a child or adult with a tracheostomy site who develops an obstruction.

Non-traumatic exsanguination: There is evidence that acute and catastrophic loss of blood occurred in a short period of time. May include disconnection of a hemodialysis line; vomiting of blood; blood in stool.

Radiation: Radiation requires an acute and massive radiation exposure that temporally (typically within seconds to minutes) produces a cardiac arrest. May include radiation exposure NEMSIS 9615. May include industrial exposure or terrorist event with presumed high radiation levels.

Respiratory: Adult cardiac arrest due to a medical history of COPD or asthma or a witnessed reported clinical course prior to arrest implicating respiratory difficulties. May evolve over hours or even days with progressive shortness of breath as the principal symptom rules. May have been using inhalers with increased frequency or increased dose of prednisone. May have been at home with oxygen with an increase in oxygen requirement over the hours prior to arrest. Pediatric (patients < 16 years) cardiac arrest due to 1) an established history of an underlying disease that places the patient at higher risk for respiratory disease (see below examples) and 2) a witnessed reported clinical course of an acute respiratory problem prior to

the arrest. This does not include a child with a supported airway (i.e. Tracheostomy) found pulseless and apneic--this would be 'mechanical suffocation'.

SIDS (sudden infant death syndrome, less than 13 months of age): Cases of death where an infant, ages 1 month to 12 months is found in their crib/bed and death was unwitnessed. All three criteria—age, crib/bed location, and unwitnessed death—must be present to be categorized as SIDS. See Etiology of arrest 'Obvious cause' definitions for background on SIDS.

Smoke inhalation: Cases of collapse in a fire setting with significant smoke exposure. This is defined as the patient who was exposed to fire in a closed space (Ryan et al N Engl J Med, 1998). May include smoke inhalation NEMSIS 9625.

Strangulation: Strangulation is a form of asphyxia (though not categorized as 'contributing factor' asphyxia) characterized by closure of the blood vessels or air passages of the neck as a result of external pressure on the neck (McClane et al J Emerg Med 2001) The paramedic usually describes crush marks or bruising around the neck.

Terminal illness (includes end-stage diseases such as cancer): "Terminal" illness is one in which death is expected and for which there is evidence of poor function or functional decline prior to death.

Trauma (includes blunt, penetrating or burns): Patients who have experienced a cardiac arrest directly caused by blunt, penetrating or burn injury should be enrolled in the Trauma Epistry cohort, not the cardiac arrest cohort.

Venomous stings and venomous bites: This category will include cases where there is evidence or witnessed attack of a venomous organism (e.g., animal, reptile, insect) that immediately preceded and presumably precipitated the cardiac arrest. Evidence may include visible localized skin findings (e.g., local erythema or edema at site) and/or witnessed report by bystanders of history that supports this etiology. If a venomous sting precipitated anaphylaxis, the contributing factor "Anaphylaxis" should be marked. (may include bites NEMSIS 9510 and venomous stings either plans or animals NEMSIS 9645)

Other obvious cause, specify: enter other causes that are obviously related to this arrest (60 characters maximum).

Item C3 –Structured Chart Review Tool for Assessment of Cerebral Performance Category at hospital discharge (optional):

Cerebral Performance Category (CPC) indicates final neurological status at time of final hospital discharge or death. Use chart review to categorize the patient's condition. The below responses will be later mapped (in analysis) to traditional CPC codes. Consider each of the below questions separate from each other—they are not intended to be dependent responses.

a. Is the patient able to follow any simple commands or say any words? Indicate no or yes if these capabilities are indicated or implied in the ED/hospital patient care records as a patient condition at the time of discharge. If no, skip parts b, c, and d of this section and

go to question C4. If yes, proceed to part b.

b. Is the assistance of someone essential for all or part of the day for activities of daily living (dressing, preparing meals, local travel, shopping)? Indicate no if, in your judgment after reviewing the hospital chart, it appears that assistance is not likely to be essential for activities of daily living after hospital discharge. Your judgment may be based upon in-hospital assessments made by occupational or physical therapy, nursing notes speaking to independence, stability, mobility, etc. Indicate yes if, in your judgment it appears that assistance is essential after discharge. If yes, skip parts c and d of this section and go to question C4. If no, proceed to part c.

c. Is the patient able to return to work or social activities in any capacity (even limited)? Indicate no or yes whether, in your judgment after reviewing the hospital chart, it appears the patient is able to return to even a limited capacity of work or social activities. This does not require that the patient have plans or a desire to return to work, only if they are capable of doing so. If no, skip part d of this section and go to question C4. If yes, proceed to part d.

d. Does the patient have any problems that are more than mild, i.e. problems that prevent him/her from doing things he/she would like or have to do (such as dysphasia, hemiplegia, ataxia, dysarthria, memory, cognition, personality)? Indicate yes, if the patient is documented to exhibit/experience impairments that are, in the judgment of the reviewer, to be more than mild in nature at the time of discharge.

Definitions of selected terms:

Dysphagia—difficulty in swallowing

Hemiplegia—paralysis of one side of the body

Ataxia—an abnormality of coordination, as might cause an abnormal or staggered gait.

Dysarthria—speech that is characteristically slurred, slow, and difficult to produce. May have problems the voice qualities of speech.

Item C4 –Modified Rankin Scale at hospital discharge (optional):

Using chart review at time of patient discharge enter the MRS.

Definitions of Modified Rankin Scale:

MRS0 –no symptoms at all.

MNRS1 –no significant disability: despite symptoms, able to carry out all usual duties and activities.

MRS2 –slight disability: unable to carry out all previous activities but able to look after own affairs without assistance.

MRS3 –moderate disability: requiring some help, but able to walk without assistance.

MRS4 –moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance.

MRS5 –severe disability: bedridden, incontinent and requiring constant nursing care and attention.

Death at discharge—modified Rankin Scale is not applicable as the patient was not alive at discharge

Name of person responsible for data on this form:

Name of the individual that logged into the electronic data transmission system for clinical study forms or to execute batch up-load of files. This individual will have registered as a member with the CTC for the purpose of participating as a coordinator or investigator in a ROC clinical trial and has designated a user name and password as their “Electronic Signature.” The individual has agreed to consider their electronic signature as equivalent to their handwritten signature, to maintain the confidentiality of their user name and password, and to not let others use it. Refer to the “Electronic Signature Agreement” (accessed after logging on to the ROC website) posted at https://roc.uwctc.org/tiki/roc-data-entry.

After verifying the entered data and electronic signature are correct, print the web-forms for your files, or convert the web-forms to pdf format and store electronically. Edits made later to the original web-entered forms or batch up-loaded data posted to forms are associated with the electronic signature of the individual making the changes and are documented in the file’s edit history.

ATTACHMENT A -- Electronic Signature Agreement

ELECTRONIC SIGNATURE AGREEMENT

This Agreement is between you and the Resuscitation Outcomes Consortium (ROC) Clinical Trial Center (CTC), and provides for your informed consent to the use of your designated user name and password as an "Electronic Signature". You have registered as a member with the CTC for the purpose of participating as a coordinator or investigator in clinical trials under the ROC. The ROC CTC has created an electronic data transmission system for all clinical forms and requires the use of Electronic Signatures. The CTC believes that this system reduces the time and expense of data submission and facilitates efficient and accurate data transmission from a clinical trial site to the CTC, without compromising data integrity, or the rights of the parties. Therefore:

1. You agree that the use of your user name and password constitutes your Electronic Signature when submitting or transmitting documents or data via the internet ROC CTC website.
2. Your Electronic Signature shall be considered for all such purposes as equivalent to your handwritten signature, provided below.
3. Your Electronic Signature, used in accordance with this Agreement, shall have the same legal weight associated with that of an original signature.
4. You agree not to raise the use of an Electronic Signature as a defense in connection with an internet ROC CTC website transmission, if your Electronic Signature is used in accordance with this Agreement.
5. Because the combination of your user name and password constitutes your Electronic Signature and bears the same legal weight associated an original signature when engaged in transmissions via the ROC CTC website, you understand that you are entirely responsible for maintaining user name and password confidentiality. You are accountable for any and all activities that occur using your user name and password. You agree to notify the CTC immediately of any unauthorized use of your user name or password, or any other breach of security known to you.
6. You agree to notify the CTC when you leave your position as a ROC member in order for the CTC to deactivate your Electronic Signature.

YOU REPRESENT THAT YOU HAVE READ THIS AGREEMENT. YOU UNDERSTAND THAT YOU ARE AUTHORIZING ALL FUTURE DATA TRANSMISSIONS BY YOU TO BE MADE ELECTRONICALLY VIA THE INTERNET ROC CTC WEBSITE AND THAT SUCH ELECTRONIC SUBMISSION CONSTITUTES YOUR ORIGINAL SIGNATURE. YOU AGREE THAT YOUR FACSIMILE SIGNATURE ON THIS DOCUMENT, SHALL BE DEEMED TO BE, AND MAY BE RELIED UPON BY THE CTC AS, AN ORIGINAL SIGNATURE.

Please print this Agreement. Sign and date where indicated below.

Return your signed Agreement to the ROC CTC, at the following facsimile number **(206) 543-0131**.

_____ _____

Your signature Date

_____ _____

Your name (printed) Your ROC user name

_____

Principal Investigator signature (witness)

TO BE FILLED OUT BY MAIN COORDINATOR OR PRINCIPAL INVESTIGATOR ONLY:
Please give person named above data entry access to:
☐EMS Structures ☐Epistry ☐Trauma protocols ☐Cardiac protocols