

EPISTRY

MANUAL OF OPERATIONS

Revised April 26, 2011

(form version 3.00.00—Patient Enrollment, Time Record, ED Admit, Hospital; form version 3.01.00 Prehospital Form, Procedures Form; form version 3.00.01 CPR Process)

April 6, 2011 initial launch of version 3 forms

Summary of changes made to MOO (April 26, 2011 version vs April 5, 2011 version):

1. List of abbreviations updated
2. Rules of usage and legally binding signature added
3. Prehospital Time Record
 - a. 'Event Order' clarified
 - b. Align Time/Stop Aligning toggle clarified
4. Prehospital Form
 - a. Item 4--Witnessed before fire/EMS arrival clarified
 - b. Item 5—Bystander definitions clarified; use of 'uncertain' if resuscitation attempted clarified
 - c. Item 9—King LT added
 - d. Item 12—Disposition definitions clarified (considered futile, written DNR, verbal directive/family wishes, obviously dead)
5. CPR Process Form
 - a. Item 1—revised for only devices applied to be entered and associated with agency/rig pairing; file merge, naming of upload, power on, and pads on clarified;
 - b. Item 2—fire/EMS shocks clarified when using lay AED
 - c. Item 4—clarifications for Device Order and Start Time for scenarios where accelerometer or puck used; other clarifications for when multiple devices used, ECG files merged, fire/EMS witnessed, no Pad On time for device 1, and lapse in minutes. Compression depth and release now required for devices that provide those values.
 - d. Miscellaneous edits throughout
6. Procedure Form
 - a. Item 2—1st ECG clarified as 1st 12-lead ECG

Table of Contents

EPISTRY OVERVIEW	3
PATIENT ENROLLMENT	3
CARDIAC ARREST INCLUSION CRITERIA	4
HUMAN SUBJECTS	4
Population.....	4
Inclusion of Children and Vulnerable Populations	4
Source of Information	5
REGULATORY	5
Institutional Review and Research Ethics Boards	5
Waiver of Informed Consent for Participation	5
Data Overview	6
Linkage.....	6
Multiple Episodes	6
Capture.....	7
Quality Assurance	7
Site Audit	7
Security.....	7
General Policy Statement on Privacy and Confidentiality.....	7
List of Abbreviations	8
DATA COLLECTION FORMS	10
Rules of Usage and Legally Binding Signature.....	10
Case Deletions and Changes to Date of Episode.....	10
Closing a Case Where Discharge Status from ED or Final Hospital is Unknown	10
Patients Dead/Not Treated by EMS –Limited Data Set for Cardiac Arrest	11
PATIENT ENROLLMENT FORM.....	12
PRE-HOSPITAL TIME RECORD	21
PRE-HOSPITAL DATA.....	31
CPR PROCESS.....	50
ED ADMIT – CARDIAC ARREST	67
PROCEDURES	70
HOSPITAL ADMIT	75
ATTACHMENT A – Electronic Signature Agreement.....	81
ATTACHMENT B – Medtronic CODE-STATE Software	80

EPISTRY OVERVIEW

The burdens of out-of-hospital cardiac arrest 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.
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 beginning December 1, 2005, subject to ongoing renewal by the main ROC, and local, Investigational Review Boards (and Research Ethics Boards). Site and agency participation in Epistry is approved by the ROC Study Monitoring Committee. 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.

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 EMS personnel; or
- b. are pulseless but do not receive attempts to defibrillate or CPR by 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.

HUMAN SUBJECTS

Population

This prospective cohort study of individuals with out-of-hospital cardiac arrest 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 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. 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. . 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 on a periodic basis 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

ABG	Arterial blood gas
AED	Automated External Defibrillator
ACLS	Advanced Cardiac Life Support
ALS	Advanced Life Support
AMA	Against Medical Advice
BLS	Basic Life Support
CA	Cardiac Arrest
CABG	Coronary Artery Bypass Graft
CAD	Coronary Artery Disease
CHF	Congestive Heart Failure
COPD	Chronic obstructive pulmonary disease
CPAP	Continuous Positive Airway Pressure
CPR	Cardiopulmonary Resuscitation
CT	Computerized Tomography
CTC	Clinical Trial Center
CVA	Cerebral Vascular Accident, stroke
DBP	Diastolic Blood Pressure
DNAR or DNR	Do Not Attempt Resuscitation (order)
DOA	Dead On Arrival
DOB	Date of birth
DSMB	Data Safety Monitoring Board
ED	Emergency Department
ECMO	Extracorporeal membrane oxygenation
EEG	Electroencephalogram
EMS	Emergency Medical Services

EOA	Esophageal Obturator Airway
EtCO ₂	End-tidal CO ₂ (carbon dioxide)
ETT or ET	Endotracheal Tube
FiO ₂	Percent inhaled oxygen
HCO ₃	Bicarbonate
HTN	Hypertension
IABP	Intra-aortic balloon pump
ICD	Implantable cardioverter defibrillator
IO	Intraosseous
IV	Intravenous
LMA	Laryngeal Mask Airway
LVAD	Left Ventricular Assist Device
LVEF	Left Ventricular Ejection Fraction
MI	Myocardial Infarction
MRI	Magnetic Resonance Imaging
MRS	Modified Rankin Score
OD	Overdose
OOH-CA	Out-of-Hospital Cardiac Arrest
PAD	Public Access Defibrillation
PaCO ₂	Partial pressure of carbon dioxide in the blood
PaO ₂	Partial pressure of oxygen in the plasma phase of arterial blood
PCI	Percutaneous coronary intervention
PCR	Patient Care Report (also known as “run report”, “incident report”)
PE	Pulmonary Embolus
PEA	Pulseless Electrical Activity
pH	Measure of blood acid or base
QOL	Quality of Life
ROSC	Return of Spontaneous Circulation
RSI	Rapid Sequence Intubation
SALT	Supraglottic airway laryngopharyngeal tube
SaO ₂	Oxygen saturation
SBP	Systolic blood pressure
SCA	Sudden cardiac arrest
SOB	Shortness of Breath
SSDI	Social Security Death Index
STEMI	ST-elevation myocardial infarction
TKO	To keep open
VAD	Ventricular assist device
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia

DATA COLLECTION FORMS

Rules of Usage and Legally Binding Electronic Signature

Users of the ROC website are under a signed agreement where they have affirmed to follow the Data Coordinating Center ROC rules of usage and agree that their username and password constitutes a legally binding electronic signature under current US and Canadian law. Electronic signatures are associated with each form's history of data entry and edits. For complete details, please refer to the text of the current ROC Electronic Signatures and Data Entry Website Usage Agreement, which can be found at <https://roc.uwctc.org/tiki/roc-data-entry>. See Appendix 1.

Case Deletions and Changes to Date of Episode

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 is entered into the Patient Enrollment form. This 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" 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 Request Home page.

Closing a Case Where Discharge Status from ED or Final Hospital 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 (including, social security death index (SSDI), family/friend, 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.

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.

Patients Dead/Not Treated by EMS –Limited Data Set for Cardiac Arrest

Patient cases with a date-of-episode of May 1, 2007 or later are subject only to the below minimum data set located on the Patient Enrollment form. No error checks will prompt additional data entry for dead/not treated cases that occur after this date. The Episode List will indicate all forms other than the Patient Enrollment form as not required (blank), rather than as 'O' (optional), 'R' (required), or 'E' (error).

Patient Enrollment form: Limited Dataset for cardiac arrest patients 'dead/not treated by EMS'

Header	Date of episode
	Time call received at dispatch
	Source of time (any, not only 'dispatch')
Item 1—EMS response	1 st responding Agency name (ROC or non-ROC) OR If 1 st responding agency is non-ROC, also provide name of earliest responding ROC agency on line 2
Item 2—Episode characteristics	Cardiac arrest
	Not treated by EMS or Dead at scene without EMS treatment
	Age (either calculated from date of birth or estimated by fire/EMS; if no age available, age category or unknown/not noted) Gender (male, female, or unknown/not noted)

PATIENT ENROLLMENT FORM

Complete this form for any out-of-hospital cardiac arrest as defined by the episode characteristics in Item 2 below. Each eligible out-of-hospital cardiac arrest is considered an episode. *Episode information* includes the date of episode and the time the call was received at dispatch (24 hours clock). Date is entered for both the US and Canada as yyyy/mm/dd.

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 first ring, call answered, first 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 or where the time of is (rarely) not available for a ROC dispatch. 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). 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 optional. 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, Patient Care Record 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 when it is successfully stored in the CTC database. The *CTC Episode ID* provides the CTC 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*.

Beginning with modification of Epistry, beginning April 6, 2011 (version 3.00.00), the format of the *CTC Episode ID* will change from AAA-xxxxxx-x (where AAA is the three character abbreviation for the site) to AAA-xxxxxxCA-x (where CA represents Cardiac study).

Item 1 –EMS Response:

Agency name: Provide the name of the agency for each of the first four responding EMS units (vehicles). 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 in list", "unknown", and "no additional responders." An entry must be selected for each of the four fields provided for 'Agency Name.'

"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 in list" and save the form with errors. Return to the EMS Structures database and submit a Request to update its information to include the newly identified ROC agency—this will update the 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 responders” is selected to indicate that all responding agencies have been entered. If one, two or three vehicles responded to the cardiac arrest, enter that data, then indicate “no additional responders” for remaining Agency Name fields, (after the last agency name entered) . This will enable the CTC to know that no further vehicles are expected for this episode. Enter ‘No additional responders’ only after you have entered all of the vehicles that arrived at the scene. If you are waiting for more vehicle information, wait until you have entered all agency and vehicle data prior to entering ‘no additional responders.’

If more than four vehicles arrive at the scene, the site should prioritize based on those agencies/vehicles with EMS providers who actively treated the patient. For example, if the fourth vehicle to arrive is the fire chief, and he observes the cardiac arrest but does not treat the patient, and ALS providers arrive as the fifth vehicle on scene and treat the patient, the fire chief vehicle should not be listed, but the ALS vehicle (fifth to arrive) should be listed.

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)	Vehicle pull down menu (error condition)
ROC agency pick list (OK)	ROC vehicle name picklist (OK)
	Non-ROC (OK)
	No vehicle (OK)
	Not in list (save with errors)
	Unknown (can override, save w/o errors)
Non-ROC agency (OK)	Non-ROC (OK)
Not in list (save with errors)	Not on list (no error message)
Unknown (save with errors)	Unknown (no error message)
No additional responder (save without errors)	blank (no error message)

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, provide information for the first arriving vehicle and for those vehicles with evidence of providing care to this patient. 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* and have an effective date that encompasses the *date* of the episode. Where a “ROC Agency” has been previously selected, the pull down menu also allows for selection of “non-ROC vehicle”, “no vehicle”, “not in list” and “unknown” vehicles. The “non-ROC vehicle” 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 in list” vehicle – when selected, the form can only be saved with errors, until the EMS Structures database is updated and the *Agency Name* 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 “non-ROC agency” ROC and the associated vehicle identified.

Where ‘no additional responders’ has been selected for Agency, no additional information is required.

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.

Number of Personnel: Indicate the number of crew members for each of the first four responding EMS units (vehicle). The typical number of personnel that staff the selected rig has been previously entered into EMS Structures and will pre-populate the field for *Number of Personnel* on the Enrollment form. This number is to be reviewed by the coordinator and edited to reflect the staffing on that rig for the specific episode. This information may be on dispatch reports or evident in the PCR. Where *Vehicle Name* is “no

vehicle”, the *Number of Personnel* field is blank (sites are encouraged to work to determine the number of responders that arrived other than by vehicle). 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). Some agencies employ a vehicle as a BLS or an ALS rig depending upon the agencies’ needs so the service level is not pre-filled.

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 when available). *Time of Arrival* should be provided hh:mm:ss when available. Where only hh:mm is 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 agencies” or “non-ROC vehicles”.

Item 2 –Episode characteristics:

Indicate if the patient meets the below definitions for inclusion in the Treated by EMS or Not Treated by EMS. Patients that suffer a cardiac arrest that is associated with blunt,

penetrating, or burn trauma (also called “traumatic arrest”) are not included in Epistry. Patients that suffer a cardiac arrest associated with injuries NOT deemed to be blunt, penetrating, or burn trauma (conditions such as those listed in Table 2) ARE enrolled in Epistry.

Occasionally, there are cases where it may be difficult to determine whether the cardiac arrest occurred prior to an injury, or lead to the injury (such as patient found at foot of ladder). In these cases the site research team should do their best to determine whether the arrest caused the trauma, or vice versa.

Patients that experience a cardiac arrest and that are attended in the field by an organized ROC EMS response are enrolled in Epistry. This applies to patients coming from inside the ROC ground 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 inter-facility transfer), the patient is NOT enrolled in Epistry. If the patient is being transported by an ambulance (such as going from home to the kidney center for dialysis), arrests in transit, and 911 is called to activate an organized emergency response, the cases is enrolled in Epistry—the ambulance care is considered ‘bystander’ as would be that of healthcare providers in a medical clinic that witness an arrest).

Out of hospital cardiac arrest (not associated with burn, blunt or penetrating trauma, or with any cause or mechanism of injury listed in the Table 3), were evaluated by EMS personnel that are part of an organized response are enrolled. Indicate if the patient was either *Treated by EMS or Not treated by EMS*:

- 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 no chest compressions are given, 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 who are not part of the organized EMS response.

What agency and vehicle was FIRST to initiate chest compressions?: Indicate what agency and vehicle (either ROC or non-ROC) was the first EMS or fire provider to initiate chest compressions. Select the starting agency from the pull-down menu or mark ‘No fire/EMS compressions’. ‘No fire/EMS compressions’ is to be marked for cardiac arrest cases where attempts at external defibrillation (either bystander or EMS), rather than EMS compressions, qualified the patient for Epistry enrollment.

It is expected that for most cases, the Agency Name and Vehicle Name will be one of the four responding combinations listed in Question #1. The pull down menus list all agency and vehicle identifiers entered into the EMS Structures

database; 'non-ROC agency/vehicle'; 'not in list' and 'unknown.' Guidelines for the selection of the initiating agency/vehicle and the ability to save a form without errors are the same as detailed for *Fire/EMS Response (Question #1)*, with one exception. If 'unknown' is selected to indicate that source documents do not identify the first agency to begin chest compressions, the Patient Enrollment form may be saved without errors after overriding the resulting error message. The Patient Enrollment form may also be saved without errors when the selected agency/vehicle matches one of the agency/vehicle pairings provided for questions #1 *Fire/EMS Response*.

b. *Not treated by EMS* — is pulseless but does not receive attempts to defibrillate or chest compressions by EMS personnel. This group will include patients with a '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. For patients marked as "Not treated by EMS", provide their age and gender in fields provided on the Patient Enrollment form. No other study forms are required for these patients.

Age: Enter a whole number (integer) 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". Indicate if age has been calculated from date of birth or estimated by EMS.

If no age is available use categories: Provide the approximate age of the patient using the list provided: Infant (if < 1 year); Child (1-11 years); Adolescent (12-17 years); Adult (18-39 years); Middle age (40-60 years); Older (61-75 years), or Elderly (> 75 years); or unknown/not noted. Note that the age ranges for Adolescent and Adult have changed from those used prior to April 6, 2011 launch of version 3.0 forms.

Gender: select either male, female, or unknown/not noted.

TABLE 2: Mechanisms included in Epistry—injury conditions of the following nature, or with listed e-codes/NEMSIS codes are not considered burn, blunt, or penetrating injuries. Cardiac arrest cases associated with the below injuries that also meet the above definitions for 'Treated by EMS' or 'not treated by EMS', are enrolled in Epistry.

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."

TABLE 3: Mechanisms NOT in Epistry—the below mechanisms of injury are considered to be burn, blunt, or penetrating trauma. Cardiac arrests associated with a below mechanism of injury or associated E-code or NEMESIS code, are not eligible for enrollment in Epistry.

Type or Mechanism of Injury	E-code	NEMESIS
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: NEMESIS v2.2, p265 of 463, variable E10_01 “Cause of Injury” and p.268 of 463, variable E10_03 “Mechanism of Injury.”

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 trauma trial (cardiac trials will be incorporated in the same Enrollment form and are not separately here marked) or non-ROC trial—prior to admission to the ED/Hospital. If the patient was enrolled in a ROC trauma clinical trial, provide that study’s CTC assigned ID number including the 3 character site name (i.e. DAL for Dallas, SDG for San Diego) and the 5 digit ID (including any leading zeroes, '0'). 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.

This form was last saved by: (name)

Users of the ROC website are under a signed agreement where they have affirmed to follow the Data Coordinating Center ROC rules of usage and agree that their username and password constitutes a legally binding electronic signature under current US and Canadian law. Electronic signatures are associated with each form’s history of data entry and edits. For complete details, please refer to the text of the current ROC Electronic Signatures and Data Entry Website Usage Agreement, which can be found at <https://roc.uwctc.org/tiki/roc-data-entry>. See Appendix 1.

PRE-HOSPITAL TIME RECORD

The purpose of the Pre-Hospital Time Record form is to document and 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 treated by fire/EMS.

Event Order: For each event listed that are known to have occurred in a given order during the course of prehospital care, provide the Event Order (1, 2, 3, etc), the *Watch* (PCR/ACR) time (hh:mm) and/or the Dispatch/Defib time (on 24 hour clock, hh:mm:ss). Where an event is known to have occurred, but the source documents are not adequate to know the sequence for assigning an event order, enter ‘-’ to indicate the event occurred, but the order of the event is unknown/UK (such as when a portion of the chart is missing, but the event is known to have happened); leave remaining fields *blank* in that row. Where documentation is missing or inadequate to determine if an event order occurred during the course of prehospital care, leave the Event Order *blank* and submit an online REQUEST for the form to be closed out. An example of missing or inadequate information might be where only the BLS chart is on hand, and the ALS chart is missing so it cannot be determined if or when an advanced airway was placed.

For episodes for which all documentation is available and it is known that an event did not occur during the course of prehospital care, enter '0' for not applicable (N/A) 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'). 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 (e.g. 1st fire/EMS AED turned on and 1st fire/EMS shock), 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 (hh:mm). 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,,2, 3, etc, provide either the Watch or Dispatch/Defib times when available. Where a time has been documented as hh:mm, leave the seconds ('ss') field blank, do not enter '00' as a place holder. If no documented time exists (from either the PCR/ACR or dispatch/defib) for a specific event that occurred, check the 'No Doc Time' box and leave the associated time fields blank. For events with a '0' (not applicable, NA) 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/ACR, 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 the documented time 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. If you choose to remove the time entered that automatically checked the 'Adj' box, you can click on that check box using your mouse, then the check mark will disappear and the aligned time will revert to the automatically calculated time.

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 'Event' times and adjust the time to reflect the 'true' time, entering it in the 'Aligned Time' column, creating a check in the 'Adj' column to reflect a manual entry.

Info (Question '?' and exclamation '!' marks): When the Time Record is open for editing, each row with an event order will display a question mark '?' or an exclamation mark '!'. Click on a displayed '?' to read the source for the Aligned Time in that row (whether adjusted by the user or calculated by the computer algorithm). Click on a displayed '!' to learn if something obvious is missing (such as 'no 'doc time' not checked for line item with an event with an Event Order and no times entered).

Buttons at the bottom of the form:

- “Sort Events” - Sorts events into numerical order (0, 1, 2, 3, etc), followed by those with ‘-’ (unknown) entered for Event Order, followed by those with Event Orders of 0. Sort Event does not calculate or automatically fill aligned times (as does the button, “Align Times”
- “Align Times” (toggles from ‘Stop Aligning Times’)- sorts events into numerical order (0, 1, 2, 3, etc), followed by those with ‘-/unknown Event Order, followed by those with and Event Order of 0) and moves Watch Time, Dispatch/Defib Time or a computer aligned time into the “Aligned Time” column. Events with Watch Time only will be aligned via computer algorithm if adjacent event(s) have both a Watch Time and a Dispatch time or a Defib time marked as Synched to Atomic Clock. When the 'Aligned Times” button is pressed, aligned times 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 aligned time is based on.

- “Stop Aligning Times” (toggles from ‘Align Times’)— 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. 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 'Align 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. The most recently entered numbers or characters for 'Event order' are not erased.
- “Clear form” – So that you can start over, pressing this button erases/blanks out all previously entered data on the time form and returns the rows to their original order.

Events *(Item numbers here are for reference only; not intended for use as sort order)*

Item 1 - 1st 911 Call received at dispatch:

Auto-filled time: If the Enrollment Form has been previously saved (with or without errors) and the ‘Time call received at dispatch’ is completed and the source marked as ‘From 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). This time should almost always come from dispatch logs or record. It may come from the PCR if the times on the PCR are automatically

downloaded from dispatch (the 'source' for such a downloaded time would be marked as 'dispatch'). Do not confuse electronically downloaded dispatch times to the PCR with electronically charted times—working knowledge of the agency practices is necessary to differentiate the two. The source for the 'Time call received at dispatch' on the Patient Enrollment form must match the source entered for the time for '1st 911 call received at dispatch' on the Time Record'.

Time of the 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.

Item 2 - 1st vehicle dispatch:

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 3 – 1st non-fire/EMS shock:

Where a shock was delivered by a bystander, provide an 'Event Order' to reflect when the first non-fire/EMS shock was delivered during the course of the resuscitation effort. A non-EMS shock refers to a shock from an AED or manual defibrillator which was operated by a bystander prior to EMS or fire provider arrival at the scene. A bystander is defined as any person who responds and is NOT on duty with a fire/EMS agency at the time of the arrest. Bystanders include laypersons, nurses or physicians in a health clinic, dialysis center, nursing home or a cardiac rehabilitation center; police officers; or off-duty fire-fighters or paramedics. Non-EMS AED/defibrillators also include 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.

This does not include where an AED or defibrillator is provided/applied by a non-fire/EMS responder (such as at an airport where a bystander placed an AED, or in a medical clinic where the nurse applied the defibrillator), but is operated by the fire/EMS responders. In this circumstance, do not enter the shock as 'non-fire/EMS'; instead consider it a shock delivered by fire/EMS.

The site Coordinator should attempt to get an electronic or paper copy of the ECG in order to obtain the time of the 1st non-EMS shock. If obtained, provide the time of this first shock in the Dispatch/defib columns for 'Time of Event' and mark the 'Source' as '1' to indicate it was obtained from the first defibrillator used. If a time for the 1st non-fire/EMS shock is obtained from the PCR/ACR, enter it in the 'Watch' column.

Item 4 - 1st vehicle arrival at scene:

Time the first responding vehicle arrives on the scene is when 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'.

Auto-filled time: Time for '1st vehicle arrival at scene' is auto-filled and the '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.' Values that have been auto-filled can be edited.

Item 5 - 1st fire/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 fire/EMS and initiates CPR, but the continuous ECG recording or PCR is not available, provide the sort order for the event and indicate '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').

This data element includes those cases where an AED or defibrillator is provided/applied by a non-fire/EMS responder (such as at an airport where a bystander placed an AED, or in a medical clinic where the nurse applied the defib), but is operated by the fire/EMS responders. In this circumstance, enter the shock as delivered by fire/EMS, not as one delivered by 'non-fire/EMS'.

It is recognized that this data element is a challenge to acquire. Sites are encouraged to work with EMS agencies to standardize practices that provide accurate time documentation or surrogates for time of '1st EMS CPR' including training them to power on the AED/defibrillator when they arrive at patient side and begin CPR.

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 all documented times and/or inferred times routinely incorporated into local practices.

Watch times: those written in the patient care record.

Defib/dispatch times: 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.

Aligned times: 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 6 - 1st ALS arrival at scene:

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.

Auto-filled time: ‘Time of Event’ for ‘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, ALS marked as the ‘Service level’, and the source of that time marked as ‘From dispatch.’ Auto-filled values can be edited.

Item 7 - Arrest witnessed by fire/EMS:

Time of initial cardiac arrest is used when the responding fire or EMS 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 an EMS witnessed arrest. 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.

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 fire/EMS AED/defib turned on:

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

Item 9 - 1st fire/EMS shock:

The time when the first shock is delivered by the fire or EMS responder to patient with a shockable rhythm. This does not include shocks delivered by lay responder 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.

Item 10 –1st successful fire/EMS IV/IO access:

Time the first vascular access is successfully established, whether intravenous (IV) or intraosseous (IO). The preferred source is time captured by voice recording or real-time event marker of a time-synchronized device (defibrillator, electronic PCR/ACR or handheld device). Success may be stated or it may be implied. Implied success may include EMS notation of the infusion of fluid, the administration of medications (without note of infiltration or concern), number of attempts documented. Unsuccessful attempts at placing an IV or IO are not here captured.

Secondary source is documentation made on hard-copy PCR/ACR or entered manually on an electronic PCR ideally with the time of administration corresponding to the time-synchronized device used during the resuscitation. If no time is available, but it is known an IV or IO was successfully placed, provide a sort order number for 'Event'. If time is available, 'Watch' times are those documented in the PCR/ACR (whether electronic or hardcopy). 'Dispatch/Defib' times are those captured from an electronic defib recording (whether voice and or event markers).

Item 11 - 1st epinephrine or vasopressin:

Time that either epinephrine or vasopressin (e.g. Pitressin) is first administered as a bolus injection by EMS (whether IV, IO, or endotracheal). This Event is not intended to capture self- or bystander-injected formulations (e.g. Epipen, Twinject) prior to arrival of EMS. The preferred source for the time of first dose is that captured by voice recording or real-time event marker of a time-synchronized device (defibrillator, electronic PCR/ACR or handheld device). Secondary source is documentation made on hard-copy PCR/ACR or entered manually on an electronic PCR ideally with the time of administration corresponding to the time-synchronized device used during the resuscitation. If no time is available, but it is known that the drug was given, provide a sort order number for 'Event'. If time is available, 'Watch' times are those documented in the PCR/ACR (whether electronic or hardcopy). 'Dispatch/Defib' times are those captured from an electronic defib recording (whether voice and or event markers).

Item 12 - 1st successful fire/EMS advanced airway:

Time the first advanced airway was performed by ROC or non-ROC fire/EMS (whichever is earliest). Advanced airways include endotracheal tube, Combitube, esophageal obturator (EOA), I-gel, King LT-D, Kind LTS-D, laryngeal mask airway (LMA), supraglottic airway laryngopharyngeal tubes (SALT), and cryothyrotomy. Where the advanced airway used by fire/EMS is the continuation of a pre-existing advanced airway placed by other than responding fire/EMS (e.g. tracheostomy), enter '0' for the 'Event' sort order.

Item 13 - 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 14 - Hypothermia started by fire/EMS:

Time when fire/EMS first implements hypothermia therapy, prior to arrival at the emergency department. External methods of hypothermia therapy that might be started in the field include (but not limited to): adhesive cooling pads (e.g. EM Cools); adjustable cooling pads (e.g. Arctic Sun); cooling blankets; or ice packs. Internal methods of hypothermia therapy that might be started in the field include (but not limited to): cold IV fluids; endovascular (e.g. Alsius), or intranasal (e.g. Benechill). This data element is important to capture as recent studies suggest a potential interaction of hypothermia

therapy and some medications. Enter a sort order for 'Event' to reflect initiation of hypothermia, as reflected in documentation.

Item 15 – Resuscitation stopped due to death:

Time when chest compressions are 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. Where a patient that dies at the scene or enroute and is transported to the morgue, here enter an event order and a time associated with the time of death (do not enter data for 'Fire/EMS destination arrival').

Item 16 - Patient transported from scene:

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

Item 17- Fire/EMS destination arrival:

Time when vehicle transporting the patient arrives at the first emergency department or hospital and wheels of the vehicle stop moving, and there is ongoing resuscitation efforts or ROSC is present. Neither a time or sort order should be entered here for a patient who died at the scene or enroute, but was transported by EMS to the morgue. For patients who died at scene or enroute, an event order and a time should instead be entered for "Resuscitation stopped due to death." with the time of death as either prior to leaving the scene or en route rather than the time of arrival at the morgue.

This form was last saved by: (name)

Users of the ROC website are under a signed agreement where they have affirmed to follow the Data Coordinating Center ROC rules of usage and agree that their username and password constitutes a legally binding electronic signature under current US and Canadian law. Electronic signatures are associated with each form's history of data entry and edits. For complete details, please refer to the text of the current ROC Electronic Signatures and Data Entry Website Usage Agreement, which can be found at <https://roc.uwctc.org/tiki/roc-data-entry>. See Appendix 1.

PRE-HOSPITAL DATA

The purpose of the Pre-Hospital Data form is to collect information from the time the 911 call was received at dispatch through the time that the patient either died at the scene or enroute, or arrived at the first emergency department or hospital. The information for this form may come from a variety of sources including the pre-hospital PCR/ACR, the electronic electrocardiogram (ECG), and dispatch. 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.aspx> Select the most current from the pull-down menu for 'year' as (defaults to 2010 as of April 2011). 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: CTUID is an expression of census tract location in Canada and can be derived by conversion of local postal codes using specialized software. 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. Further indicate if 'Assisted living', 'Nursing home', or 'other type residential institution.

'Assisted living' includes an environment with services such as physical therapy, occupational therapy; or a group home, adult home or halfway house. It is distinguished from a 'Home residence' 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.

'Other' includes jail and other residential facilities.

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 (12-17 years); Adult (18-39 years); Middle age (40-60 years); Older (61-75 years), or Elderly (> 75 years); or unknown/not noted. NOTE that the age ranges for Adolescent and Adult have changed from those used prior to April 6, 2011 launch of version 3.0 forms.

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. Though it is recognized that this may be imprecise, sites are encouraged to report information as recorded in the PCR/ACR or dispatch records.

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 – Is weight estimated to be < 100 lbs (45 kg)?

Estimated weight or body habitus may be used to titrate the amount of drugs given in the field (such as less amiodarone given for a small adult). Indicate if fire/EMS has documented the patient to be of small body habitus, the weight being < 100 lbs (45 kg). Mark 'Yes' if it the weight is so estimated and documented. Mark 'No' if comment is documented suggesting the patient is heavier than 100 lbs or 45 kgs (such as 'patient obese', 'heavy', 'large'). Mark 'Unknown/not noted' where documentation does not meet the stated criteria.

Item 4 - Cardiac arrest occurred:

Indicate if the cardiac arrest or collapse occurred before or after the arrival of the organized fire/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). Select the corresponding bubble to indicate the time of collapse relative to fire/EMS arrival.

After fire/EMS arrival (witnessed by fire/EMS): limited to a cardiac arrest or collapse that is witnessed (seen or heard) by a fire/EMS responder that is part of an organized fire/EMS response to this episode. Includes NEMSIS 2245, cardiac arrest after EMS arrival. Does not include police. If 'after fire/EMS arrival' marked, skip to Item 6.

Before fire/EMS arrival: If the cardiac arrest occurred before arrival of the organized fire/EMS response indicate if the arrest was either:

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, police officer, or an off-duty fire/EMS provider who is not part of the organized fire/EMS response to this episode. If the collapse is heard (such as in the shower), but someone does not check on the patient as a result of the sound, then it is not considered 'witnessed'. It is not considered bystander witnessed if a person was awakened by sounds of gurgling or snoring. It is not considered bystander witnessed if the patient calls 911 prior to the arrest, is alone, then arrests (whether or not on the phone with dispatch) prior to fire/EMS arrival. A witnessed arrest is known to be a key element associated with cardiac arrest outcome. Includes NEMSIS 2310, NEMSIS 2315, and NEMSIS 2240.

Not witnessed –occurrence of cardiac arrest that was not seen or heard by someone prior to fire/EMS arrival. Includes NEMSIS 2320.

Unknown/not noted—reserved for cases where documentation from dispatch or fire/EMS is insufficient to deduce if the cardiac arrest was witnessed or not witnessed. Includes not known NEMSIS -10. For example, if fire/EMS documentation indicates that neighbors peering in the window found the patient dead on the floor, the incident was very likely ‘not witnessed’ (rather than ‘unknown/not noted’) even though it is not explicitly stated as such in the fire/EMS documentation.

Item 5 - Was resuscitation attempted by bystanders (includes police) prior to fire/EMS arrival?

Indicate whether or not resuscitation attempts were made by bystanders prior to arrival of the organized fire/EMS response, or if it is ‘uncertain’ attempts were made. Resuscitation attempts are efforts to provide CPR (chest compressions and/or ventilations) or to apply an AED/defibrillator. A bystander is defined as any person who responds and is NOT on duty with a fire/EMS agency at the time of the response. Bystanders include doctors, nurses, police, off duty paramedics, off duty fire providers, and laypersons. Bystanders also include healthcare providers at satellite healthcare facilities such as day surgery, dialysis centers, nursing homes, assisted living and cruise ships. Responding fire providers that are part of the organized 911 response (whether paid or volunteer) are NOT considered bystanders.

If ‘yes’ resuscitation attempts were made by bystanders, indicate:

- a. Was CPR attempted prior to fire/EMS arrival? CPR is defined as chest compressions and/or ventilations. If ‘yes’, CPR was attempted by bystanders, check all types of bystanders that attempted CPR (Lay person, Police, Healthcare, or Other/specify). Mark Unknown/not noted if dispatch and fire/EMS documentation do not indicate the nature of the bystander that attempted CPR. For type of bystander that attempted CPR:

Mark ‘Healthcare’ only for those who are on-duty at the time of arrest, such as a nurse, aid, or doctor working in a kidney center, day surgery center, or patient care setting that initiated the organized 911 response, and may have started CPR, defib, or other treatment prior to fire/EMS response.

Mark ‘Police’ only for law-enforcement members who are on-duty at the time of arrest. They may or may not be part of the organized 911 response. This does not include security guards (consider them as ‘lay person’).

Mark ‘Lay person’ for those who provide assistance, whether someone not associated with healthcare or emergency response, or those professionals that are not defined above as ‘Police’ or ‘Healthcare’. Lay person also includes off-duty fire/EMS (paid or volunteer) that is not part of the organized 911 response. Lay person is not intended to distinguish level of training or experience.

For 'Other, specify', contact the site PI or main coordinator to determine if 'Healthcare', 'Police', or 'Lay person' are not adequate to describe the bystander. Please contact the DCC with any questions.

- b. Was AED/defib applied prior to fire/EMS arrival? Indicate 'no' or 'yes' if a bystander (such as lay or public access) AED was applied. If 'yes' an AED/defib was applied, indicate if shocks were delivered to the patient (yes, no, unknown). If shocks were delivered, indicate the number of shocks (1 shock, 2 or more shocks, unknown/not noted). This data may come from the fire/EMS PCR/ACR or from dispatch records. Where an AED/Defib was applied by a bystander, characterize them—see Item 5.a. for definitions of 'Healthcare', 'Police', and 'Lay person' bystander.. Mark Unknown/not noted if dispatch and fire/EMS documentation do not indicate the nature of the bystander that attempted CPR.

If 'no' resuscitation attempts is marked, select the statement that best describes how this was determined, distinguishing if 'no' is from a designated yes/no field on the PCR/ACR (includes data from a designated yes/no field on a dispatch report). Or, if 'no' is deduced from reading the narrative provided in the PCR/ACR (includes narrative or free-form entry made on a dispatch report). 'No' may be derived from the narrative where fire/EMS clearly documents that no CPR was attempted or an AED/defib applied. 'No' may also be derived where narrative is sufficient for one to deduce that neither was done (for example, bed-ridden wife calls to report she heard her husband collapse in the shower).

If 'uncertain' that resuscitation attempts were made, indicate which statement best describes this dilemma. If both statements are true—"Narrative is insufficient to determine if bystanders performed CPR or applied AED/defib" and "Designated field for 'bystander CPR' not marked where yes/no are response options"—select the latter statement ("Designated field..."). Where neither of the two statements applies to the circumstances, please contact the DCC to discuss before marking 'other, specify'.

Item 6 - Was pulse lost after documented 1st ROSC, prior to ED arrival?

'First ROSC' (return or spontaneous circulation) is documented on the Time Record form. 'ROSC present' at ED arrival is documented, if applicable, on the Pre-Hospital form. This Item 6 allows for indication of intermittent ROSC, asking if the pulse was subsequently lost at any point (re-arrest) during the course of prehospital care, and prior to ED arrival. Indications of pulse lost after documented 1st ROSC include resumption of CPR and/or shocks delivered. Mark 'not applicable' if ROSC did not occur at any point during the course of prehospital care.

Item 7 – Evidence of bloody fluid or frank blood in airway?

Indicate 'yes' or 'no' if available source documents indicate that either bloody fluid or frank blood was noted in the airway, at anytime during the prehospital course of care. Mark 'no' if only pink frothy or blood tinged sputum is noted in the PCR/ACR. Mark 'no' if the PCR/ACR documentation is silent on this topic.

Item 8 - Evidence of implantable cardioverter defibrillator?

Indicate 'yes' if available source documents indicate that the patient had an implantable cardioverter defibrillator (ICD, AICD, implantable defib, defib pacemaker). Evidence of an implantable defibrillator may include notation of shocks delivered by the implanted device prior to or during resuscitation, or the family informed fire/EMS of having this type implanted device. If 'yes' is marked, indicate if a shock was delivered during (not before) the prehospital course of care (yes, no, unknown/not noted). A pacemaker is not an implantable defibrillator, though pacing can be incorporated in an implantable defibrillator. 'Unknown/not noted' is marked if the PCR/ACR documentation is silent on this topic.

Item 9 - Pre-hospital intervention by fire/EMS:

Mark 'No fire/EMS prehospital interventions from the list below were recorded' where no one item in the provided list was 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 fire/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 fire/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'.

Definitions for pre-hospital interventions:

Chest compressions by fire/EMS: any number of chest compressions provided by fire/EMS (includes NEMSIS 99.60, attempted cardiopulmonary resuscitation). If compressions 'done', indicate if either/both 'manual' or 'mechanical' (Thumper, LUCAS, vest, Autopulse) methods provided.

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

Airway advanced, endotracheal: check all methods that were attempted. Indicate 'yes' or 'no' if placement was successful. Successful airway placement may be indicated by notation in the PCR/ACR of breath sounds present, breath sounds equal bilateral, absence of gurgling in stomach when ventilated, confirmed by CO2 detector, ETCO2.

Oral ET: oral endotracheal tube (NEMSIS 96.040). Indicate 'yes' or 'no' if oral

intubation was successful

Nasal ET: nasal endotracheal tube (NEMESIS 96.041). Indicate 'yes' or 'no' if nasal intubation was successful.

Airway advanced, supraglottal and other: check all methods that were attempted. Indicate 'yes' or 'no' if placement was successful. Successful airway placement may be indicated by notation in the PCR/ACR of breath sounds present, breath sounds equal bilateral, absence of gurgling in stomach when ventilated, confirmed by CO2 detector, ETCO2.

Local documentation practices may require sites to know standing orders for types and sequence of airways used (such as where 'King' tubes are used, so as to determine if the LT-D or the LTS-D is stocked. Indicate 'yes' or 'no' if placement was successful.

Combitube--Includes NEMESIS 96.051.

EOA (esophageal obturator airway): Includes NEMESIS 96.030.

I-gel

King LT

King LT-D

King LTS-D

LMA—laryngeal mask airway. Includes NEMESIS 96.052.

SALT—supraglottic airway laryngopharyngeal tube.

Other airway—not commonly encountered, select other advanced airways that were employed during the prehospital course of care. 'Continuation of non-EMS airway' includes fire/EMS use of a previously placed advanced airway as might have been placed by a medical provider in a clinic, dialysis center or cardiac rehabilitation center where the arrest occurred. It also includes fire/EMS use of a temporary or permanent tracheostomy ('trach'). Cricothyrotomy includes needle and surgical, NEMESIS 31.110 and NEMESIS 31.120. Mark 'other' for advanced airways not otherwise listed and specify the type (this will be uncommon; it is recommended the coordinator discuss with the PI to determine if the advanced airway type is represented by a listed type).

Hypothermia: Mark if hypothermia therapy was used at the scene or enroute prior to arrival at the ED. If done in the field, indicate 'no' or 'yes' if either External or Internal methods were used. External methods of hypothermia therapy that might be started in the field include (check all applicable): adhesive cooling pads (e.g. EM Cools); adjustable cooling pads (e.g. Arctic Sun); cooling blankets; or ice packs. If another external method is used, mark 'other' and specify. Mark 'unknown' if the type used is not documented. Internal methods of hypothermia therapy that might be started in the field include (check all applicable): cold IV fluids; endovascular (e.g. Alsius), or intranasal (e.g. Benechill). If another internal method is used, mark 'other' and specify. Mark 'unknown' if the type used is not documented.

IV/IO line: marked when one or both intravenous (IV) or intraosseous (IO) procedures is

attempted by fire/EMS during the course of prehospital care. This includes the continuation of an existing IV if the access was initiated by a nurse or physician prior to arrival of the EMS providers, such as at a clinic or dialysis center.—Indicate ‘yes’ or ‘no’ if the attempted IV or IO placement(s) was successful. If ‘yes’, placement(s) of either was successful, indicate the extremity(ies) in which each successful vascular access was placed—right or left arm, right or left leg—and/or external or subclavian/internal jugular sites (IV) or sternum (IO). If a location other than listed, mark ‘other’ and specify the anatomical location. Mark ‘unknown/not noted’ if source PCR/ACR is silent. IO NEMSIS codes include 41.920, 41.921 and IV NEMSIS codes include 38.991, 38.992, 39.995, 39.996, 38.993, 38.994, 89.620.

Was fluid given? Indicate whether fluids were given (yes, no, TKO, unknown/not noted). Mark ‘yes’ if a measurable volume was infused; enter the approximate collective volume infused (in milliliters/ml/cc, not liters) via all vascular accesses, or mark ‘unknown/not noted’ if the volume is not known. TKO is a slow drip rate ‘to keep open’ the line.

Monitor, advanced: Marked when one or more of the listed advanced monitoring procedures is attempted by non-ROC or ROC fire/EMS—EtCO₂ (end-tidal CO₂, includes NEMSIS 96.991); pacing (external cardiac pacing, NEMSIS 99.624); and 12-lead ECG (NEMSIS 89.820). If the patient arrested at a clinic, and the clinic nurse or physician did a 12-lead ECG, but the EMS provider did not do one, check ‘no’. If a 12-lead was done by fire/EMS, indicate if ST-elevation was documented in the prehospital PCR/ACR or captured on voice recording (stated as ST elevation present, ST elevation absent/no evidence). If documentation is silent about ST elevation, mark ‘no results reported’.

Item 10 - Drug therapies noted:

Indicate which of the listed drugs were administered (‘yes’) at any time during the pre-hospital fire/EMS course of care. Mark ‘NA/NR’ if not documented. Suspected extravasation of a drug is considered to have been administered. A provision for marking ‘Check if no drug given from list below’ is made, if documentation indicates that none of the (less common) medications was given by fire/EMS during the prehospital course of care. The invoked list is: Beta blocker category of medications, bicarbonate, dextrose, Dopamine, magnesium, procainamide, paralytics category, pressors category, and sedation category. This list is extensive; sites are encouraged to assure data abstractors are familiar with the drug types and names. Examples of specific drugs included in each of the ‘drug categories’ are listed on the data form.

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. Do not mark ‘check if no drug given from list below’ if partial documentation is missing. 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).

Where indicated provide the total dose administered and all routes used. Total Dose is the sum of all bolus doses (does not include drip/titrated route) of a drug administered during the course of pre-hospital care, regardless of the route of administration. Doses are expressed in milligrams (mg) for amiodarone, atropine, epinephrine, and lidocaine; and international units (IU) for vasopressin. For these same drugs, provide all routes of administration that include: intravenous (IV) (NEMSIS 4205); endotracheal tube (ETT) (NEMSIS 4175); intra-osseous (IO) (NEMSIS 4191), or drip (as for a titration)

Item 11 - 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 defined below. The site classification is 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 (this is a traumatic arrest and should not be entered in Epistry; 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: Salomez 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 NEMESIS 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 NEMESIS 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 12 –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 fire/EMS to the ED/hospital.

“Died at scene or enroute”: Treatment was halted during the pre-hospital course of care, whether at the scene or while enroute prior to arrival at ED, wheels stopped. This does not include if treatment halted after wheels stopped. Includes NEMSIS 4820. Indicate why treatment was halted:

Considered futile: Withholding or termination of care at discretion or with judgment by the provider and/or direction by medical control or base hospital. 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. Includes use of ‘termination of resuscitation’ (TOR) rules in patients for whom prehospital care has run its course. Does not include use of TOR rules that apply to patients that are obviously dead and care ceased promptly when the authorized tier of providers arrives to invoke the rules (these cases would be marked ‘obviously dead.’) Includes presentation of non-legally binding documents such as Living Wills (these are legal documents, but their execution is subject to clinical interpretation) that require a base hospital medical decision to honor.

Written DNR presented: Legally binding directive (such as Ministry approved) to not resuscitate the patient, presented in writing to fire/EMS responders, by the patient, family, or guardian; and which can be honored without contacting the medical director. This includes situations where the written DNR is not available at the scene, but a lawyer or personal MD reached by phone gives verbal confirmation of a DNR having been drawn up and signed. This does not include situations where family, LAR, or bystanders claim there is a written DNR, but are unable to present it. Includes NEMSIS 2650, 2660, 2655, 2645.

Verbal directive/family wishes: Where provided for by local law, care is terminated when the family verbally claims a DNR is in effect (but no presented in writing) or

strong family sentiments are expressed that cause the usual course of resuscitative care to be terminated early.

Obviously dead: Includes patients with rigor mortis, lividity, or decapitation for whom no resuscitation efforts are started. Where applicable, includes 'Legally Dead as per local legislation' as defined by local or state legislation. Includes situations where BLS cannot withhold care and are required to await ALS assessment of whether the patient meets stated criteria for stopping. Includes cases where BLS initiates CPR and ALS finds rigor when attempting advanced airway (such as stiff jaw) and ceases efforts. Where TOR rules are in effect, it is important to distinguish those that apply to patients who are obviously dead and care ceased promptly versus those that apply to patients for whom prehospital care has run its course and TOR rules are invoked (see *Considered futile*).

'Transported by fire/EMS to ED/hospital with ROSC or ongoing resuscitation': status of the patient upon ED arrival. This does not include cases where a patient is transported from scene, but dies enroute and resuscitation efforts ceased prior to wheels stopped (delivery to morgue is not here considered a 'transport').

'ROSC present' is intended to include any patient with a pulse at ED arrival/wheels stopped. This includes a statement of ROSC, or inferred from source documents (such as vital signs after 1st ROSC without resumption of CPR or shock, patient awake or moving). This data element is not intended to capture the recovery of ROSC between wheels stopped/arrival and the ED door (such as might occur on the ramp to the ED).

'Ongoing resuscitation' includes CPR, rhythm analysis, and other interventions up to the time of wheels stopped. It is not intended to capture resumption or initiation of CPR between wheels stopped/arrival and the ED door (such as an arrest or re-arrest on the ramp to the ED).

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. This is expected to be a rare occurrence (such as patient remains in nursing home after 911 called for an arrest, is resuscitated and then an DNR produced). When marked, a non-overridable error is generated; submit a Request for the DCC to review and then override (when done, the form will go into 'C' status).

This form was last saved by: (name)

Users of the ROC website are under a signed agreement where they have affirmed to follow the Data Coordinating Center ROC rules of usage and agree that their username and password constitutes a legally binding electronic signature under current US and Canadian law. Electronic signatures are associated with each form's history of data entry and edits. For complete details, please refer to the text of the current ROC Electronic Signatures and Data Entry Website Usage Agreement, which can be found at <https://roc.uwctc.org/tiki/roc-data-entry>. See Appendix 1.

CPR PROCESS

The purpose of the CPR Process form is to document the elements of cardiopulmonary resuscitation and the electrocardiogram data. The CPR process measurements can be utilized for quality assurance purposes with the EMS providers. The information will include the initial (EMS and non-EMS) rhythm, the device manufacturer(s) used in this resuscitation, minute-by-minute notations of the number of ventilations, compressions, the rate of compression, and CPR fraction (the ratio of compressions to lack of compressions). Additional data fields are provided for sites that use devices that report compression depth and compression release, and for sites with capnography data collection. This form also provides for the capability to attach the electronic ECG recordings (with or without the capnography channel), to associate the available ECG files with the providing agency, and to 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 - Device info and ECG data:

Device Order and Type: Each row of data is related to one AED/defib that was brought to the scene by a designated agency/rig pairing, and applied to the patient. The 'Device order' is the sequence that each AED or manual defibrillator was applied to the patient during the course of care. The first device used to monitor, analyze, or shock a patient is considered 'Device Order 1'. The second device used to monitor, analyze, or shock the same patient (whether or not a different set of pads was applied) is considered 'Device Order 2', and so on for devices three and four.

In no devices were applied to the patient during the prehospital course of care, mark 'No device' for 'Device Order 1' and subsequent rows will be auto-filled as 'No device'. If 'No device' is marked, then no further data is to be entered on that row.

If a device was applied to the patient, indicate the type used, whether AED (automatic external defibrillator) or a manual defibrillator. Where a defibrillator with dual capability (to function either in AED or manual mode) is used, select the 'Device type' that indicates the mode in which it was used by the agency/rig pair that brought it to the scene (for example, mark 'AED' where fire arrives with an MRX and uses it in AED mode to analyze and shock, then paramedics arrive and switch that same device to manual mode and continue the course of care).

Agency and rig: -- For each AED or manual defib that was applied to the patient, use the drop-down menu to select the agency and rig pairing that brought that device to the scene and applied it to the patient. Do not select agency/rig pairings where 'No device' is brought and applied.

Manufacturer—for each 'AED' or 'Manual defib' applied, indicate the brand of device. If 'other' than Medtronic, Philips, or Zoll, mark that, and specify the manufacturer (30 characters maximum).

ECG recording exists?—for each agency/rig combination, indicate ‘yes’ or ‘no’ if a continuous electronic ECG recording exists *and* is available to the site for review. This is not intended to include 12-lead ECG recordings, 'snap shot' recordings, or 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 ‘no’ recording exists, do not enter data for the subsequent items in that row (merged, file upload, time power or pads on, synched to atomic clock, adjusted time, CPR process measures available).

ECG recording merged (with another ECG)?: Where ECG files are available from more than one device are, some sites choose to merge the ECG files for review and upload. Where the ECG file for Device 2 is merged with that of Device 1, see Example 1 screenshot. Where the ECG file for two devices are merged, but not with that of Device 1, see Example 2 screenshot:

Example 1 screenshot: Where the ECG file for device 2 is merged with that of device 1: The ‘Merged?’ field for Device 1 is always blank. For Device 2, indicate ‘yes’ the file was merged. Enter ‘1’ in the box to indicate the file was merged with that of Device 1. This designates that the files of the first two devices were combined—the File Upload button activates (turns green) for Device 1 to allow upload of the merged ECG file to the device indicated as being the initial one in the series.

Device				ECG Recording			
Order	Type		Manufacturer		Exists? N Y	Merged? N Y, with...	File Upload
	No Device AED	Manual Defib	Medtronic	Philips Zoll Other (specify)			
1	<input type="radio"/>	<input checked="" type="radio"/>	Test New Winnie's rig	<input type="radio"/>	<input checked="" type="radio"/>	- - -	<input type="button" value="Upload"/>
2	<input type="radio"/>	<input checked="" type="radio"/>	Test Capital Fire and Engine411	<input type="radio"/>	<input checked="" type="radio"/>	1	<input type="button" value="Upload"/>
3	<input checked="" type="radio"/>	<input type="radio"/>	-	<input type="radio"/>	<input type="radio"/>		<input type="button" value="Upload"/>

Example 2 screenshot: Where the ECG file for devices, other than Device 1, are merged with one another: This might occur where different brand devices are used during the resuscitation. In the example below, the file for Philips Device Order 3 is merged with the file for Philips Device Order 2. For the first in the series to be merged (Device 2) mark ‘no’ for ‘Merged?’ and leave the box blank. For Philips Device Order 3, mark ‘yes’ for ‘Merged?’ and enter ‘2’ in the box to indicate the file was merged with that of Device Order 2 (the initial one in the merged series). The File Upload button activates (turns green) for Device 2 to allow upload of the merged ECG file to the device indicated as being the initial one in the merged series.

Device						ECG Recording		
Order	Type			Manufacturer		Exists? N Y	Merged? N Y, with...	File Upload
	No Device	AED	Manual Defib	Agency and Rig	Medtronic Philips Zoll Other (specify)			
1	<input type="radio"/>	<input checked="" type="radio"/>		Test New Winnie's rig	<input type="radio"/>	<input checked="" type="radio"/>	- - -	<input type="button" value="Upload"/>
2	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Test Capital Fire and Engine411	<input checked="" type="radio"/>	<input type="radio"/>	- - -	<input type="button" value="Upload"/>
3	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Test SeaTac Fire IIB AMB A1	<input checked="" type="radio"/>	<input type="radio"/>	- 2 -	<input type="button" value="Upload"/>

File Upload--Use the 'upload' button to browse the site local database to identify and attach the ECG file that corresponds to the indicated device. It is the responsibility of the site to assure that uploaded ECG files do not contain protected health information (PHI). For each file uploaded to the ROC-web, the site must attest that the file to be uploaded contains no protected information in any file field, that the de-identification function provided by the manufacturer (if commercially available) has been applied, and that the file name conforms to specifications below detailed.

Click 'Upload' to attach an ECG file. Read the three criteria, and mark if you 'agree' they have been fulfilled by the site. If 'agree' is marked, the 'Select a file for upload' function is enabled.

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 (version 3) case ID: DAL-123456CA-1 or ARC-000456CA-3 or PGH-123450CA-2 (include site code, all dashes and leading and trailing zeros, CA for cardiac, 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-000000CA-0 you would rename the file CTC-000000CA-0-dev1-2007-12-31.ZOL.

Only one recording is intended to be uploaded for each device. Where more than one recording exists for the same device (such as when a device was applied, then turned off, and later turned on) combine 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). Refer to directions above for Item 1, "Device info and ECG data", section titled 'ECG recording merged?'.

NOTE for Medtronic records: It is the responsibility of each site to upload only ECG files

to the ROC-web that have been de-identified, using manufacture-provided processes for doing this. See Attachment B for specific instructions to set, the otherwise optional, functions within the CODE-STAT software to enable manufacturer-provided de-identification when exporting ECG files prior to uploading them to the ROC-web.

NOTE for ZOLL recordings: The ROC website currently accepts only files with '.ZOL'. The .ZOL file format is acquired by choosing *File->Rename* from the menu. 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.

Another NOTE for ZOLL recordings: To apply the manufacturer-provided process to de-identify a .ZOL file, follow the below outlined process. This process 'strips' identifying data from specific fields. There are other text fields within the file that the site should review to assure no identifying information is contained in any field:

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 Rescue Net Code Review 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 does not function properly 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.

Power On time: Time each device was turned on. Enter the time recorded by the device, preferably the time synchronized to the atomic clock. If the recorded time is not synchronized to the atomic clock, provide the 'raw' time recorded; do not here enter an adjusted time (such as what might have been entered on the Time Record, there marked as 'adj').

Pads On time, Synched to atomic clock, Adjusted time: If 'yes' a recording exists, 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 or impedance signal. If pads lose contact and there is more than one time to pad placement time, use the first time the pads were placed. Do not use time ECG-only electrodes (sometimes called 'pads') are placed. Provide the synchronized (preferred) or unsynchronized time for 'Pads on' provided by the defib . Indicate if this 'Pads on' time was synched to the atomic clock; if it is apparent that the device was not synched (for example the device is one hour off from the dispatch and watch times and daylight savings just occurred), mark 'no' and enter the adjusted time. The synchronized, or the adjusted 'Pads on' time is used to auto-fill row 1 of Item 4, the table for CPR process measures. If reporting data for devices with an accelerometer or puck, see directions for Item 4 ("Did the ECG provide CPR process measurements?") 'Start time'—different scenarios of time 'Pads on' and accelerometer/puck on are reviewed and specific guidance given.

Fire/EMS witnessed arrest: Enter time pads were placed for 'Pads on' whether arrest occurred before or after pads were placed. See below Item 4 ("Did the ECG provide CPR process measurements?") for further guidance entering data for fire/EMS witnessed cases, 'Start time'.

CPR process measures available—indicate 'yes' if the site was able to extract or calculate CPR process measures (compression rate, CPR fraction, etc) from the available continuous electronic ECG recording. Mark 'no' if the available ECG recording provides no whole or partial minutes with CPR process measures (such as when the device is a monitoring lead inconsistent with capture of CPR process measures, or the 'puck' was not applied where required for capturing measures).

Item 2 - Were any shocks delivered by fire/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. Includes shocks by a public access defibrillator or non-EMS defibrillator IF the shock was given by the fire/EMS provider using the lay-device. For example, EMS arrives and a lay AED has been applied, a second shock is recommended and fire/EMS presses the shock button; another example, fire/EMS arrives at a dialysis center where a defibrillator is applied by nursing staff, but fire/EMS delivers the shock. 'Shocks delivered by fire/EMS' does not include 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 fire/EMS responders, indicate how many.

Item 3 - Initial rhythm:

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 healthcare providers (includes on duty doctors and nurses), on-duty police, and laypersons (includes lifeguards, off duty doctors, nurses, paramedics, firefighters, and police). 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. This includes an AED shock if the documentation clearly indicates that the shock was given for the initial rhythm present, not a subsequent rhythm. 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.

Time of the rhythm: Look for the EARLIEST rhythm from the time the pads or electrodes 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 AED/defibrillator' after pad placement and prior to documentation of the pads of the fire or EMS AED/defibrillator being applied or drugs given or a shock delivered by EMS or fire. Use time of first shock to indicate '1st CA rhythm with non EMS AED/defibrillator' only if another time of earliest rhythm cannot be otherwise determined.

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 CA rhythm with non EMS AED/defibrillator'. Use your best judgment (or discuss the case with your Principal Investigator) 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 non-EMS AED or 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 than “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: (in order of preference)

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 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 a fire/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. 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).

If the first vehicle treating the patient was non-ROC EMS and you don't have access to the ECG or PCR information, check "cannot determine".

If the arrest was fire/EMS witnessed, and pads placed prior to the 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.

NA-(not applicable)- Not applicable means there was not a fire/EMS cardiac arrest rhythm, as in the case where: a) there was a bystander administered AED shock so qualified for Epistry, but by the time the EMS arrived the rhythm was perfusing and the patient never rearrested; OR b) fire/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 (earliest) 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 or electrodes 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 five minutes** after pad placement and prior to

documentation of drugs given or a shock delivered by EMS or fire. Use time of first shock to indicate 'EMS 1st CA rhythm' only if another time of earliest rhythm cannot be otherwise determined.

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 CA EMS rhythm'. Use your best judgment (and also discuss with your Principal Investigator) 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 than "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 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 4 – Did the ECG provide CPR process measurements:

‘Yes’ will be auto-filled here if ‘yes’ was marked for the same question in Item 1. Indicate ‘no’ if the available ECG information did not provide or allow 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, see ‘Pads on’ time definition for special circumstances). Sites are encouraged to provide data for each minute of the resuscitative effort, up to 20 minutes.

Definitions for CPR process measurements:

Device order and Start Time: Device order and Start time (and subsequent minutes) are auto-filled for all rows IF time for ‘Pads on’ has been entered in Item 1 (Device info and ECG data). The auto-filled time may be edited and subsequent minutes will adjust to 1 minute increments from the edited time. Devices applied by non-ROC agencies are to be reflected in Item 1, and here by device order. 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.

Multiple devices used—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 auto-filled with ‘2’ (and so on for subsequent devices). Where a fire/EMS device was applied during the resuscitation, but no CPR process measures are available from that device, enter 1, 2, or 3, etc to indicate the chronologic order that device was applied and mark ‘no ECG data’ (no other data for that row is expected).

Merged ECG files—if two or more ECG files (collected by different devices) have been merged (and indicated in Item 1), retain the Device orders entered for Item 1 (irrespective of merging of ECG files) and associate the data captured by that device.

Fire/EMS witnessed arrest—where the arrest was witnessed by fire/EMS, edit the ‘start time’ for row 1 to be the time of the EMS witnessed arrest (not necessarily when pads placed) and provide CPR process measures for the subsequent 5 minutes of the arrest. 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.

No ‘Pads on’ time for Device 1—where more than one AED/defib was placed, but the time

'pads on' for the first device is not known and there is either no access to a non-ROC download, or no download captured from ROC device, enter '1' for Device 1 in the first row, leave the 'Start Time' blank, and mark 'no ECG' (no further data is required for that device). Move to the next row and enter '2' for Device 2 in the second row and enter the 'start time' that pads were placed for that second device (subsequent minutes will be auto-filled) and provide associated CPR process measures.

Where the 'Pads on' time is not known for the first device, but a download is available and CPR process measures are available for a portion of the resuscitation (such as can occur with Medtronic in monitoring rather than paddles mode at the onset of recording), leave 'Pads on' time blank in Item 1 (override the resulting error message with the reason), enter '1' for Device 1 in the first row, and enter the corresponding 'Start time' when the CPR measures signal first appears (as when the device is first switched to 'paddles' mode).

Accelerometer/puck situations—see below for guidance on how to handle different conditions of pads on and accelerometer/puck on:

- a) Accelerometer/puck on first, pads on soon after—use 'Pads on' time for Item 1, and for start time in Item 4. Begin reporting CPR process measures from time 'Pads on'. Forgo counting early compressions exhibited only via puck data.
- b) Pads on first, accelerometer/puck on soon after—it can be common for the puck to be placed 1-2 minutes after the pads are placed. The site must elect to either:
 1. Not hand count compressions— enter time 'Pads on' for Item 1; that auto-fills row 1 of Item 4. For each minute with 1-60 seconds of no puck placement (so no impedance channel), enter 60 as the '# seconds with no measures' and mark 'unanalyzable'. For the first full minute with the puck on and CPR measures generated, enter the start time for that minute (which will overlap with the previous row's 60 second epoch). The 'start time' for subsequent minutes will auto-fill; enter associated data.

Example 1: Pads on first, puck later; compressions not hand counted. Row 1 Start Time is 'Pads on' for the initial 60 second epoch, during which no CPR measures are automatically calculated by the device; enter 60 seconds with no CPR measures. Row 2 is the next 60 second epoch, during which some number of seconds are with only pads, and the balance are with the puck placed; enter 60 seconds with no measures (as the time 'puck on' initiates the device calculation of CPR measures). Row 3 Start Time is edited to be the time the puck was first placed (resetting the Start Time of subsequent 60 second epochs).

Device order	Start time			No ECG Measures	# Vent	# Comp	Comp rate	CPR fraction	Why			Comp depth	Comp release	
	(Auto fill) hh:mm:ss								# secs with no measures	ROSC	Unanalyzable			
1	1	05	15	20	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	60	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	05	16	20	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	60	<input type="radio"/>	<input checked="" type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	3	05	16	40	<input type="checkbox"/>	<input type="checkbox"/>	65	100	.65	0	<input type="radio"/>	<input type="radio"/>	54	7
1	4	5	17	40	<input type="checkbox"/>	<input type="checkbox"/>	70	99	.75	0	<input type="radio"/>	<input type="radio"/>	59	10
0	5				<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>					

2. Hand count compressions-- using the available impedance channel (generated when pads are on), hand count the compressions (for '# Comp') during the full minutes with no puck, and the first minute of mixed puck and no pads. See below instructions of calculating 'Comp rate'. Then, begin with the first full minute of puck generated data and enter for the subsequent minute, providing an uninterrupted sequence of minutes with CPR process measures. This approach is strongly recommended during the course of the interventional trials.
- c) Only accelerometer/puck on—in the rare instance where no pads are placed during the resuscitation, the site must elect to either:
1. Not hand count compressions—if only one device applied, indicate 'no' in Item 1 for "CPR process measures?" and 'no' in Item 4 for "Did the ECG provide CPR process measurements?". Enter no further data for Item 4. If more than one device applied and CPR process measures provided by second device, enter '1' for Device order, leave start time blank, and mark 'no ECG' (to indicate that measures are not calculated for that entire ECG file); no other data for that row is expected. Then, enter '2' for Device order, enter the start time for when CPR measures ensue; see device specific guidance for reporting of measures.
 2. Hand count compressions—if only the puck was applied and it is elected to hand count compressions, enter time of puck placement for Start Time in Item 4 (table for CPR measures). Leave time for 'Pads on' in Item 1 blank. Override the resulting error, indicating that 'only the puck applied and measures hand counted.' See device specific guidance for how to report '# Comp', 'Comp rate', and 'CPR fraction'. This approach is strongly recommended during the course of the interventional trials.
- d) Monitor mode selected by user during all or part—in the absence of the compression channel, the force and acceleration channels provide a signal to allow hand counting. This situation is analogous to 'b' or 'c' above, depending on the duration of the situation.

Lapse in minutes—where the change of devices causes a lapse in time (minutes not contiguous), enter the next device number and enter the 'start time' of that device. Times for

subsequent minutes will be auto-filled from that edited 'Start time.' If a portion of a minute is affected by the placement of an accelerometer or puck, enter the # seconds with no measures, and then for the first full minute with the puck on and CPR measures generated, enter the start time for that minute. The 'start time' for subsequent minutes will auto-fill; enter associated data.

Done entering measures—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.

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 field for ‘# vent’ 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 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 the time entered for ‘Pads on’ 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; times entered on Time Record).

CPR fraction: The portion of time during which chest compressions were administered, expressed as a fraction. Report the value calculated/documentated 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. 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 (based on highlighted sections of the ECG) and reported on the device CPR process summary. Be certain that the complete resuscitative effort is included in the device statistics—that is, the highlighted start time corresponds to that time for time ‘Pads on’ and highlighted 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, either 'ROSC' (such as patient had a pulse so no CPR performed) or '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 Compression Ratio)*0.6.

Compression depth: for those machines capable of reporting compression depth. 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: for those machines capable of reporting the number of compressions with incomplete release (as assessed by the device) on the upswing of the compression. 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): for 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.'

This form was last saved by: (name)

Users of the ROC website are under a signed agreement where they have affirmed to follow the Data Coordinating Center ROC rules of usage and agree that their username and password constitutes a legally binding electronic signature under current US and Canadian law. Electronic signatures are associated with each form's history of data entry and edits. For complete details, please refer to the text of the current ROC Electronic Signatures and Data Entry Website Usage Agreement, which can be found at <https://roc.uwctc.org/tiki/roc-data-entry>. See Appendix 1.

ED Admit

The purpose of the ED Admit form is to document information occurring during the Emergency Department (ED) course of care. One ED Admit form is used to collect data from the first and subsequent ED's to which the patient may be transferred. The form is to be completed for patients who were transported by fire/EMS and arrive with ROSC present or for whom resuscitative efforts are ongoing.

Item 1 - Name of first ED transported to:

Select name of receiving emergency department from the pull-down menu. The name of the hospital links with the ROC EMS Structures Database to provide service characteristics 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. If the patient is transported to a non-ROC ED, select 'non-ROC hospital' from the pull-down menu and type the name of that institution in the provided field.

Patient bypassed ED and admitted directly to hospital: Infrequently, a patient is transported by fire/EMS to an ED, but circumstances or policy cause the patient to not be treated in the ED, and he is instead taken straight to the hospital coronary care unit, operating room, or interventional or diagnostic laboratory. If this occurs, mark the provided field and complete only Item 4 (Demographics/birth year, race, ethnicity). The form can be saved without errors with only the specified data entered. Save the form and proceed to the Hospital Admit form where you will be required to provide the date and time of hospital arrival.

Item 2 - Date/time of first ED arrival/ admit:

Provide the date (yyyy/mm/dd) and time (24 hour clock hh:mm) of patient arrival at the initial emergency department Sourced from ED admit sheet or patient care record. In the rare instance that time of arrival cannot be located in the ED chart, default to entering the

time arrival at ED documented by fire/EMS (wheels stopped). The 'Time' of arrival/admit entered in this field is used to calculate the 'cutoff' date and time prefilled on the Procedure Form for reference when providing information keyed to occurring within 24 or 72 hours of first ED arrival. Where the patient has bypassed the ED and is admitted directly to the hospital, CCU, OR, or cath lab), the time admission there is used for calculating 'cutoff' date and times (see instructions for Hospital Admit form).

The date of ED arrival may be different from the date on the Patient Enrollment form if the cardiac arrest occurred late in the evening and the patient was not admitted to the ED until early the following morning.

Item 3 - Was patient transferred to another ED?

Indicate if the patient was transferred from the initial ED to a different acute care ED or hospital during the course of care associated with this cardiac arrest. If yes, the patient was transferred to another ED, select the name of that facility from the pull-down menu and enter the date of transfer to that ED. If 'non-ROC hospital' is selected from the pull-down menu for name of next ED, then provide the name of that non-ROC ED in the adjacent field. This form provides for up to two hospital transfers and allows for some assessment of patient longevity/duration of care, should final vital status later not be attainable. The pull-down menu provides names of ROC hospitals entered in the EMS Structures database (with effective dates of study approval that encompass that of the episode being entered) 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.

Item 4 – Demographics (obtained from either ED or hospital information):

For those patients that are transported to the ED/Hospital, demographic information is asked only on the ED form (not duplicated on the Hospital form). For patients that bypass the first ED and are directly admitted to the hospital (or to the CCU, OR, or cath lab), Demographic information is required on this form before it can be saved without errors. Data entered for Demographics on the ED form may be collected from either or both the records from the ED and the Hospital. This information is often in the admission office face sheet.

a. Birth year (yyyy)—if conflicting years of birth are documented, use the earliest year. If year not documented in the chart, but age is referenced, calculate the year of birth (such as age 51 years; year 2011 minus 51 indicates year of birth to be 1960).

b. Race (check all applicable)—more than one category of race may be reported. Check all that apply, or mark if unknown/not noted. It is anticipated that race will be either self-reported or indicated by the patient's friends or family during the ED or Hospital course of care. Though it is recognized that this may be imprecise, sites are encouraged to report information as recorded in the PCR/ACR or admission records.

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.

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.

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.”

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

c. Ethnicity (check one)—check on only from the list provided. Though it is recognized that this may be imprecise, sites are encouraged to report information as recorded in the PCR/ACR or admission records.

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.”

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.

Item 5 – Discharge status from final ED:

Provide the date, time, and patient status/disposition when discharged from the last ED in which the patient was treated. If a patient was transferred from the first ED to a second ED, the discharge status here entered would be that—when died, was discharged alive, admitted to the same or transferred to another hospital—from the second ED. If trying to document an ED-to-ED transfer, that is instead reported in Item 3. For cases admitted or transferred to a hospital, the Hospital Admit form is required.

The intended and preferred source for *Discharge status from final ED* is the ED patient care record. When an ED record cannot be accessed, the 'social security death index' (SSDI) is the second preferred source. A date of death less than 14 days from the date of the 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. In some instances, the fire/EMS crew that transported the patient will be on scene and have documented or reported when the patient died in the ED or was taken from the ED elsewhere. If an alternate source for status was used, other than those listed, mark ‘other’ and specify the source. Epistry is an observational study and contact of patient family to determine

discharge status is not approved.

PROCEDURES

The Procedures form is intended to capture the occurrence and details of specific procedures, therapies and tests that were done in either the ED or the hospital during the course of care.

Item 1 – CPR done in ED or hospital?:

Mark 'yes' if the ED or hospital record indicate that CPR (chest compressions) was done. Continuation in the ED of CPR initiated in the field is considered to have been done in the ED. If 'yes', further indicate if chest compressions were delivered by either/both *Manual* or *Mechanical*, and the location where compressions were 'done'. A patient that moves from the ED to the cath lab or operating room is considered to be 'in hospital', not a continuation of the ED care. If no mention of CPR is made in the ED or hospital notes, mark 'not available/not recorded'.

Item 2 – Major procedures while in any ED or acute care hospital:

Procedures are categorized into three time frames: if done within 24 or 72 hours of arriving at the first ED; and, any time after first ED arrival. The header for each of the time-specific sections provides a prefilled area with the 'Cut-off' date and time that would be the latest boundary for which to inspect the chart for the specific procedure. 'Cut-off' date and time cannot be edited. The prefill for 'Cut-off' date and time is made when the Procedures form is opened for data entry or editing after the time of arrival at the first ED is entered on the ED form.

If '*No major procedures from the list below were noted*' is marked, no data is to be entered within the table. This response will most often be associated with a brief resuscitative effort made in the ED before the efforts are ceased. Before marking this response, be certain to review all the listed items to confirm (without marking NA/NR) that they were not performed.

Where at least one procedure was done, all listed procedures must be marked as 'NA/NR' (not available, not recorded) or if done in the ED, the hospital, or both the ED and hospital.

Within 24 hour hours of first ED arrival: Review the 'Cut-off' date and time and assess if each of the listed items was done prior to that. If a patient is transferred from the first ED to another, it is the time of arrival at the first ED that starts this time window. It is intended that this table reflect procedures as NA/NR or done at any ED or hospital the patient was cared for during the defined window. If the patient was at multiple EDs or hospitals and all the charts cannot be accessed for the specified time period, then mark those procedures as 'done' for which documentation is available, and do not enter 'NA/NR' or 'done' for others—in the absence of complete records, it would not be known if a procedure (not mentioned in the partial documentation) was 'NA/NR' or was done, but documented in the missing chart. In the absence of complete records, and after marking those items that were documented in

available records, request the form to be 'closed-out' (F status) indicating the circumstances for making the request.

1st cardiac catheterization—If patient had a cardiac cath, mark 'hospital' for where done. The cath lab is here considered part of the 'hospital' course of care, even if the patient is sent from the ED directly to the cath lab prior to admission to the hospital. If a cardiac cath is done within 24 hours of first ED arrival, indicate if it was 'percutaneous coronary intervention (PCI)—a PCI is sometimes referred to as coronary angioplasty, PTCA (percutaneous transluminal coronary angioplasty), stenting, or balloon angioplasty. PCI does not include diagnostic only catheterization (angiography).

If 'yes' PCI was done, refer to the physician's procedure note and indicate if an angioplasty balloon was inflated, and if so, the time of first balloon inflation. If either the date or time of first balloon inflation is not in the report, mark 'time/date not noted' (enter what you do have). This time is not the 'needle time' when vascular access for the procedure was made. Also, indicate 'yes' or 'no' if a stent was placed—this includes any type coronary stent including drug-eluting or resorbable. PCI does not include intravascular ultrasound (IVUS), angiography, angioplasty, or rotational atherectomy (Rotablator, RotaLink).

1st CXR—If had a chest x-ray during the course of care within 24 hours arrival at first ED, indicate whether done in the ED or in the hospital. If done, provide the date and time of the first CXR, regardless of where done. If done, refer to the progress notes or the formal report of the first CXR and provide the date and time of the procedure. Indicate if a formal report is available from which to indicate if specific findings were documented. If either the date or time is not available, mark 'time/date not noted' (enter what you do have). Mark 'yes' or 'not noted' if these conditions are stated in the formal report for the first CXR done within 24 hours arrival at first ED:

Pulmonary edema—mark 'yes' if the formal radiographic interpretation states any specified vocabulary: pulmonary edema, alveolar or interstitial edema, bilateral pleural effusion, pulmonary venous congestion, or cardiomegaly. A specific diagnosis or one that is 'consistent with' is accepted. All vocabulary are considered validated predictors of heart failure and intended to be here captured. Carlson KJ, et al. J chron Dis. 1985;38:733-9; Wang CS et al. JAMA 2005 Oct 19;294(15):1944-56.

Aspiration—includes aspiration pneumonia; 'consistent with'

Pneumothorax—includes collapsed lung; spontaneous pneumothorax, tension pneumothorax. Does not include atelectasis

Rib fractures—includes flail chest. Does not include fracture of clavicle or sternum.

1st 12-lead ECG—If had a 12-lead electrocardiogram (ECG) is done within 24 hours arrival at first ED, indicate if done in ED or hospital. Determine the earliest date

and time the first ECG was done. For the first 12-lead ECG done, review the physician progress notes (whether ED or hospital, where ever the first ECG done) and indicate if it is noted in the narrative that the first ECG showed evidence of 'acute STEMI (ST elevation myocardial infarction). STEMI indicates that at large amount of heart muscle damage is occurring and it is believed that its recognition should lead to prompt interventional therapy. Also, locate the formal report for this same first 12-lead ECG done within 24 hours first ED arrival, and indicate if the formal interpretation is STEMI. Mark 'no' for STEMI for either the physician notes or the formal interpretation if it is stated 'no evidence of STEMI' or 'no evidence of ST elevation' (or similar intent). Mark unknown/not noted if no mention of ST elevation is made (whether absent or present). If no report available, mark that response option. If either the date or time is not available, mark 'time/date not noted' (enter what you do have)

Fibrinolytics, 1st dose—indicate whether fibrinolytic agents were given within 24 hours of arrival at first ED. Examples of fibrinolytics are TNKase (tenecteplase); Retrovase (Reteplase); Streptase; kabikinase (streptokinase). Provide the date and time of the first dose given. It is likely that Fibrinolytics may be given in a similar time-frame as when the first ECG indicated STEMI and/or when the patient goes to the cardiac catheterization laboratory. If either the date or time is not available, mark 'time/date not noted' (enter what you do have). Does not include antiplatelet or antithrombin agents such as heparins, clopidogrel, 2B3A inhibitors, or aspirin.

Initial temp—provide the date and time of the first documented temperature taken in either the ED or hospital, whichever was first. If a temperature is documented in the chart, but time no noted, mark that response option. Provide the documented temperature and indicate the units of measure. From the pull down menu, select the route or method of that first temp; select unknown/not noted if not otherwise documented. If either the date or time is not available, mark 'time/date not noted' (enter what you do have)

Within 72 hour hours of first ED arrival: Review the 'Cut-off' date and time and assess if each of the listed items was done prior to that. If a patient is transferred from the first ED to another, it is the time of arrival at the first ED that starts this time window. It is intended that this table reflect procedures as NA/NR or done at any ED or hospital the patient was cared for during the defined window. If the patient was at multiple EDs or hospitals and all the charts cannot be accessed for the specified time period, then mark those procedures as 'done' for which documentation is available, and do not enter 'NA/NR' or 'done' for others—in the absence of complete records, it would not be known if a procedure (not mentioned in the partial documentation) was 'NA/NR' or was done, but documented in the missing chart. In the absence of complete records, and after marking those items that were documented in available records, request the form to be 'closed-out' (F status) indicating the circumstances for making the request.

Echocardiogram—indicate if an echocardiogram was done at any time during the 72 hours following arrival at first ED. Includes 'echo' or ultrasound of the heart.

Hemodynamic monitoring—specifically, was either pulmonary artery (PA, Swan-Ganz) catheter or arterial line monitoring done of systemic pressures during the 72 hours after arrival at first ED. Evidence of pulmonary artery or arterial line monitoring include reports of cardiac output, cardiac index, pulmonary artery ‘wedge’ pressure, systemic or pulmonary vascular resistance. Evidence of arterial monitoring include reports of mean arterial pressure. Does not include central venous pressure (CVP) monitoring or other forms of hemodynamic monitoring.

Hemodynamic support, pressors—indicate if pressor medication support was given during the initial 72 hours after arrival at ED. If given, were such drugs given in the ED, the hospital, or both the ED and hospital. Includes bolus and drip administration. Examples of pressors are vasopressin, dobutamine, norepinephrine. Does not include magnesium or calcium.

Hemodynamic support, devices—indicate if devices were implemented to provide hemodynamic support within 72 hours of first ED arrival. Physician orders and progress notes are to be reviewed to determine if the listed device methods were employed.

Any time after first ED arrival: Review physician orders or procedure records to determine if any of the listed procedures were done at any point during the course of ED and hospital care. If a patient is transferred from the first ED to another, it is the time of arrival at the first ED that starts this time window. It is intended that this table reflect procedures as NA/NR or done at any ED or hospital the patient was cared for during the defined window. If the patient was at multiple EDs or hospitals and all the charts cannot be accessed for the specified time period, then mark those procedures as ‘done’ for which documentation is available, and do not enter ‘NA/NR’ or ‘done’ for others—in the absence of complete records, it would not be known if a procedure (not mentioned in the partial documentation) was ‘NA/NR’ or was done, but documented in the missing chart. In the absence of complete records, and after marking those items that were documented in available records, request the form to be ‘closed-out’ (F status) indicating the circumstances for making the request.

EEG—electroencephalogram; mark as done if either a standard diagnostic EEG done (a discreet ‘test’, ‘spot’ or ‘snapshot’) or continuous monitoring EEG was conducted.

Hypothermia started in the ED—either internal or external methods that were initiated in the ED. Does not include continuation of a hypothermia method that was initiated in the field. For example, if cold fluid was initiated in the field and continued in the ED as the only form of hypothermia, this item would be marked NA/NR. But, if cold fluid was initiated in the field, continued in the ED, then adjustable cooling pads instead applied, this item would be marked as ‘done’ in ED. If hypothermia was started in the ED, mark if it was an external (see applicable list) or internal (see applicable list) method. More than one method may have been initiated and used during the ED course of care; check all methods started and used in the ED. Provide the date and time that the first ED hypothermia therapy that was started.

Hypothermia started in the hospital—either internal or external methods that were

initiated in the hospital. Does not include continuation of a hypothermia method that was initiated in the ED. For example, if cold fluid was initiated in the ED and continued in the hospital as the only form of hypothermia, this item would be marked NA/NR. But, if cold fluid was initiated in the ED, continued in the hospital, then adjustable cooling pads instead applied, this item would be marked as 'done' in ED. If hypothermia was started in the ED, mark if it was an external (see applicable list) or internal (see applicable list) method. More than one method may have been initiated and used during the hospital course of care; check all methods started and used in the hospital. Provide the date and time that the first hospital hypothermia therapy that was started.

ICD implanted this stay or transferred to other hospital for ICD—Indicate if an implantable cardioverter defibrillator (ICD) was implanted in the patient during this hospital course of care, or if was transferred to another hospital for that implant. Included AICD, pacemaker with defibrillator capability. Source this from a cath lab or defib implant procedure note.

Item 3 – Glucose control: Was insulin given (bolus or drip) within 48 hours of first ED arrival?:

Indicate if any insulin was administered within 48 hours first ED arrival. Answer this question 'no' only if have all ED hospital records available for review for this period of care (otherwise, leave blank and request the form to be closed-out (F status). Answer 'yes' if available records indicate insulin was given by subcutaneously or IV (bolus) or a drip hung to be titrated over a period of time to stabilize the patient's glucose levels. Does not include oral hypoglycemic drugs. If insulin dose given or drip hung, provide the date and time of that first medication. If 'yes' insulin was given, review progress notes and admission notes during the 48 hour period of course of care to identify if a history of diabetes (prior to the cardiac arrest) is documented (mark 'yes' and 'no' if directly addressed in the notes; mark 'unknown/not noted' if no mention made of having or not having a history of diabetes).

Item 4 – Arterial blood gases (ABG) drawn within 24 hours of first ED arrival:

The source for this item is the clinical laboratory or ED/ICU flow sheets. Provide the reported arterial blood gas values for every sample drawn during the 24 hours after first ED arrival. Include the date and time of the blood sample and the corresponding level of oxygen (FiO₂) being delivered to the patient when the sample was drawn (or indicate that value missing)—if the lab report does not include the associated FiO₂, review the ED or ICU flow sheets to cross reference time to establish the FiO₂. Where only a partial set of results is provided (such as HCO₃ is missing), provide the values reported and leave the missing value blank—do not enter '0' as a place holder (it will be misconstrued as a reported value). Does not include venous blood gases.

Select one of the three statements that best describes the completeness of the number of blood gases entered. If either of the 'no' statements is selected, enter no data in the table. If 'yes' is selected, enter data for each reported set of ABG's (date, time, ph, PaO₂, PaCO₂, HCO₃, and FiO₂) from available records. It will not be uncommon for only a few ABG samples to have been drawn. Twenty-four rows have been provided for instances where

many more ABG's have been drawn. After values from available documents for ABG's have been entered, select one of two statements at the bottom of the table to indicate if 'all available information entered' (indicating all source documents were available, reviewed, and all documented ABG results entered); or 'some records missing, entered ABG's drawn and documented' (from those records available). These distinctions will assist in analysis to distinguish where 'all available' or 'all done' are reported.

This form was last saved by: (name)

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HOSPITAL ADMIT

The purpose of the Hospital Admit form is to document information occurring after departure from the ED and during the hospital course of care. One Hospital Admit form is used to collect data from the first and subsequent hospitals to which the patient may be transferred. When a patient moves from the ED to the hospital intensive/ coronary care unit, he may first go to a catheterization lab (diagnostic or interventional) or operating room. All aspects of care or condition that occur after departure from the ED are considered part of the hospital course of care and entered on the Hospital Admit or Procedures form.

Item 1 – Hospital admit information (1st hospital):

Provide the date (yyyy/mm/dd) arrival at the initial hospital. Sourced from Hospital admit sheet or patient care record. The date of hospital admission may be different from the date on the Patient Enrollment or ED Admit forms if the cardiac arrest occurred late in the evening and the patient was not admitted to the hospital until early the following morning.

'Time' of hospital admission is required only if the ED was bypassed and the patient taken directly to the hospital/CCU, operating room, or diagnostic/interventional laboratory (e.g. cath lab). If the ED was bypassed, the 'Time' of hospital admit will serve as 'time zero' and be used to calculate a surrogate for the 'cutoff' time prefilled on the Procedure Form for reference when providing information keyed to occurring within 24 or 72 hours 'of first ED arrival'. In the rare instance that time of hospital admit is required and cannot be located in the chart, default

to here entering the earliest time documented after leaving care of fire/EMS that transported the patient—the preferred earliest time would be from a procedure note associated with the earliest time of hospital care.

'Hospital name' is here entered for the first hospital to which the patient is either transferred from an ED (either the first or subsequent) or to which the patient is directly admitted, having bypassed the ED. The name of the hospital links with the ROC EMS Structures Database to provide service characteristics cardiac catheterization laboratory, and cardiac electrophysiology laboratory. If a receiving hospital is not listed, update the EMS Structures database and resume Epistry data entry. If non-ROC hospital is selected, provide the name of that hospital in the provided field.

If the patient is transported to a non-ROC ED, select 'non-ROC hospital' from the pull-down menu and type the name of that institution in the provided field.

Item 2 - Was patient transferred to another acute care hospital before final discharge?

Indicate if the patient was transferred from the first Hospital to a different acute care hospital(s) during the course of care associated with this cardiac arrest. If yes, the patient was transferred to another hospital, select the name of that facility from the pull-down menu and enter the date of transfer to that hospital. If 'non-ROC hospital' is selected from the pull-down menu for name of next ED, then provide the name of that non-ROC hospital in the adjacent field. This form provides for up to four hospital transfers allowing for some assessment of patient longevity/duration of care, should the final vital status later not be attainable. Contact the Data Coordinating Center for guidance if more than four hospitals are involved. The pull-down menu provides names of ROC hospitals entered in the EMS Structures database (with effective dates of study approval that encompass that of the episode being entered) 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 center, or other non-acute care facilities for this item. Transfer to one of these three entities constitutes a hospital discharge and should instead be reported in Item 9, 'Discharge status from final hospital'

Item 3 – History prior to arrest: [This data element is temporarily blocked for data entry until further notice; if and when un-blocked, retrospective data abstraction of otherwise completed forms will NOT be required or requested.]

The purpose of this item is to capture potential co-morbidities that may influence outcome from cardiac arrest (the provided list as guided by the article, Influence of "Comorbidity on the Outcome of Patients Treated for Out-of-Hospital Ventricular Fibrillation" (*Circulation*. 1996;93:2019-2002). Data for the requested history should be abstracted from the ED record and hospital admission history and physical (H & P) notes; do not use the prehospital PCR/ACR. Indicate if each of the listed conditions is noted ('yes') or 'not noted. Respond 'yes' for mention of the history or current condition, whether or not thought to be directly

associated with this episode.

Item 4 - Residential status prior to arrest:

The type/location of where the patient lived prior to study enrollment . Select one location::

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).

Inpatient rehabilitation facility: 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. Includes skilled nursing 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 study enrollment is not known or is not noted in the patient care record.

Item 5 – CCU/ICU days, initial continuous:

Indicate the number (integer) of calendar days in a row the patient was in an intensive care setting (includes CCU, ICU, CCC, SICU, etc) during their initial stay before moved to a step-down, telemetry, or regular nursing unit/ward/floor. If the patient returns to the intensive care setting, those days are not included for this data item. A day is defined as any portion of a 24 hour period ending at midnight (24:00). For example, if a patient arrives in the CCU/ICU at 11am on Monday, then goes to the floor at 7pm on Monday, that is stay of 1 CCU/ICU day. If a patient arrives in the in the CCU/ICU at 11am on Monday, then goes to the floor on Tuesday at 3am, that is a stay of 2 CCU/ICU days.

Item 6 – Ventilator days, initial continuous:

Indicate the number (integer) of calendar days in a row the patient was first on a ventilator If the patient returns to the intensive care setting, those days are not included for this data item. A day is defined as any portion of a 24 hour period ending at midnight (24:00). For example, if a patient arrives in the CCU/ICU at 11am on Monday, then goes to the floor at 7pm on Monday, that is stay of 1 CCU/ICU day. If a patient arrives in the in the CCU/ICU at 11am on Monday, then goes to the floor on Tuesday at 3am, that is a stay of 2 CCU/ICU days.

Item 7 - Order written for DNR or care limited/withdrawn hospitalization?:

Choose “yes” to indicate that a physician’s order was written in the hospital to change the patient’s status to ‘do not resuscitate’ (DNR) or to actively withdraw life support or limit treatment for the patient. Provide the date of the order written for DNR. If no order for DNR

written, but comfort care (CC) measures are ordered, consider the date of that order to be a surrogate for DNR and withdrawal of care. If order not written for DNR or CC measures, but orders are written to limit care (such as stop pressors, decrease O2 to room air, extubation, removal ventilatory support, don't treat arrhythmias), provide the date of the initial set of such orders as an indicator of withdrawal of care. Where more than one of the above is ordered, enter the date of the earliest order.

Item 8 - Date and time of acute care hospital discharge, reclassification, or death:

Date (yyyy/mm/dd) and time (24 hour clock hh:mm) that the acute hospital 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) acute care hospital to which the patient was admitted or transferred. If the patient is discharged dead, the time and date recorded should be the official time of pronouncement.

Item 11 – Discharge summary listed conditions (check all applicable):

Use the discharge summary written for the final acute care hospitalization for this episode. Discharge or transfer summaries from hospitals attended earlier in the course of care are not used for completing this data item. If the final acute care hospital was non-ROC, leave this item blank (do not mark 'none of the below conditions noted') and request the DCC to close out the form. Check all the listed conditions that are noted (with identical or like meaning vocabulary) in the final hospital discharge summary. It is recognized that additional details may be revealed elsewhere in the chart, but restricting the source for this item to the discharge summary is intended to standardize data collection. Mark each item if noted, regardless if thought to be associated or not with cardiac arrest.

General:

- Airway bleeding—mark only if bloody fluid or frank blood in the naso or oropharynx or upper respiratory system is noted. Does not include mention of pink frothy sputum or blood tinged fluid.
- Bleeding requiring intervention—transfusion, surgical, ligation; anywhere. Does not include internal bleeding of abdominal cavity (instead, mark Bleeding, internal for Abdomen)
- Cerebral bleeding, stroke, CVA (cerebral vascular accident)—does not include TIA (transient ischemic attack)
- Hypotension requiring vasopressors—includes Dopamine, Dobutamine, Ephedrine
- Recurrent cardiac arrest—re-arrest that was treated
- Seizures—such as epilepsy, focal or generalized
- Sepsis—includes septic shock

Abdomen:

- Internal abdominal injury—includes laceration of spleen
- Liver laceration
- Bleeding, internal—regardless of what associated with (including liver or spleen)

lacerations)

Chest:

- Internal thoracic injury—includes pleurisy, pericarditis, empyema
- Pneumothorax—does not include atelectasis
- Pneumonia—includes consolidation, aspiration
- Pulmonary edema—includes alveolar or interstitial edema, bilateral pleural effusion, pulmonary venous congestion, or cardiomegaly
- Rib fractures
- Sternal fractures—does not include sternotomy

Other: Specify other major medical or surgical conditions listed.

Item 12 –Modified Rankin Scale at hospital discharge:

Review the patient chart at time of discharge and assess the degree of assistance the patient needs and select the one category that best describes their condition at that time. Consult notes by physical therapy and occupational therapy (especially those written as part of transfer/discharge packet) will be an important source. Do not distinguish if the assistance required is ‘temporary’ or imposed (such as post-operative recovery or following prolonged bed rest).

MRS0 –no symptoms at all.

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

Symptoms might include difficulty reading or writing, speaking or finding the right word; problems with balance or coordination; visual problems. Symptoms might also include dysphagia (difficulty swallowing), numbness or loss of movement (such as face, arms, hands, feet).

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

Unable to carry on all of one’s own prior usual duties and activities. Usual duties and activities include their baseline ability to study as a student or work, carry on family responsibilities, ability to participate in social and leisure activities. Exhibit communication problems, quick temper, irritability, mood swings, depression, and unreasonable behavior.

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

Assistance is needed for patient to look after their own affairs. Assistance includes physical assistance (help), verbal instruction, or supervision by another person. Assistance is essential for preparing a simple meal (breakfast or snack); for basic ‘every day’ household chores (finding/putting away clothes, cleaning up after meal). Walking ‘without assistance’ allows for use of an aid such as a stick/cane or frame/walker.

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

Assistance includes physical assistance (help), verbal instruction, or supervision by another person. An aid, such as a stick/cane, walking frame/walker, is not considered assistance. Inability to attend to bodily needs without assistance would include: needing help eating; needing help reaching the toilet/commode, to undress, clean self and get dressed; needing help to wash face, do hair, clean teeth.

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

Care may be provided by either a trained or untrained caregiver. Someone needs to be available at all times.

MRS6 Death at discharge—patient was not alive at discharge.

This form was last saved by: (name)

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ATTACHMENT A -- Electronic Signature Agreement

A link to the Electronic Signature Agreement, and other documentation needed to establish a ROC-account, is located on the Home page. The link is titled 'Need an account? Click here', located below the standard Login box asking for user name and password. Below is a copy of the agreement dated 2011-01-24. Check the link for the most current version if applying for ROC-access.

Form revision 2011-01-24a

University of Washington
Clinical Trial Center
Resuscitation Outcomes Consortium

Electronic Signatures and Data Entry Website Usage Agreement

This agreement is between you, your main coordinator or principal investigator, and the University of Washington Clinical Trial Center (CTC) for activities related to the usage of the Resuscitation Outcomes Consortium (ROC) data entry website.

Various laws, such as the United States Uniform Electronic Transactions Act, the United States Electronic Signatures Act, and the Canadian Uniform Electronic Commerce Act, legally support or stipulate the following:

- The username and password assigned to you by the CTC for using the website also serves as your electronic signature.
- Your electronic signature is the equivalent to a written signature and the CTC intends to use it as such.

Also, the CTC stipulates that:

- You will not enable anyone else to use your website account, such as by sharing your username and/or password.
- While signed into the website with your account, you take responsibility for all actions taken by you on the website.
- You will immediately report to the CTC actual or suspected misuse of your account by someone else. The ROC Management Committee will determine further action, if needed.
- You recognize that facsimiles or digitized versions of this document (created by you or the CTC) serve as equivalents to the original.
- All content on the website is considered confidential unless stated otherwise.

Finally, your main coordinator or principal investigator attests and recognizes that:

- They have verified your identity.
- They are primarily responsible for reporting to the CTC when you should no longer be using the website. You have secondary responsibility.

Sign below to indicate that you understand and agree to this document.

You (website user)

Name:

Signature:

Date:

Main Coordinator / Principal Investigator

Name:

Signature:

Date:

Return this form to the CTC via fax 206-543-0131 or as a scanned PDF emailed to rocsiteadmin@uwctc.org

ATTACHMENT B – Medtronic CODE-STATE Software

ROC Site Instructions for using Medtronic CODE-STAT software

All ECG files that are uploaded to ROC cases must have all patient identifiers removed. The following are instructions for configuring and using the Medtronic CODE-STAT software for de-identifying ECG files to attach to ROC cases. This assumes that you have imported files into CODE-STAT. The import process is beyond the scope of this document. Please see the CODE-STAT documentation for details on how to import files. You may receive files from various agencies or other sources. It is the responsibility of the site to ensure that all files regardless of source are imported into the CODE-STAT software and exported properly to de-identify them.

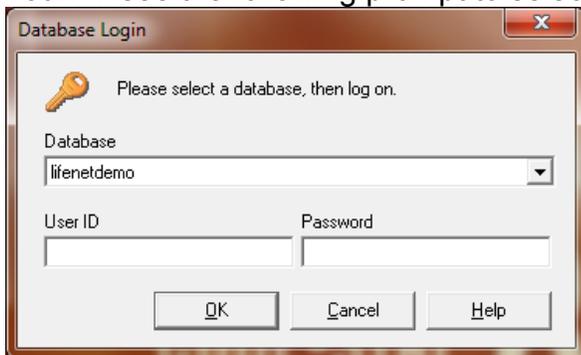
Configuring the Exporter

You must configure a special CODE-STAT Reviewer “ROC export” process to handle de-identification of ECG files. Only upload files that have been exported via this special export process. The “ROC export” configuration (steps 1-5 below) only needs to be done once. After you have configured the ROC exporter any file that you export via the ROC exporter will be deidentified. If you install updates to the CODE-STAT software review your ROC exporter to ensure that it still works properly.

To configure the ROC export process follow these steps:

Open CODE-STAT Reviewer

You will see the following prompt to select a database:



At the prompt you must select the database that holds the files you will be attaching to ROC cases. This may be different for each site depending on how your site manages ECG files. (The examples here use the ‘lifenetdemo database’ that contains sample cases)

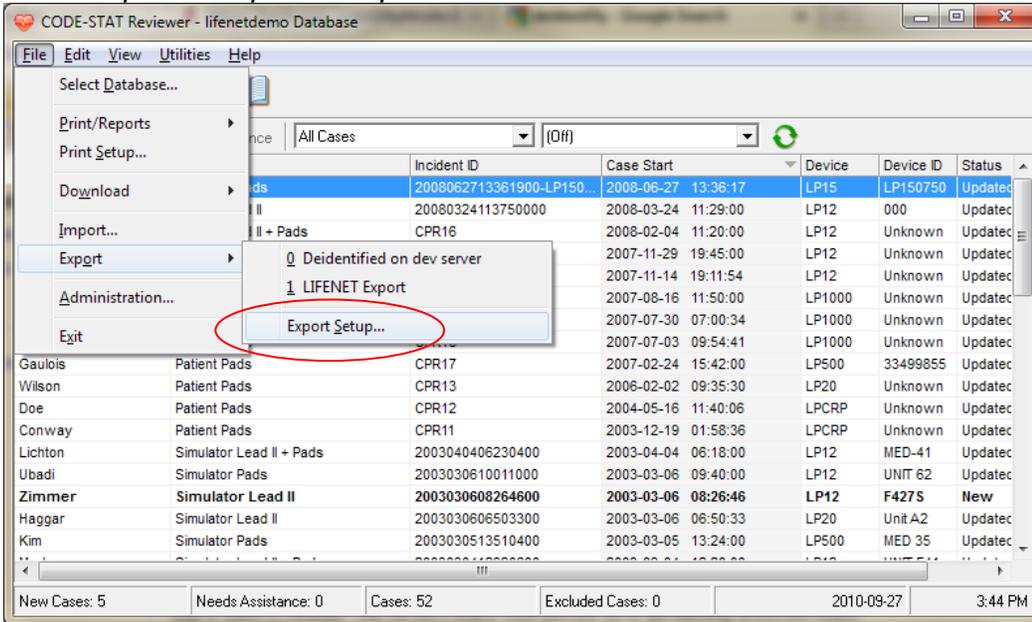
You must enter a User ID that has administrative permission to manage the database that you have selected. Your site probably has its own accounts and passwords configured. If you don’t know what user id or password to use you need to ask someone at your site who configured the software. The CODE-STAT software comes with 2 default administrator users already configured. These users may or may not exist in your system depending on how your site manages ECG files. If these users exist they are as follows:

User ID	Password
physio	control

User ID	Password
medtronic	ers

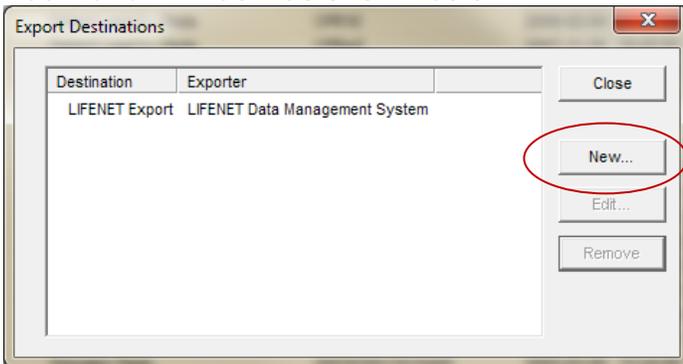
Open the Export Destinations Window

When you have logged into CODE-STAT Review open the Export Setup window by selecting *File – Export – Export Setup* from the menu as shown below:



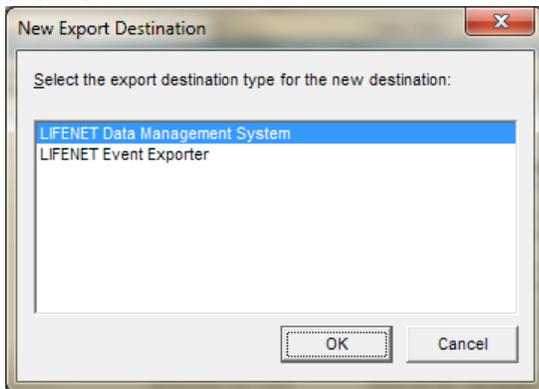
Open the New Export Destination Window

When the Export Destinations window appears select *New* to open the *New Export Destination* window as shown below:



Select the Export Destination Type

This will bring up the *New Export Destination* window. This window will prompt you to select the export destination type. Select LIFENET Data Management System as shown below and click *OK*:

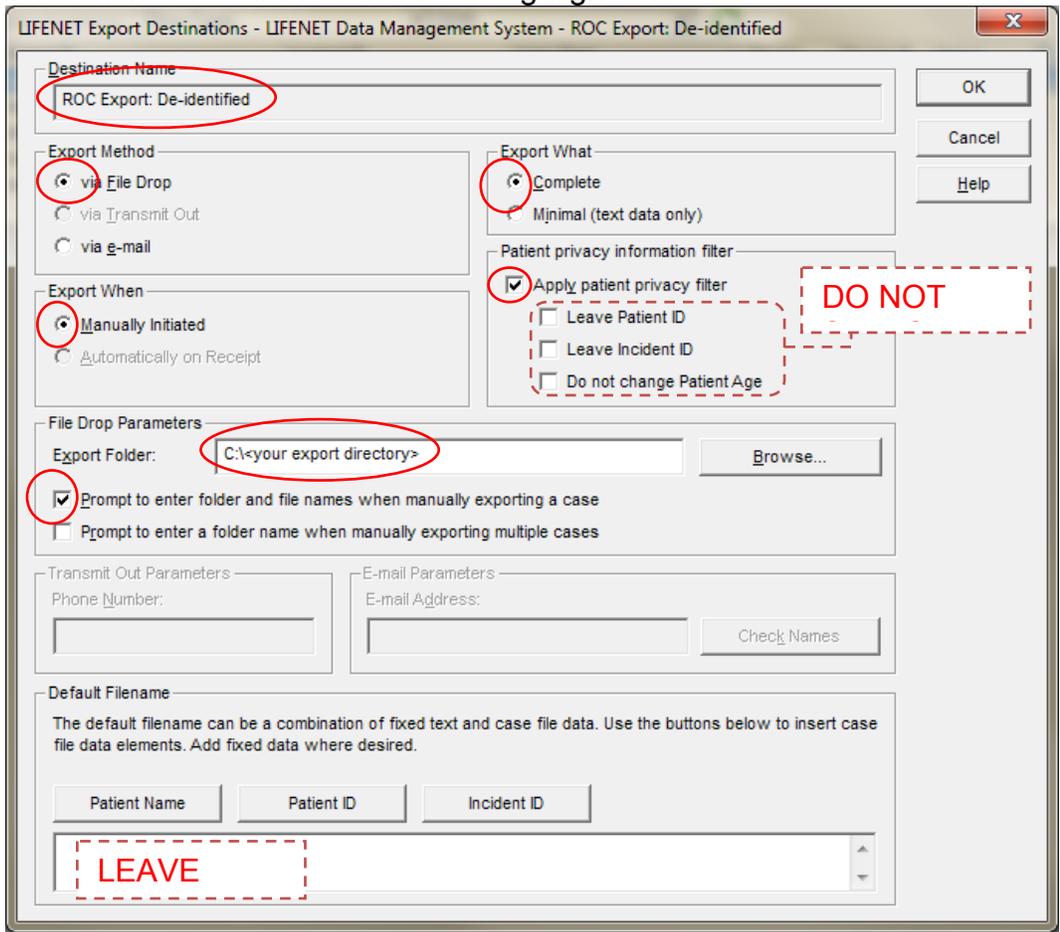


Configure the New Destination

This will open the *New Destination* window. Select the following values for each setting listed below and click *OK*:

Setting	Value
Destination Name	ROC Export: De-identified
Export Method	Via File Drop
Export What	Complete
Export When	Manually Initiated
Patient privacy information filter	Apply patient privacy filter (IMPORTANT: checking this box turns on the de-identifier. Do not check any of the other boxes in this section)
File Drop Parameters	<p><i>Export Folder</i>: Browse to a location where you will export all files that are to be uploaded to ROC cases. We recommend that this folder be named ROC ECG Exports or something similar.</p> <p><i>Prompt to enter folder and file names when manually exporting a case</i>: checked (We recommend that you check this box so that you are prompted to set the file name every time you export. This makes it easier for you to include the ROC case id in the file name which is required for all uploaded files.)</p> <p><i>Prompt to enter a folder name when manually exporting multiple cases</i>: unchecked (We don't recommend exporting multiple files for ROC cases because it is difficult to match files with cases once they have been de-identified.)</p>
Default Filename	Leave Blank

When you are done the screen should look like the following screen shot where each of the fields mentioned above have been highlighted:

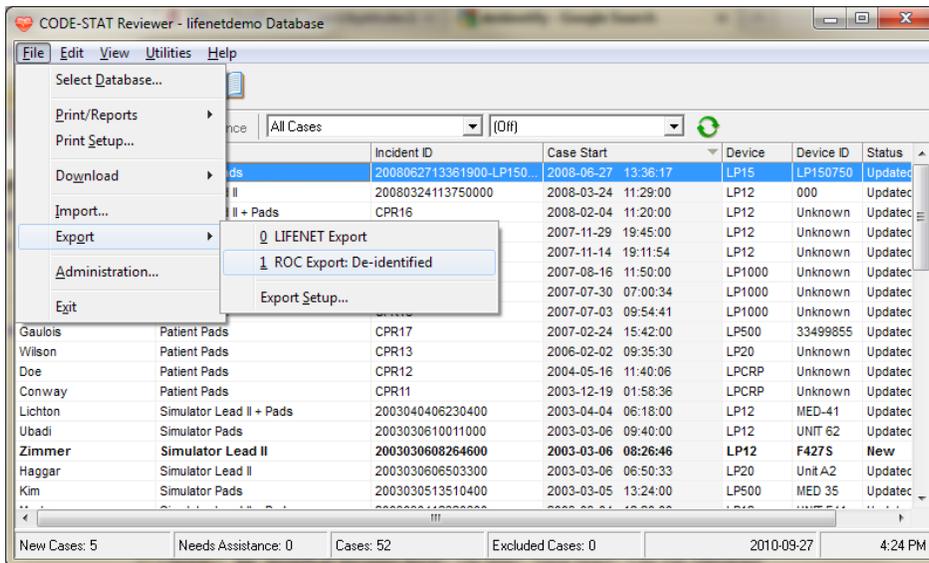


Exporting Files with the ROC Exporter

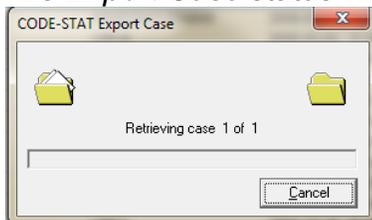
To export a case with the de-identifier configured as above follow these steps:

Open the Case with CODE-STAT Reviewer

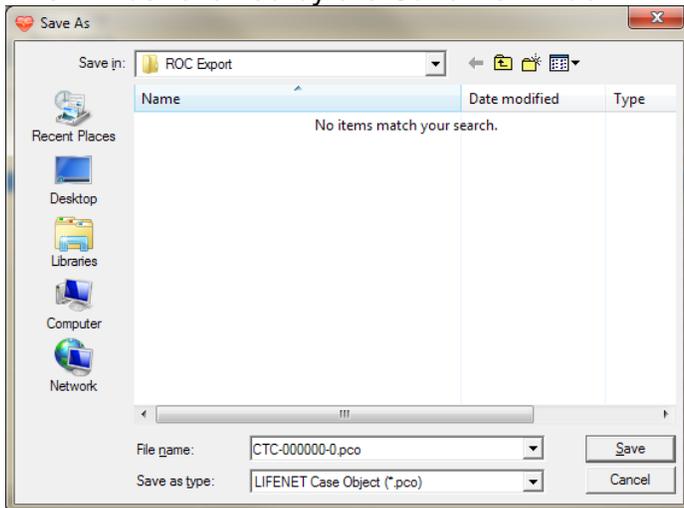
Open CODE-STAT Reviewer and select the database that holds the ROC case you wish to export. Log in using your normal CODE-STAT Reviewer account. This may be the same as the administrative account that you used in step 1 or it may be different. As mentioned in step 1 your site most likely has its own account names and passwords configured. If you don't know your login information you will need to consult your site staff. Use the case list to select the case that you want to export and select *File – Export – ROC Export: De-identified* as shown below:



The *Export Case* status window will briefly appear while the case is prepared for export:



This will be followed by the *Save As* window:



When this window appears enter a name for the export file and click *Save*. The file name must contain the ROC case id as described in the general ECG upload instructions