CCC Manual of Operations

The following Manual of Operations consists of elements for 3 ROC studies: Epistry (Epidemiologic cardiac arrest registry), CCC and Amiodarone, lidocaine or placebo for out-of-hospital cardiac arrest due to ventricular fibrillation or tachycardia (ALPS). Required elements for the CCC trial are included in the relevant datasets. ALPS data are not included in the CCC datasets.

Cardiac Manual of Operations

OVERVIEW CARDIAC STUDIES

With the launch of the Continuous Cardiac Compressions (CCC) protocol, data collection forms and the Manual of Operations for all cardiac studies (Epistry, CCC, ALPS) are merged. The ROC-web data entry forms detect pre-specified response sequences that determine which data elements are related to a given case. Epistry (the ROC cardiac observational database) data elements serve as the basis for the cardiac interventional studies. Data variables specific to the CCC and ALPS interventional trials are labeled as such. Data forms within the ROC-web data entry system are programmed to detect site and agency eligibility for enrollment in each of the studies and controls access to related data elements.

It is the responsibility of the site investigators, coordinators, and data entry staff to be knowledgeable of

each Cardiac study protocol, including the aims of each study, enrollment criteria, sources for patient related data, and regulatory requirements. Conduct of each study will be in a manner consistent with federal regulations and local standards in Canada and the United States.

A dedicated page for each of the Cardiac studies is located on the ROC-web. There posted for view and download is each study's approved Protocol, related criteria for run-in or study start, relevant regulatory documents, and training materials. The link for each study page follows:

Epistry (Epidemiologic Registry): https://roc.uwctc.org/tiki/epidemiologic-db

CCC (Continuous Chest Compressions versus Standard CPR in patients with Out-of-Hospital Cardiac Arrest): https://roc.uwctc.org/tiki/roc-ccc

ALPS (Amiodarone, lidocaine or placebo for out-of-hospital cardiac arrest due to ventricular fibrillation or tachycardia): https://roc.uwctc.org/tiki/roc-alps

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.

Multiple Episodes

Although knowledge of multiple episodes for a given patient may not be important for the stated purposes of each study, 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.

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
EtCO2	End-tidal CO2 (carbon dioxide)
ETT or ET	Endotracheal Tube
FiO2	Percent inhaled oxygen
HCO3	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
PaCO2	Partial pressure of carbon dioxide in the blood
PaO2	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
SaO2	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

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 Screening and 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.

Changes to Date of Episode

Date of episode is entered into the Patient Screening and 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.

Changes to Patient Screening and Enrollment Form

This form collects data to determine eligibility for Epistry and the CCC and ALPS interventional trials. Data entered is used by the web-system to determine what forms are required and within those forms, what study-specific data elements are required. When sufficient data has been entered into the Screening and Enrollment form (to indicate if a case is only in Epistry or is also qualified for CCC or ALPS) and the form is saved (in either ‘E’ or ‘C’ status), other required forms (and data elements) are made available for data entry. Where other than the Patient Screening and Enrollment Form are designated as required (‘R’) AND any data entry has been initiated in those forms, the site is restricted from making changes to the Screening and Enrollment form. This is so as to assure that only study-specific data is entered or retained in the subsequent forms. The site must submit a Request (as is similarly done to change the date-of-episode for a case) asking that specific data on the Screening and Enrollment form be changed. The CTC will make the requested edits to the Screening and Enrollment form and assure that other forms retain only the newly defined set of data.

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 for ‘Epistry only’ cases. 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. For the CCC and ALPS interventional trials, it is expected that final vital status will be collected on all enrolled patients. Where a date for final vital status cannot be attributed to an 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.

Epistry 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).

Table 1: 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	1st responding Agency name (ROC or non-ROC) OR If 1st 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 SCREENING AND 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.*

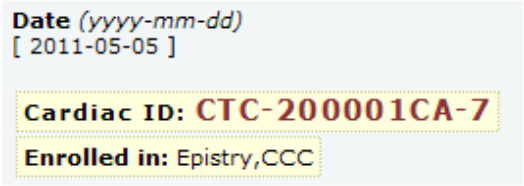
CTC Episode ID:

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.*

On April 19, 2011 the format of the *CTC Episode ID* for all cardiac studies changed from AAA-xxxxxxEP-x (where AAA is the three character abbreviation for the site) to AAA-xxxxxxCA-x (where

CA represents Cardiac study).

With completion of the CCC and/or screening for Inclusion and Exclusion criteria sections, the ROC-web will confirm the eligibility of the case for enrollment in the CCC study, will indicate that status on the Enrollment form just below the CTC episode ID, and will control which data variables are made available for data entry in other forms.



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. Each agency selection indicates en-parentheses which studies ('Epi', CCC, ALPS) it is approved for on the date of the given episode. 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 2: Summary of *Agency* and *VehicleName* 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 vehicle name picklist (OK)

ROC agency pick list (OK)	Non-ROC (Non-overridable error, save with errors; Request CTC to close out form) No vehicle (OK) Not in list (save with errors) Unknown (Non-overridable error, save with errors; Request CTC to closeout form)
Non-ROC agency (OK)	Non-ROC (no error message when coupled with 'non-ROC' agency)
Non-participating agency (name in EMS Structures, but indicated as not participating in any ROC cardiac studies) (OK)	Non-ROC (no error message when coupled with 'non-participating' agency)
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 2) must be selected for each of the four lines provided for 'Agency Name' AND at least one of the agency/vehicle combinations MUST be ROC agency/ROC 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 the *Agency Name* selected is for one not participating in any current ROC cardiac studies, enter 'non-ROC' for the associated rig. This combination can be saved without errors. This combination might be encountered where an agency previously participated in a ROC cardiac study and was entered into the EMS Structures database.

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), King airways, 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 *a*gencies" or "non-ROC vehicles"*.*
- *ALPS Drug Kit*: This item is intended to capture the information specific for the kit that was associated with the patient episode, regardless of the amount of drug given to the patient. Indicate whether the ALPS kit was opened in the presence of a patient. Indicate whether or not the drug was administered to the patient. Enter the ID of the drug kit opened for this patient, even if no drug was administered to the patient.
    - Kit opened prior to arrival at patient's side—if a kit is opened prior to the rig arriving at the patient's side, a Patient Enrollment form should not be completed. An Alert form not associated with a patient episode should be generated, and the kit ID number and the reason for opening the kit should be explained on the Alert form.
    - More than one kit opened — If more than one kit was opened at the scene, enter the above information for both kits. An Alert form is required if more than one ALPS kit is opened at the scene or if the kit is opened but not used.

Item 2 - 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.

EPISTRY ENROLLMENT

All episodes of treated and un-treated non-traumatic out-of-hospital cardiac arrest are to be entered into Epistry. Cases enrolled into cardiac interventional trials, such as CCC and ALPS, are co-enrolled in Epistry. If a patient arrests at a long term **acute** care hospital which is staffed by nursing personnel and physicians who provide ACLS care, the patient is NOT enrolled in Epistry. In trying to determine if a facility meets these criteria, consider level of nursing expertise, nurse to patient ratios, and presence of an in-house physician. If you are in doubt as to whether a facility qualifies for this exclusion, contact the CTC for discussion. Epistry data elements serve as the basis for interventional trial data collection, to which data elements specific to either CCC or ALPS are added. Data elements specific to the interventional trials are made available for data entry subject to 'visibility rules' based on pre-specified criteria for arriving agencies, which agency initiated CPR or placed pads (whichever was first), and/or if a study kit was opened in the presence of a patient. Review the Enrollment and Screening criteria for each of the listed

studies.

Item 3 - Epistry Episode characteristics:

Indicate if the patient meets the below definitions for Epistry inclusion as Treated by EMS or Not Treated by EMS. Patients that suffer a cardiac arrest that is associated with blunt, penetrating, or burn trauma (Table 4; 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 3) 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, in consultation with the site Principal Investigator, 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. For clarification, patients who have Left ventricular assist devices (LVADs) or Total artificial hearts (TAHs) who do not receive external defibrillation or EMS delivered chest compressions are not included 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 a patient arrests at a long term **acute** care hospital which is staffed by nursing personnel and physicians who provide ACLS care, the patient is NOT enrolled in Epistry. ACLS care includes IV insertion, administration of cardiac arrest drugs, and insertion of ETT. Note that CA’s that are attended to at cardiologists offices and dialysis centers should be included in Epistry if all other requirements are met. 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).

For each out-of-hospital non-traumatic cardiac arrest that is evaluated by fire/EMS personnel that are part of an organized response, indicate if the patient was either *Treated by EMS or Not treated by EMS*:

- *Treated by EMS* — receives attempts at external defibrillation (by lay responders/bystanders or emergency personnel), or receives chest compressions by organized EMS personnel. See definition for bystander (Prehospital form, item #5). 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? : This data element is included in the algorithm to later discern eligibility of the case for the CCC trials. 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*.

- 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.

- ALPS ONLY: *Not a cardiac arrest*—such as when ALPS drug kit opened in presence of patient and patient is not defined as ‘Treated’ or ‘Not treated’. It will be an unusual circumstance where this is marked. When an ALPS drug kit is opened in the presence of a patient that is not in cardiac arrest, mark this response option—it assists with triggering of required data and Alert forms.

TABLE 3: 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 4: 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 NEMSIS code, are not eligible for enrollment in Epistry.

Type or Mechanism of Injury	E-code	NEMSIS
Blunt		2035
Penetrating		2050
Burn		2040
Aircraft related accident	E84X.0	9500
Bicycle accident	E826.0	9505
Bites	E906.0	9510
Child battering	E967.0	9520
Falls	E88X.0	9550
Fire and Flames	E89X.0	9555
Firearm assault	E965.0	9560
Firearm injury (accidental)	E985.0	9565
Firearm self inflicted	E955.0	9570

Machinery accidents	E919.0	9580
Motor vehicle non-traffic accident	E82X.0	9590
Motor vehicle traffic accident	E81X.0	9595
Motorcycle accident	E81X.1	9600
Non-motorized vehicle accident	E848.0	9605
Pedestrian traffic accident	E814.0	9610
Rape	E960.1	9620
Stabbing/cutting accidental	E986.0	9630
Stabbing/cutting assault	E966.0	9635
Struck by blunt/thrown object	E968.2	9640
Water transport accident	E83X.0	9650

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

CCC SCREENING

All non-traumatic cardiac arrest episodes that were treated by ROC fire/EMS agencies participating in CCC (received compressions by EMS or shock) will be required to be screened for CCC. Mark ‘screened’ if the patient received at least one EMS chest compression *and* any arriving ROC agency is currently participating in the CCC Trial (at the time of the date-of-episode as evidenced in the Agency drop-down list for Item 1); continue to Item 4. Mark ‘not screened’ if the patient received no EMS chest compressions *or* none of the arriving ROC agencies is participating in the CCC Trial on the date-of-episode; no further data items are required, nor can be entered, for CCC screening.

Chest compressions performed by police, clinic staff, or other bystanders is considered ‘bystander CPR’; An AED or defibrillator used by police, clinic staff, or bystanders is considered ‘bystander AED’—the definitions to ‘screen’ or ‘not screen’ patients for CCC are not affected by receipt of police, clinic staff, or other bystander compressions or AED. See CPR Process form directions for how police or bystander AED use is there captured..The ROC Regulatory System is automatically referenced at the point data is entered in item #1 to determine which agencies are participating in which trials. Where only a portion of an agency’s responding rigs are in a study, the system will expect all agency cases to be screened. If you have a circumstance where only a portion of rigs are in a study and their cases are not to be screened for enrollment eligibility, contact the CTC to discuss—the Enrollment form will likely need to be ‘closed out’ (F status) after details have been discussed. To date, this circumstance is known to only apply to the Vancouver/BC ROC site.

Item 4 - Therapy assignment:

Enter the randomization therapy **assigned by the CTC** to the first ROC CCC participating agency that initiated CPR for this episode, either continuous compressions or 30:2. This will be resident knowledge to the ROC Regional Coordinating Center (RCC) and should there be sourced based on date-of-episode (not date reported or entered), rather than from the prehospital record (which may instead reflect what the

crew delivered). The ‘therapy assignment’ may or may not be the therapy that was delivered.

Item 5 - Inclusion criteria:

Check the bubble "Yes" or "No" for each line item to indicate if any inclusions existed. All responses must be ‘yes’ for the episode to be enrolled in the CCC study. Provide ‘yes/no’ responses based on information learned only during the prehospital course of care. The Enrollment form is not intended to capture the presence or absence of inclusion criteria learned in the ED or Hospital after the prehospital course of care. Required forms and data fields are made available for data entry based on specific inclusion criteria.

- *Age ≥ age of consent* - age of consent is ≥ 18 years at most sites, but each site must follow their local regulations. Using information learned during the prehospital course of care, mark ‘yes’ or ‘no’ if the patient meets the age criteria. If ‘yes’ the patient meets age criteria based on prehospital sources, but the birth-year learned in the ED/hospital indicates the patient may not have met age criteria, complete an Alert form (either auto-triggered when birth-year entered on the Hospital form; or site-generated if patient died in ED and age learned there).
- *Non-traumatic cardiac arrest*- If the patient experiences a cardiac arrest due to a traumatic cause such as blunt or penetrating trauma or burns (as listed in Table 3 above), the patient is not included in the study nor should the case be entered into Epistry.
- *Initial fire/EMS chest compressions provided by CCC participating ROC agency*- The vehicle and agency in Item 3-’Episode characteristics’ as the initial agency to initiate chest compressions must be a ROC CCC agency and the agency must be in the run-in or evaluable period of ROC CCC.

Item 6 - Exclusion criteria:

Check the bubble "Yes" or "No" as to whether any exclusion existed. Any ‘yes’ response will exclude the episode from enrollment in the CCC study. Provide ‘yes/no’ responses based on information learned only during the prehospital course of care. The Enrollment form is not intended to capture the presence or absence of exclusion criteria learned in the ED or Hospital after the prehospital course of care. Required forms and data fields are made available for data entry based on specific exclusion criteria.

- *Written advance directive to not resuscitate (ie DNR)* — if written Do Not Resuscitate (DNR) orders are given to the EMS providers, or a written DNR order is substantiated by the patient’s physician, during the prehospital course of care, mark ‘yes’, even if the family/LAR asks EMS to treat the patient despite the directives. **This exclusion applies regardless of when the written DNR was presented or substantiated during the course of prehospital care**. This exclusion does not apply to episodes in which the family tells the EMS providers that the patient did not want to be resuscitated or the family asks the EMS providers to stop the resuscitation due to the patient’s age or medical condition. The latter situations are considered as a ‘verbal directive’ or per ‘family wishes’; mark ‘no’ here and indicate as such on the Pre-Hospital form.
- *Blunt, penetrating, or burn related injury* — Mark ‘yes’ if the patient experienced cardiac arrest due to a traumatic cause that is blunt,penetrating, or burn (see Table 4 above for mechanisms of examples of injuries considered to be blunt, penetrating or burn).
- *Obvious cause of arrest is asphyxia or respiratory (ie drowning, strangulation, hanging)* — see definitions for these ‘obvious causes’ in Item 13 of the Pre-hospital data form. This includes ‘choking’.
- *Exsanguination* — cardiac arrest due to exsanguination and determined to be the obvious cause (etiology) of the arrest. Very few patients are expected to arrest due to this cause, and it may be difficult to determine at the time of the resuscitation. If a patient has a small amount of fresh blood around the mouth or vomits old blood, this cannot be considered an arrest due to exsanguination.
- *Known prisoner* — EMS providers have been instructed to exclude known prisoners for enrollment in the ROC CCC study. A known prisoner is one who arrested while incarcerated, at a correctional facility or jail, or while in police custody.

- *Known pregnancy* - If a patient is known to be pregnant prior to initiation, during or after treatment for the cardiac arrest and prior to arrival at the ED/hospital, the patient is excluded from the study. If the pregnancy is not known until after the patient arrives at the ED or hospital or upon family LAR notification, check 'No' and complete an Alert form to indicate when the pregnancy became known to the site staff when reviewing ED/hospital records.
- *EMS witnessed arrest* — because the standard protocol for EMS witnessed cardiac arrest is to analyze immediately, any episode which is initially witnessed by ROC EMS is excluded from the analysis for CCC.
- *Non-ROC/non-CCC participating agency first to initiate chest compressions or place pads (whichever is earliest)* — if a non-ROC EMS provider is first on scene and that agency provider is the first to begin CPR or place defibrillation pads(which ever occurs first in the prehospital course of care), the episode is excluded. There are crossform checks in place to verify this with the CPR Process form. Data abstractors will determine which agency commenced CPR based on a review of the electronic CPR or patient care reports from fire/EMS, or the site's custom research data collection form. Mark this exclusion as 'yes' in the absence of clear, auditable documentation that a CCC participating agency was first to either start CPR or place pads (which ever was earliest). This line item does not include the circumstance where a bystander (such as in a clinic or dialysis center) applied pads or started CPR prior to fire/EMS arrival.
- *Mechanical compression device used before any manual CPR by ROC personnel* --mark 'yes' if any arriving agency applied such a device to the patient prior to any manual CPR by ROC personnel. Includes, but is not limited to, Autopulse, Thumper or Life-Stat, and LUCAS. Mechanical compression devices placed after any manual CPR by ROC personnel and before completion of the study specified four study cycles of CPR will be a protocol deviation. Mechanical compression devices placed AFTER the study specified four study cycles of CPR does NOT exclude patient from the study and is not a protocol deviation.
- *Advanced airway placed prior to CCC participating ROC fire/EMS agency arrival* — if a patient arrests at a location such as a medical clinic, dialysis center, or cardiac rehabilitation center, and the health care providers at the location place an advanced airway (includes Combitube, King, LMA, ETT, etc.) the patient is excluded. The response option for this exclusion criteria does not include 'pre-existing trach'; see the next exclusion criteria to indicate the presence or absence of a pre-existing trach. Once an advanced airway is placed, the standard treatment is continuous compressions which would interfere with the evaluation of the CCC trial intervention.
- *Pre-existing trach* — patients with a tracheostomy are excluded from enrollment in CCC as a trach is considered an advanced airway and affects fire/EMS protocols for type of CPR delivered.

ALPS SCREENING

All EMS treated cardiac arrests (as defined in Epistry) with a response from at least one agency that has started ALPS must be screened. In addition any case where the ALPS kit was opened in the presence of a patient (even if not in cardiac arrest) must be screened.

Mark 'Screened' if above criteria are met. Mark 'Not screened' if no ALPS participating agency arrived on scene, or the patient was not a treated cardiac arrest and an ALPS kit not opened in the presence of the patient.

Item 7 - Inclusion criteria

Check the bubble "Yes" or "No" for each line item to indicate if any inclusions existed. If any of the inclusion criteria are not met (marked 'no') and the study kit was opened, an Alert form is triggered to report a protocol violation, and all study data is required regardless of meeting enrollment criteria.

- *Greater than or equal to 18 years old or local age of consent* --This is age 18 years old at most sites, but each site must follow their local regulations.

- *Non-traumatic cardiac arrest* --If the patient experiences a cardiac arrest due to a traumatic cause such as blunt or penetrating trauma or burns (as listed in Table 3 above).
- *Treated by a ROC fire/EMS with ALS capability* -- A responding ROC rig provided ALS capability and is participating in the ALPS study (whether or not their rig was stocked with ALPS for that call).
- *Confirmed VF or pulseless VT after at least 1 externally delivered shock (prior to ALPS dose 1 administration)* -- IF MORE THAN ONE SHOCK WAS GIVEN FOR VF/PULSELESS VT THEN THIS INCLUSION CRITERIA HAS BEEN MET (even if the shocks are separated by some period of time). This inclusion criteria is separate from the situation of the rhythm prior to the administration of ALPS drug.

  Shocks include those given by members of the organized emergency response or by bystanders. The patient must have received at least one shock for VF/pulseless VT and remained in VF/pulseless VT, or went back into VF/pulseless VT later in the resuscitation after receiving the initial shock(s) in order to be eligible for ALPS. A shock by a bystander AED or by health care providers is counted as a shock. 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).

  If yes, select the statement that best describes the initial rhythm, as earliest determined by either bystander or fire/EMS :

  - “Initial rhythm of VF/pulseless VT (includes shock advised by PAD, non-ROC or ROC EMS AED) ” or
  - “Initial rhythm asystole/PEA (includes PAD, non-ROC or ROC EMS AED advised no shock) and VF/pulseless VT occurred later in episode”.
- *Established vascular or IO access-ALPS* --The ALPS drug can only be administered by IV or IO access per the FDA approval of the protocol. Any other method of administration such as through the endotracheal tube is a protocol violation. If ALPS durg is administered by any other method than IV or IO, an Alert form is required. Indicate if vascular or IO access obtained at any time during the course of pre-hospital care.

Item 8 - Exclusion criteria

Check the bubble "Yes" or "No" as to whether any exclusions existed. Any ‘yes’ response will exclude the episode from enrollment in the ALPS study (unless an ALPS kit was opened in the presence of the patient).

- *Hypersensitivity or allergy to amiodarone or lidocaine* — If the ALS providers are aware that a patient is hypersensitive or allergic to either drug prior to administration, it is a protocol violation. If the providers become aware of the hypersensitivity or allergy in the field but after administration it is not considered a violation. An Alert form is required for both situations.
- *Written advance directive to not resuscitate (ie DNR)* — if written Do Not Resuscitate (DNR) orders are given to the EMS providers after they have begun resuscitative efforts, or a written DNR order is substantiated by the patient’s physician during the resuscitative effort, mark ‘yes’, even if the family/LAR asks EMS to treat the patient despite the directives. **This exclusion applies regardless of when the written DNR was presented or substantiated during the course of prehospital care.** This exclusion does not apply to episodes in which the family tells the EMS providers that the patient did not want to be resuscitated or the family asks the EMS providers to stop the resuscitation due to the patient’s age or medical condition. The latter situations are considered as a ‘verbal directive’ or per ‘family wishes’; mark ‘no’

here and indicate as such on the Pre-Hospital form .

- *Blunt, penetrating, or burn related injury* — Mark 'yes' if the patient experienced cardiac arrest due to a traumatic cause such as blunt or penetrating trauma or burns (see Table 3 above). Unless an ALPS kit was opened in the presence of the patient, these cases should not be screened for ALPS or included in Epistry.
- *Exsanguination* — cardiac arrest due to exsanguination and determined to be the obvious cause (etiology) of the arrest. Very few patients are expected to arrest due to this cause, and it may be difficult to determine at the time of the resuscitation. If a patient has a small amount of fresh blood around the mouth or vomits old blood, this cannot be considered an arrest due to exsanguination.
- *Known prisoner* — EMS providers have been instructed to exclude known prisoners for enrollment in the ROC ALPS study. A known prisoner is one who arrested while incarcerated, at a correctional facility or jail, or while in police custody. If the ALPS kit is opened in the presence of, or given to a prisoner, complete only the Patient Enrollment, Alert CTC and Patient/Family Notification form.
- *Known pregnancy* — If a patient is known to be pregnant prior to initiation, during or after treatment for the cardiac arrest and prior to arrival at the ED/hospital, the patient is excluded from the study. If the pregnancy is not known until after the patient arrives at the ED or hospital or upon family LAR notification, check 'No' and complete an Alert form to indicate when the pregnancy became known to the site staff.
- *Prior receipt of amiodarone or lidocaine during pre-hospital course of care (by bystander or fire/EMS)* — If amiodarone or lidocaine is given during the course of ***pre-hospital care prior to meeting all other ALPS eligibility***, ALPS drug should NOT be given.

  <u>This exclusion exists due to the dosing limit for lidocaine, and the blinding of the ALPS drug. Examples include:</u>

  1. Non-ROC provider (including clinic or dialysis staff) administer amiodarone or lidocaine prior to ROC ALS arrival and
  2. Patient receives amiodarone or lidocaine during a time when a pulse is present and did not previously meet ALPS eligibility.

  <u>This **DOES NOT** include instances where:</u>

  1. Patient met all other ALPS eligibility and received amiodarone or lidocaine in lieu of opening a kit or
  2. Patient had previously met ALPS eligibility, but medics did not open a kit at that time. The patient later developed a pulse and medics gave amiodarone or lidocaine.

Item 9 - If patient met inclusion/exclusion criteria AND no ALPS drug kit opened in Item 1, why not?

- Select 'Forgot/Misunderstood Protocol' when medics forgot to administer ALPS or do not administer ALPS due to a misunderstanding of the protocol. If 'Forgot/Misunderstood Protocol' is checked, the providers should be reminded of the study and the protocol reviewed.
- Select 'No ALPS drug at scene' when a rig or medic bag (from stockroom) was not stocked with an ALPS kit or medics forgot to take the kit to the scene regardless of reason. This can vary depending on how the agency has chosen to stock kits. If the medic bag should be stocked from inventory, but was not, please select this option. If the rig was stocked from inventory, but the medic did not take the kit to the scene, select 'other' as the reason.
- Select 'Rhythm no longer eligible at time of intended administration' when the rhythm is no longer VF/VT when the medics are ready to administer drug. If 'Rhythm no longer eligible at time of intended administration' is checked, please indicate whether the reason was 'delayed IV access' or 'Other': if other is selected, specify reason. Some examples of other reasons the rhythm may no longer be eligible may include: recurrence of VF/VT at ED arrival (after already

meeting eligibility criteria), IV/IO no longer patent, and ROSC before kit could be opened.

- Select the 'Other' category when the reason does not meet any of the aforementioned 3 categories. If other is selected, specify reason the ALPS kit was not opened. These may include kit not at scene (but available on rig), no time to administer ALPS (such as met eligibility at ED arrival), protocol confusion, and termination of resuscitation.

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 (either paper or some implementations of electronic charting) by the field provider, likely having been sourced from a wristwatch or clock (hh:mm). Enter the time as a 'watch time' if field documentation is made on an

electronic PCR where times are manually scribed into the system, or events are documented on the electronic PCR at a later time after the resuscitation effort (such as when the medic charts at the ED, marking all procedures/events that occurred that are then marked with similar or identical times generated by the time synchronized electronic chart or hand written notes are referenced).

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. Dispatch/Defib time also includes electronic PCR charted times where documentation is done real-time during the resuscitation and the electronic PCR time-stamps events and it is routinely synchronized to the atomic clock.

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 (sometimes includes times from electronic PCRs as above defined) 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). Click on the red '? icon in the 'Calculation info' column 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.

Out of Order, Unable to calculate, and Calculation info columns: Click on a displayed '?' in the 'Calculation info' column 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 '!' icon in the 'Unable to calculate' column 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) that prevents the system from providing and aligned time. The '!' in the Out of Order column and the red upward arrow to the left of the 'Aligned time' column indicates that provided times create a negative order; the coordinator is encouraged to assess if the correct data has been 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'.
- "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*)

NOTE for Zoll users: Be aware that software ‘updates’ (at least through v 10.05) have caused some sites when reviewing ECG files to find substantial differences between times noted within the ‘Magnified ECG’ tab and the ‘Log’ times listed in the left hand side of the review software. When a discrepancy is noted, it is recommended that the times within the ‘Magnified ECG’ tab be used to abstract event times (such as pads on, analysis times, shock times) from the ECG waveform displayed in that tab of those in the log. And, it is recommended to use more than one form of documentation to confirm times are accurate.

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 mechanical compression device (CCC only):

Time an EMS agency initiated a mechanical compression device. This includes Autopulse, Thumper or Life-Stat, LUCAS, and other similar devices. Mechanical compression devices are only allowed to be used after the full complement of assigned CPR cycles (initial approximate 6 minutes) of the study intervention. If the time is not known, mark 'no doc time'. Review available documentation to at least provide the relative Event Order for when the device was applied. If no documentation is available as to the Event Order for the placement of the mechanical compression device, complete and Alert CTC form.

Item 7 – 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 8 – 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 9 – 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). Mark 'No Doc time' in the rare circumstance in which the AED/defib on time is clearly in error (e.g. the AED/Defib was left on from a previous run, the EMS turned on the AED as the rig was leaving the station, etc.). If the defib has voice or other methods to determine an approximate defib 'on' time then enter this in the 'aligned time'.

Item 10 – 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.

If an EMS agency elects to continue using a police/clinic/bystander AED or defibrillator to provide care, and during the course of care EMS uses that device to shock the patient, a time for '1st EMS shock' will be here entered.

Item 11 – 1st successful fire/EMS IV/IO access:

Time the first vascular access is successfully established, whether intravenous (IV) or intraosseous (IO). This is not intended to capture unsuccessful attempts at placing an IV or IO. Nor, is it intended to capture use of an existing IV or IO as might have been placed by clinic staff prior to fire/EMS arrival, or long term vascular access such as PICC, Hickman, or dialysis shunt.

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. 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 by fire/EMS, 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 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 13 – 1st dose ALPS study drug:

Time the 1st dose of the ALPS study drug was given as indicated by the ALS providers ECG marker or voice recording, or PCR documentation. The 1st dose refers to the initial two syringes for patients estimated by the providers to weigh ≥100 pounds(45 kg), or one syringe if the patient is estimated to weigh <100 pounds (45 kg).

Item 14 – 2nd dose ALPS study drug:

Time the 2nd dose of the ALPS study drug was given as indicated by the ALS providers ECG marker or voice recording, or PCR documentation. A second dose would be expected if VF or pulseless VT persisted despite ALPS dose # 1 and a subsequent shock. A second dose ALPS would not be given if the patient converted to a perfusing rhythm or to asystole/PEA following ALPS dose # 1 and a subsequent shock.

Item 15 – 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 crycothyrotomy. 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 16 – 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 17 – 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 18 – 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 19 – Patient transported from scene:

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

Item 20 – 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 2.

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:

Item 1a - 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 https://geomap.ffiec.gov/FFIECGeocMap/GeocodeMap1.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).

Item 1b - 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:

Item 2a. 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.

PREMATURE births requiring EMS CPR should be included in the Epistry as long as the baby is greater than or equal to 23 weeks gestation.

Item 2b - Gender:

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

Item 2c - 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'. If the collapse is heard (such as in the shower) and someone does react to the sound and goes to check on the patient, the arrest is considered as '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.

*Patient not in cardiac arrest in the presence of fire/EMS (*ALPS only*):* This response option is limited to cases enrolled in ALPS, where the ALPS drug study kit was opened in the presence of a patient that was not in cardiac arrest and the study drug was either given or not given.

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:

- 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.

  Where CPR was attempted by bystanders, the American Heart Association has asked that ROC further inquire about their role. Indicate if the bystander was coached by Dispatch how to do CPR while awaiting arrival of fire/EMS. This information will come from Dispatch records. It may require the site to speak with Dispatch to recognize where it is documented on standard reports, or to facilitate its reporting on documentation otherwise provided to the site. Bystanders may have been coached to provide only chest compressions or compressions with ventilations—where Dispatch provides ‘telephone CPR’, a standard protocol will be followed by each Dispatch group. Where Dispatch telephone CPR is not known to have

occurred, review the fire/EMS documentation to review for comment of hands only (compressions) or hands plus rescue breathing (compressions plus ventilations or CPR).

- 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 1 st 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 1 st 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? (CCC only)

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 'NR' (not 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 '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 '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’ (such as Thumper, LUCAS, vest, Autopulse) methods provided. CCC only: If use of mechanical devices is indicated, check the names of all ones used by during this episode.
- *Airway, bag-mask*: patient ventilation is assisted with a face mask and anesthesia bag (with or without oxygen)
- *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’).
- *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 (NEMSIS 96.041). Indicate ‘yes’ or ‘no’ if nasal intubation was successful.

  CCC only: If pre-hospital documentation indicates the ET was successfully placed, indicate the associated CO2 detector color, or Capnography (ETCO2) value in mmHg, kPa or % units

of measure. This does not include values known to have been recorded prior to successful placement of the advanced airway. Where oral or nasal ET was marked as successful and CO2 or ETCO2 values are documented, mark the corresponding assessment and provide the first values for CO2 or ETCO2 that follow ET tube placement (in the absence of evidence that the tube was repositioned)—it is recognized that the recorded values may be indicative of poor tube placement, though not recognized at the time by the provider (this will be reviewed in analysis). If there is no documentation of how successful intubation was assessed, indicate 'none of above recorded.'

- *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 NEMSIS 96.051.
  - EOA (esophageal obturator airway): Includes NEMSIS 96.030.
  - I-gel
  - King LT
  - King LT-D
  - King LTS-D
  - LMA—laryngeal mask airway. Includes NEMSIS 96.052.
  - SALT—supraglottic airway laryngopharyngeal tube.

  CCC only : If pre-hospital documentation indicates an advanced airway was successfully placed, indicate the associated CO2 detector color, or Capnography (ETCO2) in mmHg, kPa or % units of measure. This does not include values known to have been recorded prior to successful placement of the advanced airway. Where an advanced airway was marked as successful and CO2 or ETCO2 values are documented, mark the corresponding assessment and provide the first values for CO2 or ETCO2 that follow advanced airway placement (in the absence of evidence that the tube was repositioned)—it is recognized that the recorded values may be indicative of poor tube placement, though not recognized at the time by the provider (this will be reviewed in analysis). If there is no documentation of how the success of advanced airway placement was assessed, indicate 'none of above recorded.'

  Other airway—not commonly encountered, select other advanced airways that were employed during the prehospital course of care. Cricothyrotomy includes needle and surgical, NEMSIS 31.110 and NEMSIS 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; or if an IV or IO access is used that

was established prior to fire/EMS arrival 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, and 89.620.

- Continuation of existing IV?–mark ‘yes’ if fire/EMS use a previously placed IV line (for fluid delivery or drug administration) as might have been placed by a medical provider in a clinic, dialysis center or cardiac rehabilitation center where the arrest occurred.

  ALPS only: If ‘yes’, a pre-existing IV was used by fire/EMS providers, indicate the extremity(ies) in which the existing IV(s) were resident prior to arrival of fire/EMS—arm (right, left, not noted), leg (right, left, not noted) and/or external or subclavian/internal jugular sites. If a location other than listed, mark ‘other’ and specify the anatomical location. Mark ‘unknown/not noted’ if source PCR/ACR is silent. This location is important to know should the patient later develop thrombophlebits or other site-specific issues to assess any relationship with study drug.

- IV attempted?—mark ‘yes’ if fire/EMS made efforts to insert/place an IV line, regardless of success. If IV attempted, indicate if placement was successful and it was used for fluid or drug administration.

  ALPS only: If ‘yes’, placement(s) of an IV 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. This location is important to know should the patient later develop thrombophlebits or other site-specific issues that require medical or surgical intervention.

- IO attempted?—mark ‘yes’ if fire/EMS made efforts to insert/place an IV line, regardless of success. If IV attempted, indicate if placement was successful and used for fluid or drug administration.

ALPS only: If ‘yes’, placement(s) of an IO was successful, indicate where it was placed—right or left arm, right or left leg, or sternum. If a location other than listed, mark ‘other’ and specify the anatomical location. Mark ‘unknown/not noted’ if source PCR/ACR is silent. Mark only the locations of ‘successful’ IO placement; do not mark locations that were only ‘attempted’. The successful location is important to know should the patient later develop site-specific issues to assess any relationship with study drug.

Was fluid given?—Indicate whether fluids were given (yes, no, TKO, unknown/not noted). Mark ‘yes’ if a measurable volume was infused, regardless of which IV or IO route(s) given; 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 each of the listed advanced monitoring procedures that was attempted by non-ROC or ROC fire/EMS—EtCO2 (end-tidal CO2, includes NEMSIS 96.991) if capnography value not indicated on PCR, check ‘Not noted’; pacing (external cardiac pacing, NEMSIS 99.624); and 12-lead ECG (NEMSIS 89.820). Do not mark procedures that were initiated by someone other than the organized emergency response (such as a nurse or physician might do for a patient that arrested in their clinic or surgery center). If a 12-lead was done by fire/EMS, indicate if ST-elevation was documented in the prehospital PCR/ACR, the 12-lead machine generated report, or captured on voice recording—mark ‘present’ if sources state “ST elevation present’ (in any lead) or ‘STEMI’. This does not include mention of left bundle branch block (LBBB) or a paced rhythm; mark ‘absent’ if documentation specifically states the ‘no ST elevation’ or no ‘STEMI’; Mark ‘no results reported’ if documentation is silent on the topic.

Item 10 - Was emesis noted before the advanced airway was inserted? (CCC only)

For any advanced airway, whether ET, supraglottal or other, indicate ‘yes’ or ‘no’ if the EMS providers noted if emesis (vomitus) was present in the absence of an advanced airway (ET or supraglottal) either prior to insertion of the advanced airway, whether or not one was eventually placed ‘Yes’ includes emesis in the oro- or naso-pharynx. This does not include only documentation of needing to suction the airway to keep it clear. If there is no documentation of emesis prior to the insertion of or in the absence of an advanced airway, mark ‘not noted’. EMS providers have been trained for the CCC protocol to delay insertion of an advanced airway until after the initial four cycles of 30:2 or continuous compressions CPR. It is possible that a provider would decide to place the advanced airway prior to completion of the required compression cycles, due to emesis or the possibility of aspiration.

Item 11 - Possible ALPS related adverse events: (ALPS only): cited by fire/EMS after study kit opened

Mark ‘Yes’ for any of the below circumstances that are documented in the ACR/PCR/ECG markers or reported to the RCC as occurring after ALPS study kit opened and during the prehospital course of care, whether or not the condition is attributed to ALPS study drug. Mark ‘NR’ (not recorded) if prehospital documentation is silent any of the circumstances:

- *Anaphylaxis*—Anaphylaxis is a serious allergic reaction which can be due to an allergy (known or unknown) to a medication. What distinguishes anaphylaxis from more mild allergic reactions (such as hives) is its severity. Anaphylaxis in its full-blown form can result in asthmatic-like bronchospasm with severe wheezing, swelling of the face tongue and throat resulting in upper airway obstruction, along with hypotension and tachycardia. Check anaphylaxis if noted on the EMS record. If symptoms consistent with anaphylaxis are noted on the PCR but anaphylaxis is not stated, further discussion is needed with the EMS providers and the site investigator. Anaphylaxis is not intended to capture the more mild allergic reactions (such as associated with hives or itching).
- *Pacing initiated*—mark ‘yes’ if temporary pacing (either transcutaneous/external with pads or transvenous) was initiated by fire/EMS providers or other clinician after ALPS study kit opened, and during the prehospital course of care. This includes the rare circumstance where an arrest occurred in a clinic or other non-acute-care hospital setting and a bystander physician initiates pacing or inserts a pacemaker. This does not include pacing provide by an pacemaker placed or implanted prior to ALPS study drug given. It is possible that Amiodarone could cause severe bradycardia and/or heart block and the goal is to differentiate pacing needed prior to administration of the ALPS drug vs. after the drug is given. Report whether the first attempt at pacing first occurred before or after ALPS dose 1.
- *Atropine given (if yes, enter the time of the 1st dose)*—mark ‘yes’ if atropine was given by the EMS provider or health care provider (e.g. if the patient arrested in a clinic or dialysis center) after ALPS study kit opened
- *Shivering*—mark ‘yes’ if this is documented in the EMS record as occurring after ALPS study kit opened
- *Myoclonus*—mark ‘yes’ if documented as occurring after ALPS study kit opened. May also be referred to as muscle twitching, jerks, or spasms.
- *Seizure activity*—mark ‘yes’ if seizures are documented as occurring after ALPS study kit opened. May be also be referred to as grand mal, epileptic seizure, tonic/clonic movements, or convulsion.
- *IO complications (specify)*— this does not include issues associated with placing the IO access, such as might occur with process of assembling the device/needle, drilling, or missing the intended location. Mark ‘yes’ if EMS makes observations about the condition or integrity of the site after ALPS study kit opened. Describe the observation.

- *IV complications*—evidence of thrombophlebitis along the course of the ALPS infusion vein (check all): palpable cord, pain, infiltrated (i.e. blown), induration, redness--Check the boxes for any items documented in the EMS providers records that appear to have developed after ALPS study kit opened.
- *Malfunction of one or more ALPS syringes*—mark ‘yes’ if EMS reports any difficulties administering ALPS study drug. This may include the inability to push or pull the plunger of the ALPS syringe, or break or crack in the syringe during the course of ALPS administration. This does not include challenges EMS may have had removing the cap on the luer tip, connecting the CLEARLINK adapter to the syringe or IV port, or damage to syringes prior to or when the ALPS study kit was opened. Contact the CTC to discuss circumstances where it is unclear how to mark the response option.

Item 12 - 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 ‘NR’ if not recorded. Suspected extravasation of a drug is considered to have been administered.

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 or 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)

A ‘bolus’ of amiodarone would include a 10-minute ‘load’ or rapid infusion of amiodarone (the FDA-approved method for giving the initial loading dose of amiodarone). Documentation of this type ‘bolus’ amiodarone includes xxx mg ‘load’, or ‘bolus’, or ‘over 10 minutes’, or ‘IV push’, or ‘rapid infusion’. Lidociane may also be given as a rapid infusion (25-50 mg/minute, or a 2-4 minute infusion for a 100 mg dose).

ALPS only: Total dose is also required when magnesium or procainamide (Pronestyl) are administered during the prehospital course of care for a patient enrolled in ALPS. Where a patient is enrolled only in Epistry or CCC studies, the total dose given for these two drugs is not required; only the indication of ‘yes’ or ‘NR’ (not recorded) if they were administered.

For the list of drugs for which ‘total dose’ and ‘route’ are not required, a provision is made for marking ‘Check if no drug given from list below’. Mark ‘check if no drug given from list below’ if documentation indicates that none of these (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.

ALPS only: Magnesium and procainamide (Pronestyl) are moved from the list of medications requiring only ‘yes’ or ‘NR’, to the list of drug therapies that require ‘total dose’ and ‘route’ to be provided.

Where only partial EMS documentation is available to the ROC coordinator (as where the ALS or BLS record is missing), mark 'yes' or '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 'NR' and 'yes' blank for a prehospital drug therapies 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 or included in the ‘total dose’ administered; only medication later administered by EMS would be listed).

Item 13 - 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: *S*alomez F, Vincent JL. Drowning: a review of epidemiology, pathophysiology, treatment and prevention. *Resuscitation.* 2004 Dec;63(3):261-8.

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

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

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

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

- *Electrocution (non-lightning):* This category includes all cases where the patient has an electrical cutaneous burn in the setting of contact with a high voltage source. Electrocution would be also the obvious choice if the victim was found attached or nearly so, to a high-tension source of current. This category also includes all cases where the patient has been removed from the source of high tension current but the event was witnessed. (may include electrocution non-lightning NEMSIS 9535 or electrocution NEMSIS 2270)
- *Excessive cold:* Low ambient temperature (below 40F or 0C) where an obviously healthy individual is inappropriately clothed for the ambient temperature. (may include excessive cold NEMSIS 9540)
- *Excessive heat:* Situations in which an obviously healthy person experiences a cardiac arrest and the most significant contributing factor is increased ambient temperature i.e. exercise on a hot day or confined in a locked car or lost hiking in the desert. (may include excessive heat NEMSIS 9545)

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

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

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

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

obstruction;

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

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

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

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

  Examples of cases that fit this definition: witnessed lightning strike on golf course where members of a foursome documented direct hit to one of their group and called 911; or unwitnessed cases where there are visible signs of lightning strike including cutaneous burns described as Lichtenburg figures, flash burns, punctuate burns, contact burns, or linear burns in the skin folds.

  Example of a case that does NOT fit this definition: man found outside in the rain without witnesses to verify direct strike or blast effect or any signs or symptoms of lightning related electrocution.

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

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

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

  Examples of cases that fit this definition: hemodialysis line disconnected with obvious large loss of blood; vomiting of blood with EMS witnessed and documented large loss of blood; blood in stool (lower GI bleed) with EMS witnessed and documented large loss of blood.

  Examples of cases that DO NOT fit this definition: vomiting blood with unknown amount or small amount on face or clothes; possible or suspected ruptured aortic aneurysm (this can never be proved without autopsy or diagnostic imaging); epistaxis; hemoptysis

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

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

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

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

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

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

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

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

    1. 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.
    2. 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.
    3. Example of pediatric cases (less than 13 months of age) that are included: Although there is some controversy and a few documented cases of long QT causing what appears to be SIDS, the evidence supports that most are related to respiratory issues. A case can be made that this is mechanical suffocation, but that cannot 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 year old 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 year old 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 year old 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 14 - 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. Includes cases where medical director ordered cessation of treatment due to family wishes.
    - *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 1 st 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).

CPR PROCESS

The purpose of the CPR Process form is to document the elements of field-provided cardiopulmonary resuscitation and associated ECG data. The CPR process measurements can be utilized for quality assurance purposes with the EMS providers. Previously captured in minute-by-minute epochs, CPR measures are now captured as a series of segments of uninterrupted chest compressions, for up to the first five (for Epistry) or 10 (for CCC and ALPS) minutes of the resuscitative effort. This will later help characterize the nature of 'hands off' time (a few long pauses vs many short pauses; both scenarios could result in similar compression fractions). Additional data fields are provided for sites that use devices that report compression depth and compression release. This form also provides for the capability to attach the electronic ECG recordings, 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. The Device order number of the initial device for which a 'Pads on' time and 'CPR measures is marked 'yes', is auto-filled in row 1 of Item 4 and Item 5.

If 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 one agency arrives and applies pads to monitor a patient with pulses, then a second agency arrives and switches devices to their own and then the patient goes into cardiac arrest (EMS witnessed), data for all AED/defib devices are entered on line 1 and line 2, etc. It is the intent of Item 1 'Device info and ECG data' to chronicle all the devices that were applied to the patient during the course of care, whether applied during a monitoring period, just prior to arrest (as in EMS witnessed), or during the resuscitation effort. Item 1 will capture devices placed by fire/EMS agencies on a patient with pulses throughout the period of monitoring (patient was not in cardiac arrest at any time during the monitoring period of that device). Where a fire/EMS agency elects to

continue using an AED/defib that was applied by a bystander (including police or clinic staff) in lieu of their own AED/defib for a portion of the EMS resuscitative effort, enter that device and attribute its use to the involved agency, regardless of whether an ECG recording is available from that device.

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 and first used it to determine if a shock was required (for example, mark 'AED' where fire arrives with an MRX and uses it in AED mode to analyze to determine shock or no 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. This is intended to include circumstances where a bystander (includes police and clinic staff) AED/defib was applied and the fire/EMS responders elected to continue use of that device during a portion of cardiac arrest care in lieu of using their own AED/defib.

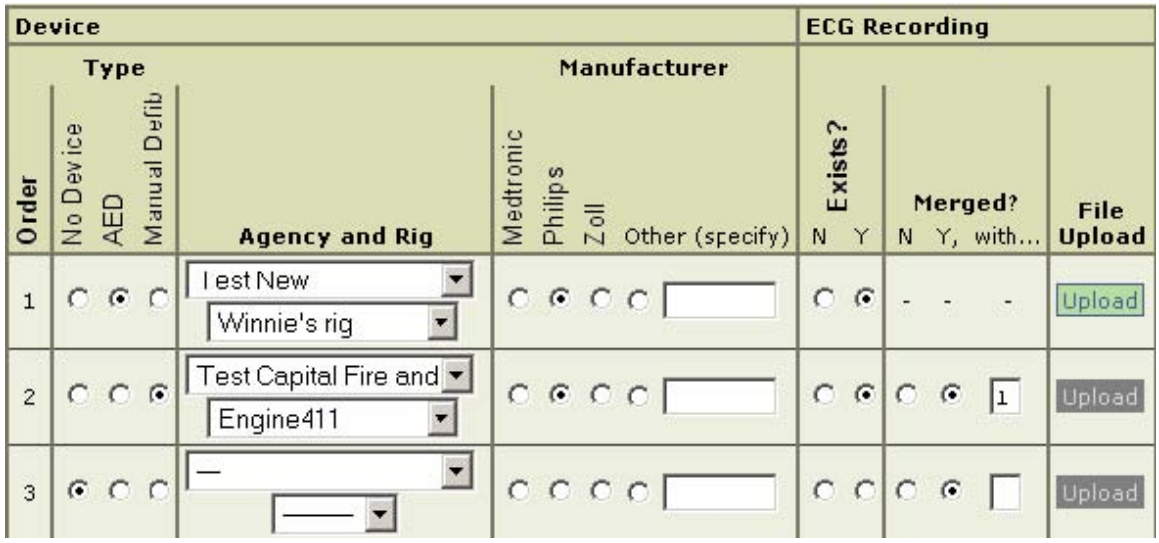
Manufacturer—for each 'AED' or 'Manual defib' applied, indicate the brand of device. If 'other' than Medtronic, Philips, or Zoll, mark that, and specify the manufacturer (30 characters maximum).

ECG recording exists?—for each agency/rig combination, indicate 'yes' if a continuous electronic ECG recording exists *and* is available to the site for review. Mark 'no' if the device 'recording' is a12-lead ECG recording, 'snap shot' ECG or file, or paper rhythm strip. This data element is not intended to include electronic ECG recordings from lay or bystander use of AEDs (such as public access, police, health care clinic) that were not continued to be used by fire/EMS (see 'Agency and rig' above). If no continuous recording exists and is available, enter no further data for subsequent items in that row (merged, file upload, time power or pads on, synched to atomic clock, adjusted time, CPR process measures available).

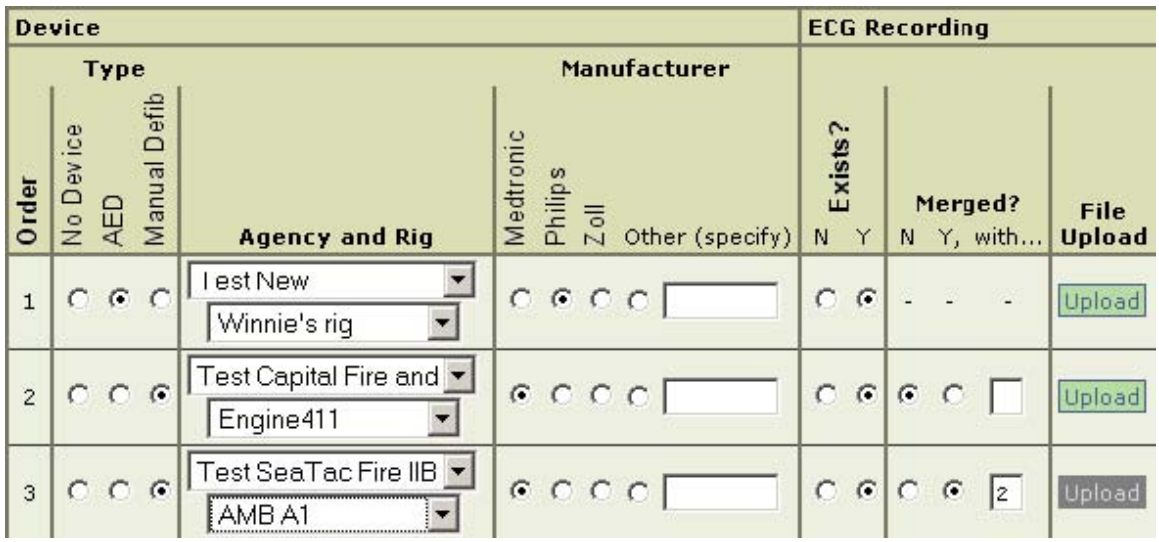
In the rare instance where a bystander (includes police and clinic staff) AED/defib is applied, fire/EMS elects to continue using it during the resuscitation effort, but a continuous ECG with CPR process data is not obtained by the site, the file will be considered 'missing for that case. SMC will monitor the proportion of patients with missing EMS CPR process data.

ECG recording merged (with another ECG)?—where ECG files are available from more than one device, 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 files 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.

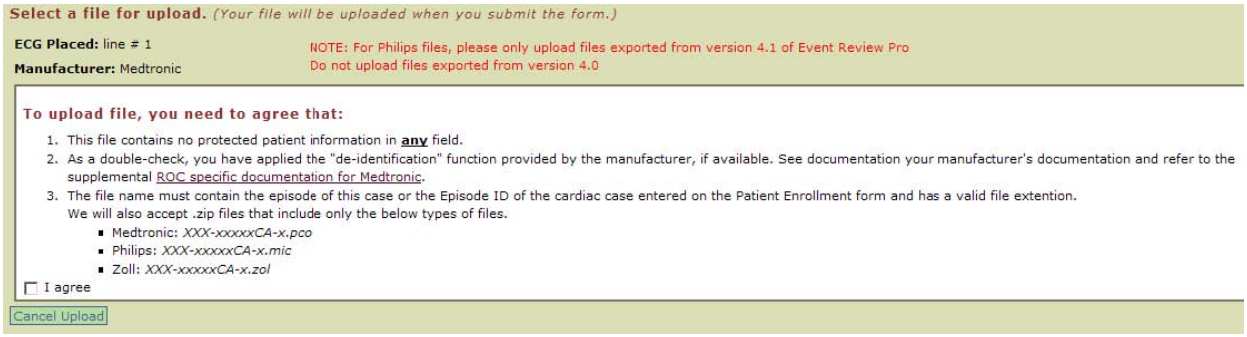


Example 2 screenshot: Where the ECG file for devices, other than Device 1, are merged with one another: This might occur where different brand devices are used during the resuscitation. In the example below, the file for Philips Device Order 3 is merged with the file for Philips Device Order 2. For the 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.



File Upload -- Use the 'upload' button to browse the site local database to identify and attach the continuous ECG file that corresponds to the indicated device. Do not upload snapshot ECG files (as created by Medtronic with the .pco file extension) unless asked to do so by the DCC for specific case audits. 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 in Figure 1.

Figure 1: Screenshot of ROC-web file upload message, providing format for file name, and confirmation of no protected health information.



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-123456CA-0 you would rename the file CTC-123456CA-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. Please contact the CTC with questions for how to ‘zip’ files.

It is expected that for each device used for which a continuous ECG 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 C 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 Philips recordings: Do not upload Philips ECG files exported from Event Review Pro, version 4.0. Only QCPR files and files created by Event Review Pro version 4.1 (and higher) are to be uploaded to the ROC-web. See Attachment D for guidance on how to de-identify Event Review Pro 4.1 files.

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 case id in the file name you need to rename the file to include this.
    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.
        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 enter an adjusted time here (such as what might have been entered on the Time Record, there marked as 'adj'). In the rare circumstance in which the device is turned on prior to the case, do not enter a power on time.

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 (pads) or impedance signal (puck). Provide the earlier time of either pads on the patient or puck on the patient. If pads or puck lose contact and there is more than one time to pad or puck placement time, use the first time the pads (or puck) were placed. Do not use time when ECG-only electrodes (sometimes called 'pads') are placed. Provide the synchronized (preferred) or unsynchronized time for 'Pads/Puck on' provided by the defib. Indicate if this 'Pads/Puck 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/Puck on' time (for the initial device with CPR process measures marked 'yes') is used to auto-fill start time for row 1 of Item 4 (table for CPR process measures) and Item 5 (table for compression rate and depth) after device number entered. If reporting data for devices with an accelerometer or puck, see directions for Item 4 'Start time' ("CPR process measures?")—different scenarios of time 'Pads/Puck on' and accelerometer/puck on are reviewed and specific guidance given. Time entered for Device 1, 'Pads/Puck on' time, is auto-filled as the Start Time in Item 4.

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 ("CPR process measures?") for further guidance entering 'Start time' data for fire/EMS witnessed cases.

CPR process measures available—indicate ‘yes’ if the site was able to extract or determine CPR process measures (compression start/stop times, compression rate, compression depth/release for specific brands) for any portion of 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 at any time during resuscitation where required for capturing measures). The number of the first device for which ‘Pads on’ time is provided and CPR process measures is marked ‘yes’ will auto-fill row 1, Device # and time pads on, in Item 4 and Item 5.

Item 2 - Were any shocks delivered by fire/EMS responders?

Indicate no or yes, if any defibrillation shocks were delivered by fire/EMS responders (includes volunteer fire) during a time of pulselessness. 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. This includes shocks provided by ROC and non-ROC fire/EMS responders. This does not include shocks provided by bystanders.

If shocks were delivered to a pediatric patient (age < 18 years), data is collected to determine defibrillation dosage and whether attenuated cables were used.

Joules—provide the documented dose given for up to the first three shocks. The preferred source for this is ‘documented by device’ as annotated in the ECG file downloaded for review of CPR process measures. If no device ECG download is available, then provide the dose as documented in the ACR/PCR. If neither source provides the dose given, mark ‘not noted’.

For a pediatric patient treated with an AED and to which special infant/child attenuated pads/cables were attached, a) the ECG and impedance signals captured in a continuous ECG will appear the same with or without an attenuated cable attached; b) the AED will annotate the ‘adult’ dose automatically delivered (such as 200, 300, 360 joules), even though the attenuated pads/cable will reduced the dose that reaches the patient. For this data item, provide the device or ACR/PCR documented dose (do not calculate the fraction of the dose delivered via the attenuated cables; instead, indicate if attenuated cables were used that would have reduced the dose).

Attenuated cables— Special infant/child defibrillator pads/cables contain electronics that attenuate, or reduce, the energy of an AED defibrillator’s shock by about 25% (selected energy ÷ 4 ± 15%). Attenuated infant/child cables are intended for use for infants and children < 8 years old, < 55 lbs (22 kg). Manual only defibrillators (such as Lifepak 12 or 15) use the type of pediatric pads that do *not* attenuate the energy; rather, the reduced defibrillation dose is manually set by the provider. Pediatric pads are used on small children—not all pediatric pads attenuate the defibrillation dose. Some combined manual/AED defibrillators are compatible with attenuated cables only in the AED mode. It is incumbent on the site to verify if attenuated cables are used or compatible with manufacture/model devices used at their agencies. Shocks delivered for cardioversion with a pulse are not included.

Item 3 - Initial CA rhythm:

This section is intended to capture the time, rhythm, and source (of rhythm) for two early rhythms (either the first rhythm obtained with a public access or other non EMS defibrillator AND/OR the first EMS rhythm). 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 recorded cardiac arrest rhythm—see below definitions for rhythms, 'No Rhythm' and 'cannot determine'. Check the one source from which the one selected rhythm was determined. Where 'No Rhythm' is marked for a rhythm event, chose the reason why there was no cardiac arrest rhythm available.

1 st 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.

- *No CA (cardiac arrest) Rhythm:* Mark the box 'no PAD/AED applied' when a bystander DID NOT place any defib or AED pads or ECG electrodes and had no knowledge of the rhythm. 'No CA rhythm' 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 recorded 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. If the time of earliest rhythm by a non-EMS device cannot be otherwise determined, use the time of first shock of the non EMS AED/defibrillator as the time for this variable.
- 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) to determine 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 that “PEA”) in the PCR (such as idioventricular, wide complex rhythm, wide complex tachycardia, sinus tachycardia)—in these cases, mark the rhythm as PEA. If PEA is marked, indicate the rate in beats per minute or if 'unknown/not noted'. If less than a 6 second window is available, use your best judgment to determine asystole vs. PEA. Determination of a rhythm is preferable to reporting “cannot determine”.
- *Asystole:* Mark ‘asystole’ where low voltage baseline activity (< 0.2 mV) and no QR S 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)

- *ECG with voice:* Audio recording of on-scene voices that augments review of the continuous ECG clarifying or confirming the provided data. This includes those circumstances where the ECG is not captured (such as when device is in the wrong mode), but voice on-scene articulates the data item sought. Mark this item only when voice recording has assisted in the documentation of the data item. Do not mark this item if voice was captured, but did not assist in documentation/confirmation of the data item.
- *Continuous ECG:* An electronic recording of the initial cardiac arrest ECG and CPR process. Where the initial 'continuous ECG' is one of multiple other 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), or a Medtronic ECG snapshot file 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 cardiac arrest rhythm that can be interpreted 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 there is not 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.

- No CA (cardiac arrest) rhythm: Mark the appropriate box for when there was not a fire/EMS cardiac arrest rhythm:

    a. **'perfusing rhythm only'** - there was a bystander administered AED shock (so qualified for Epistry, and/or ALPS) but by the time the EMS arrived the patient had a perfusing rhythm and the patient never rearrested; OR
    b. **'no defib leads attached'** - fire/EMS DID NOT place any defib or AED pads or ECG electrodes and had no knowledge of the rhythm.

  'No CA rhythm' 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 recorded (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 1 st 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) to determine the rhythm during even a few seconds of interpretable ECG. The objective is to capture the earliest cardiac arrest rhythm, not necessarily the rhythm that is the easiest or clearest to discern. This is recognized to be a tradeoff. Where the reviewer observes a rhythm different than that indicated by the AED analysis (shock or no-shock) or the PCR, defer to the reviewer's finding as long as careful consideration is given to which source contains the information from the first EMS or fire defibrillator placed.

Definitions of Rhythms:

- *VF/VT:* Ventricular fibrillation (VF)–irregular, disorganized ventricular electrical activity of variable amplitude exceeding 0.2mV, or; ventricular tachycardia (VT)—HR > 100 bpm with QRS duration greater than 110 msec (with evidence of AV dissociation where device bandwidth may allow), or; cardiac arrest rhythm for which an AED advised a shock on the first analysis as can be best determined (need not have the ECG strip), or; cardiac arrest rhythm documented in the prehospital PCR.
- *PEA (Pulseless electrical activity):* Electrical activity with QRS complexes of any width at an average rate of >10 beats per minute (e.g. organized ventricular electrical activity with QRS complexes that occur more than once over a 6-second period) that is not associated with a pulse. Occasionally, EMS will note a Pulseless rhythm (other that “PEA”) in the PCR (such as idioventricular, wide complex rhythm, wide complex tachycardia, sinus tachycardia)—in these cases, mark the rhythm as PEA. If PEA is marked, indicate the rate in beats per minute or if 'unknown/not noted'. If less than a 6 second window is available, use your best judgment to determine asystole vs. PEA. Determination of a rhythm is preferable to reporting “cannot determine”.
- *Asystole:* Mark ‘asystole’ where low voltage baseline activity (< 0.2 mV) and no QRS complexes transpire for a 6 second window (this is intended to indicate a rate of ≤ 10 bpm). If less than a 6 second window is available, use your best judgment to determine asystole vs. PEA. Determination of a rhythm is preferable to reporting ‘cannot determine’.
- *AED-no shock (no strip):* Notes from the patient record indicate that analysis was done and no shock was advised or delivered, but no ECG strip available.

Definitions of Rhythm Source:

- *ECG with voice:* Audio recording of on-scene voices that augments review of the continuous ECG clarifying or confirming the provided data. This includes those circumstances where the ECG is not captured (such as when device is in the wrong mode), but voice on-scene articulates the data item sought. Mark this item only when voice recording has assisted in the documentation of the data item. Do not mark this item if voice was captured, but did not assist in documentation/confirmation of the data item.
- *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:

The purpose of this Item 4 is to capture CPR measures as epochs of uninterrupted chest compressions without pause, defined by series of compression start and stop times. A ‘pause’ is defined as the absence of compressions for ≥ 2 seconds. By capturing the start and stop times of series of compressions, the ‘pauses’ between those series will be separately calculated. In prior versions of Epistry, CPR process measures were captured in minute epochs, defined by the clock.

‘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 for review of the electronic ECG with compressions and go to Item 6, skipping questions 4 and 5. If yes, provide a minimum of 5 minutes

for Epistry, or 10 minutes if enrolled in the CCC or ALPS trials, CPR process data for the resuscitative effort. This minimum period of data provided for each study is intended to begin with the earliest Start Time; or for EMS witnessed arrests, beginning at time of arrest.. Sites are encouraged, but not required, to provide data for up to 20 minutes of the resuscitative effort.

The minimum period of data to be provided will span the elapsed time from Start Time, inclusive of periods of ROSC followed by re-arrest and resumption of chest compressions.

Medtronic review software: First, review the ECG file and compression markers and edit as needed to correct the identification of compressions. If using Medtronic Codestat 9 review software to generate Start/Stop compression segments, select the ‘compressions and pause’ format, not ‘pause and compressions’. When generating data for Item 5 minute epochs, go into the Admin tab and change the setting manually from Segment Stop/Start to Minute Epochs. . There are two ‘thresholds’ that affect Codestat 9 Start/Stop compression segment results; access them by going to File →Admin →CPR analytics →Statistcal analysis parameters:

- CPR Pause Threshold has a default setting of ≥ 10 seconds—you must change that default setting to ≥ 2 seconds. This threshold defines the duration of a gap in compressions that defines a ‘pause’. Gaps less than the set value are incorporated into the segment of compressions as if it were uninterrupted by a pause.
- Compression Pause Threshold has a default setting of 3 seconds. Leave that setting at its default. This threshold does not affect the reporting of compression segments or pauses between them. Rather, this threshold is used to calculate compression rate and compression ratio (converted to compression fraction for ROC by dividing by 100).

Device order: Device order for the first row is auto-filled with the number of the first device in Item 1 for which an ECG recording exists and is marked as having a ‘Pads on’ time and CPR process measures. If the second device in Item 1 was the first to have CPR process measures, then ‘2’ will be auto-filled to the first row for Device #. Each Device order is associated with a specific agency/rig combination in Item 1; that association is here retained. When 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.

Multiple devices used—when (during the course of prehospital care) CPR process data comes from a subsequent device, enter the Device order # for that source, as established in Item 1. Do not enter Device order #’s where a fire/EMS device was applied during the resuscitation, but no CPR process measures are available from that device; skip that Device order # and instead enter the # of the next device used for which CPR process measures are available.

EMS witnessed arrest—edit device order to be that of the device on the patient at the time of the arrest. If the patient arrested when EMS present, but a pads were not yet placed at the time of the arrest, enter the # of the device that was soon placed.

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.

Start Time and Stop Time: Each row represents either a) an uninterrupted period of chest compressions, or b) a period of unanalyzable ECG that lasts ≥ 2 seconds. The ‘Start Time’ for Row 1 is usually the ‘Pads on’ time of the first device listed in Item 1 that is marked as ‘yes’ having CPR measures. See below tables for guidance on editing the Start Time and, and for determining the Stop Time for the first row of each device.

Provide Start/Stop times for the subsequent 5 (for Epistry) or 10 (for CCC and ALPS) minutes of the arrest.

The continuous ECG is the source for Start Time and Stop Time of segments of compressions or

unanalyzable periods. Where a clean ECG signal is not available for review—such as might occur after the device is turned on, but prior to pads placed; or as might occur when the device is in a monitoring lead/mode other than what allows viewing of the compression/impedance channels—real-time voice recording may be used for collection of these times by sites where this is available. Start Times and Stop Times must be clearly evidenced, either through articulation of compression counting or verbal cues of hands on/hands off chest. Where clear evidence is not articulated on the voice recording, indicate those segments of time as 'unanalyzable', as would be done where and ECG signal was not clear. The ECG signal will otherwise be used as the primary source for Start Time and Stop Times.

Scenarios for 'Start Time':

Different scenarios affect the 'Start Time'. Start Time for Row 1 has been auto-filled with 'Pads on' time from Item 1. Table 5 details special circumstances for providing Start Time.

Table 5: Scenarios for Start Times

	Scenarios	Start time for 1st row each device
1	Time 'Pads on' is followed at any time by a clean signal to see presence or absence of compressions	Time of 'Pads on'
2	Where voice recording is used and there is clear audio evidence of the presence or absence of chest compressions prior to time 'Pads on'	Two situations: • Clearly per voice, there is evidence of compressions being given < 2 seconds of the onset of voice recording—if time voice recording begins is prior to time 'Pads on', edit Start Time to that for when voice recording begins (generally the same as time the device is turned on). • Clearly per voice, there is no evidence of compressions being given for ≥ 2 seconds (a pause) of the onset of voice recording—if time voice recording begins is prior to time 'Pads on', edit Start Time to that for when voice recording begins (generally the same as time the device is turned on).
4	'Pads on' time is not known for the first device for which 'yes' is marked (in Item 1) for CPR measures (generated for a portion of the resuscitation)	Time when the clean CPR measures signal first appears (as when the device is first switched to 'paddles' mode), whether or not there are compressions being delivered.
3	Where voice recording is used, but it does *not* provide clear evidence of the presence or absence compressions	Voice recording is available, but is insufficient to provide evidence of compressions given < 2 seconds, or no compressions being given for ≥ 2 seconds (a pause) of onset of voice recording (the recording is unanalyzable for the defined period)—either: • Edit Start Time to the time of onset of the insufficient voice recording. Stop Time will be 1 second prior to when voice recording or the continuous ECG signal first provides clear evidence of either compressions or no

		compressions. Mark this first segment for the device as 'unanalyzable.' • Defer to 'Pads on' time as Start Time for this device and report compression segments as outlined for those scenarios.
5	Fire/EMS witnessed arrest	Two situations: • 1. If VF (ventricular fibrillation) or asystole and monitored with pads or electrodes at time of EMS witnessed arrest, Start Time is at onset of arrhythmia. • 2. If VT (ventricular tachycardia) or PEA (pulseless electrical activity), 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 • a) If first associated with CPR, Start Time is at the first compression. • b) If VT is first associated with a shock, Start Time is when rhythm check or analysis is started.
6	Accelerometer or puck	Time when the first compression is observed on any channel (compression, force, or acceleration). If using Philips QCPR review software, the impedance channel is available to view compressions in the absence of placement of the puck. In Monitor mode, the compression channel is not available, though force and acceleration channels display compressions. If using Philips Event Review Pro software, it is understood that it the software does not allow viewing of the impedance channel when the puck is absent.
7	Rhythm converted to perfusing rhythm and 'ROSC' or 'Shock, ROSC' entered as 'primary reason for stopping'—then patient re-arrests and compressions resume	For the next row, enter Start Time of the first compression following loss of ROSC.

Scenarios for 'Stop Time':

Different scenarios affect the Stop Time. Start Time for Row 1 has been auto-filled with 'Pads on' time from Item 1, or edited as appropriate in Item 4. See Table 5 for scenarios for 'Start Time'. See below Table 6 for scenarios for Stop Times.

Table 6: Scenarios for Stop Times

	Scenarios	Stop time for 1st row each device
1	Start Time is followed by a clean ECG signal or voice recording and	Time of last compression in the segment that precedes the first gap in compressions (pause) that lasts for ≥ 2 seconds

	compressions are evident for at least the < first 2 seconds	
2	Start Time is followed by a clean ECG signal or voice recording, and no compressions are evident for ≥ 2 seconds	Stop Time for the first row for the device is the same time as for 'Pads on' or start of voice recording. This indicates the initial state of pause at the onset of recording that is at least ≥ 2 seconds. For the next row, the Start Time is the time of the first compression that follows the 'pause' observed at the onset of the recording, and will be ≥ 2 seconds after the Stop Time of the first row for that device. This approach helps differentiate the absence of compression data due to a 'pause' in compressions, from the absence of compression data to a poor signal ('unanalyzable' as in Scenario 3 below).
3	Start Time is followed by an ECG signal or voice recording that is not clean (unanalyzable) for ≥ first 2 seconds	Two situations: • Signal then becomes clean and compressions are evident < 2 seconds of clean signal—enter 'Stop Time' as 1 second prior to first visible compression and mark the first row for that device as 'Unanalyzable'. This indicates the end of the initial segment for that device that could not be analyzed for the presence or absence of compressions. In the next row, the Start Time is the time of the first compression observed (1 second after end of the preceding 'unanalyzable segment')... • Signal becomes clean, no compressions are evident for ≥ 2 seconds of clean signal—enter 'Stop Time' as time signal becomes clean and mark the first row for that device as 'Unanalyzable'. This indicates the end of the initial segment that could not be analyzed for the presence or absence of compressions. In the next row, Start Time is the time of the first compression observed (which will be follow at some point after the minimum defined pause of ≥ 2 seconds after the Stop Time of the prior row) .
4	Compressions are ongoing without 'pause' of ≥ 2 seconds and the voice or ECG/compression signal is lost during that cycle of compressions	Stop Time for that compression segment is entered as time when the signal was first lost. Select 'compression signal lost' as the 'Reason for stopping' to indicate that compressions were ongoing at the time of lost signal (versus a stop in compressions for a pause)—this is incorporated in the later calculations for compression fraction. The Start Time of the next row is when the signal returns and it is possible to discern the presence or absence of compressions. See Scenario 3.2 above for how to enter Stop Time for that subsequent row.

Compression segments—each row defines a sequential Start Time and Stop Time of either a segment of uninterrupted chest compressions (with gaps in compressions of that are ≥ 2 seconds) or a segment of unanalyzable signal (lasting ≥ 2 seconds). Enter sequential segments for up to 5 (for Epistry) or 10 (for CCC and ALPS) consecutive minutes of the cardiac arrest (from Start Time of

row 1). See Figure 2 for examples of compression segments:

Figure 2: Effect on Start and Stop Times for compressions segments with gaps in compressions that are < 2 seconds or ≥ 2 seconds.

Two segments of compressions (‘C’) separated by a pause in compressions of ≥ 2 seconds; Each segment of Start/Stop Time entered on a row:

C C C C C C C C C C	No C for ≥ 2 seconds	C C C C C C C C C C
Start Stop	Pause	Start Stop

One segment of compressions (‘C’) with a lapse in compressions of < 2 seconds;

The one segment of Start/Stop entered on a row:

C C C C C C C C C C	No C for < 2 seconds	C C C C C C C C C C
Start Stop		

Unanalyzable segments—an ‘unanalyzable’ segment is one where the ECG signal (or voice where available) is not ‘clean’ for ≥ 2 seconds and the presence or absence of compressions cannot be assessed (such as during 60 cycle interference, disconnect of pads/electrodes, cable movement, monitor in wrong mode, between change of devices). The ‘Start Time’ for an unanalyzable segment is the first second of the onset of the interrupted signal that lasts for ≥ 2 seconds. See below table for determining Stop Time for unanalyzable segments. Mark the segment of interrupted signal as ‘unanalyzable’ and leave blank all remaining fields in that row.

Where an ECG signal (or voice recording) is corrupted for < 2 seconds, it is not considered an ‘unanalyzable’ segment. Instead, the lapse is integrated into the compression segment or pause period within which it occurs. If the ECG signal is interrupted for ≥ 2 seconds, the ‘Start Time’ and ‘Stop Time’ for that segment is entered in a row, and marked ‘unanalyzable’. See Figure 3 for examples:

Figure 3: Illustration of interruptions in signals that are < 2 seconds or ≥ 2 seconds on Start and Stop Times for either Compression or ‘unanalyzable’ segments.

Two segments of compressions (‘C’) followed by a segment of interrupted signal of ≥ 2 seconds. Start/Stop times for two compression segments and one ‘unanalyzable’ segment each entered on a row.

Compression segment		Compression segment	‘Unanalyzable’ segment
C C C C C C C C C C	pause ≥ 2 seconds	C C C C C C C	signal interrupted for ≥ 2 seconds
Start Stop		Start Stop	Start Stop*

One segment of compressions (‘C’) followed by a second segment of compressions that includes a

period of interrupted signal < 2 seconds in length.

Two segments of sequential Start/Stop times are each entered on a row.

Compression segment		Compression segment		
C C C C C C C C C C	Pause ≥ 2 seconds	C C C C C C	signal interrupted for < 2 seconds	C C C C
Start Stop		Start Stop		

Table 7: Two scenarios for determining 'Stop time' for an 'unanalyzable' segment (≥ 2seconds). The 'Stop Time for an 'unanalyzable' segment indicates the end of the period during which the presence or absence of compressions could not be determined.

1	Unanalyzable signal for ≥ 2 seconds; signal later becomes clean, compressions evident < 2 seconds of clean signal	Enter 'Stop Time' as 1 second prior to next compression. Mark this row as 'Unanalyzable'. In the next row, enter the time of that compression as the 'Start Time' of the ensuing compression segment.
2	Unanalyzable signal for ≥ 2 seconds; signal becomes clean, no compressions evident for ≥ 2 seconds of clean signal	Enter 'Stop Time' as that when the signal becomes clean. Mark this row as 'Unanalyzable'. In next row, 'Start Time' is the time of the next compression.

When an unanalyzable segment is followed by a shock, follow directions in Table 7 for start/stop times. If the shock occurs after compressions resume, enter the shock time on the same line as compressions (as per instructions below in 'Row by row' section). If the shock occurs after a period of no compressions, enter the shock time on the same line as the unanalyzable segment.

Change of devices

If the change of devices creates an interruption in the compression signal for ≥ 2 second, and it is not possible to know if compressions were given with or without pause, enter the Stop Time as the second the signal was lost and select 'Compression signal lost' as the 'Primary reason for stopping'. The ≥ 2 second period of unanalyzable signal that ensues when changing from one device to the second device is entered on the next row as a segment of 'unanalyzable' signal, and is attributed to the first device in the series. No pause is allowed between the Stop Time for 'compression signal lost' and the Start Time of the next row marked 'unanalyzable'. On the row following the 'unanalyzable' segment, enter the new device number. The Start Time for the new device (see Table 5, row 1 Scenarios for Start Times) is 1 second after the Stop Time of the prior row that was marked as 'unanalyzable'. Determine the Stop Time for the first row of the new device as guided in Table 6 (Scenarios for Stop Times). This approach to accounting for the 'unanalyzable' period that occurs at change of devices helps assure that period is not misconstrued as a period of pause in compressions (that would otherwise impact the compression fraction).

Figure 2*: When a change of devices creates a loss of compression signal for ≥ 2 second* —in this example, the ECG signal for device # 1 (in Row 1) is interrupted for a switch to a second device. There is known to be an interruption in signal at the change of devices that lasts ≥ 2 seconds. So, a segment of 'unanalyzable' signal is entered for Row 2, and attributed to device #1. Device #2 is entered for Row 3, with a Start Time indicating when the signal becomes clean, allowing the assessment of the presence or absence of chest compressions.

Device #	Start time (hh:mm:ss)	Stop time (hh:mm:ss)	Unan	Primary Reason For Stopping
1	1 - 05 : 24 : 00	05 : 26 : 00	☐	Compression signal lost
1	2 - 05 : 26 : 01	05 : 30 : 00	☑	---
2	3 - 05 : 30 : 01	05 : 31 : 00	☐	Shock delivered
2	4 - 05 : 31 : 10	05 : 33 : 10	☐	ROSC

If the change of devices creates an interruption in signal of < 2 seconds, the interruption is not considered a 'Compression signal lost' nor is it considered a gap in the pause or compression segment that is otherwise in progress. The < 2 second interruption in signal at time of change of device is integrated into either that pause or the compression segment that is in progress during that period. No 'unanalyzable' row (segment) is entered to reflect the < 2 second interruption that occurred at change of device. The new Device number is entered on the next row and the Start Time entered to reflect the onset of the next compression segment. The change in Device # is the only indication of device change required in this circumstance.

If the Start Time for Device 2 is earlier than the Stop Time for Device 1 (as might occur if one or both of the continuous ECG recordings is not synchronized to the atomic clock), and no other information allows adjustment of the times, enter Pads' on Time as directed in Table 5 (Scenarios for Start Time), and carry on. In this circumstance, one or both devices should *not* be marked in Item 1 as having been synchronized to the atomic clock.

Row by row—for each row with Start/Stop times of compression segments, mark the reason for that compression segment to have been interrupted, and by what sources that reason was determined. Time of shock is to be provided when 'Shock delivered' or 'Shock delivered, ROSC' is the reason for the Stop time of a compression segment.

Primary reason for stopping: It is the intent of this variable to capture obvious reasons for why chest compressions may have been interrupted for ≥ 2 seconds. Reasons that are 'suspected' are also captured. Reasons are 'obvious' if the ECG recording displays device operation modes such as 'analyzing' or 'charging'; is associated with event markers that providers use to indicate certain procedures done (such as airway placement), or if voice recording is available and medics state what is being done on scene. 'Suspected ' reasons are those situations where times separately charted may 'line up' with pauses observed on the ECG—mark the reason that appears to be relevant for Primary reason for stopping, and mark 'suspected not documented' for 'Reason determined by'. The purpose of collecting this information is to recognize what causes interruptions in compressions and to help identify where resources might be placed to minimize the number or duration of pauses in compressions. The pick-list of primary reasons:

Ventilations—may be articulated on voice recording. Philips devices record a ventilation waveform in minute segments; if available, determine if ventilations are recorded during the period following compression stop time. Capnography channels or ETCO2 tracings may indicate ventilations during pauses. Medtronic ALS devices (Lifepak 12) has a composite bio-impedance channel for which ventilations can sometimes be identified (broad parabola, duration, 2.5 seconds) when a pause in chest compressions. Zoll devices are not helpful with ventilations.

Shock delivered—joules are delivered, as annotated on the ECG; includes analyzing and charging for shock where compressions are not done during that period). Select this response option, where a) shock is delivered and compressions are promptly resumed for a period prior to assessment for ROSC, or b) compressions would be expected to resume (as when no ROSC) post-shock, though there is a prolonged pause while other patient care or assessment is being performed prior to resumption of compressions.

Shock delivered, ROSC— joules are delivered, as annotated on the ECG, ROSC ensues and, a) compressions are not resumed at all, or b) compressions resume only if the patient later re-arrests. If the patient later re-arrests, enter the Start Time of resumed compressions on the next row.

ROSC—This is intended to capture ROSC recognized at a time other than during the pause for delivery of a shock (that occurrence of ROSC is instead represented by 'Shock delivered, ROSC'). 'ROSC' as a Primary reason for stopping' is selected when a pause in compressions is made and ROSC is observed and no further chest compressions are given (unless later re-arrest). ROSC may be articulated on voice recording or indicated with an event marker. Rhythm is perfusing as indicated by no ensuing compressions and/or PCR documentation of ROSC and/or blood pressure. If the patient later re-arrests after 'ROSC,' enter the Start Time of resumed compressions on the next row.

Resus stopped—compressions stopped due to death. This is not intended to capture when compressions stopped due to return of pulses—that is, instead to be captured by reason of 'ROSC'.

Reached ED—wheels stopped at fire/EMS destination, signaling 'end' of field care; indicates 'Stop of field provider care and hand-off to ED staff. Mark Stop time of compression segment as that of wheels stopped, recognizing that care continues on the ramp and into the ED setting.

Other—intended to capture reasons for pausing compressions not otherwise provided in the drop-down list. This might include, but not be limited to, pausing for IV or IO placement or checking breath sounds (as might be indicated in a real-time voice recording), placement of mechanical compression device, change of monitor/defibrillator, placement of advanced airway, or rhythm check.

Unknown—no obvious or suspected evidence for the primary reason for stopping compressions. If marked, do not mark a response to 'Reason determined by?'.

Compression signal lost—reserved for situations where a Start Time for compressions is provided, but the ECG/compression signal is lost during the segment of uninterrupted compressions. The Stop Time for that segment is entered as time when the signal was lost; select 'Compression signal lost' as the 'Reason for stopping' to indicate that compressions were ongoing at the time of lost signal (versus a stop in compressions for a pause)—this is incorporated in the later calculations for compression fraction. The row following one marked with 'Compression signal lost' must be, followed by a contiguous segment of 'unanalyzable' signal; the Start time of that segment is 1 second after the Stop time of the prior row. See 'unanalyzable segments' for how to enter Start and Stop Times for the next row.

Selection of 'ROSC' or 'Shock delivered, ROSC' prevents trigger of web-error checks that verify long pause periods between compression segments. As well, calculation of compression fraction is modified to account for the period of time during which chest compressions would not be expected.

Selection of 'Shock delivered' keys the web-error checks to anticipate a subsequent compression segment within an expected time frame. The pause following 'Shock delivered' is incorporated in the calculation of compression fraction.

*Reason determined by:*Indicate the key source used for determining the primary reason for stopping compressions. If more than one source, Voice recording trumps continuous ECG; ECG trumps PCR. If a primary reason for stopping is marked, and deductive reasoning or judgment is based on local knowledge, mark 'suspected but no documented'.

ECG with voice: Audio recording of on-scene voices that augments review of the continuous ECG clarifying or confirming the provided data. This includes those circumstances where the ECG is not captured (such as when device is in the wrong mode), but voice on-scene articulates the data item sought. Mark this item only when voice recording has assisted in the documentation of the data item. Do not mark this item if voice was captured, but did not assist in documentation/confirmation of

the data item.

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."

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.

If Shock, time of shock : time of joules delivered; is not time of analysis or of charging. Time of shock is entered on the row in which the compression Stop time precedes the time of shock; time of Shock will precede the Start time of the compression segment in the next row. If more than one shock given during the same pause (such as for 'stacked shocks'), provide the time of the first shock.

Item 5 - Rate and depth compression:

This Item 5 is to be completed only if Item 4 was marked as 'yes' CPR process measures were available for this episode; if Item 4 is marked 'no', skip this Item 5 and go to Item 6.

Provide a minimum of 5 minutes' data for patients enrolled only into Epistry, or 10 minutes' data if enrolled in the CCC or ALPS trial. Using device specific ECG review software, report data for minute epochs, starting with same Device number and 'Start time' as auto-filled or edited for special circumstances) for Item 4. The time for each minute will be auto-filled after a device number is inserted into the row. ★ **Do not provide data after ROSC has been attained. If the patient re-arrests, do not enter the rate and depth data in this question**.

For each row with CPR process generated data for the whole or partial minute, enter compression rate, depth (Zoll and Philips devices only), and release (Philips device only). Where the device used does not provide compression depth or release, leave the fields blank for that row; do not enter '0' or '00'. The ROC-web will recognize the Device number and associated brand, releasing associated error checks for blank fields due to device specific limitations.

Device order: Enter the same number here for Row 1 as was auto-filled or edited for Item 4.

Multiple devices used—when (during the course of prehospital care) CPR process data comes from a second device source, enter the number of the next device (as defined in Item 1) for that row—all below rows will be auto-filled with that number (and so on for subsequent devices).

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.

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. For CCC enrolled patients, enter 10 minutes data unless CPR is stopped early.

Minute time: The minute time will be auto-filled based on pads on time entered in question 1. If the time is not correct, enter the appropriate time. Enter serial one minute epochs (whether for all or part of that minute).

Lapse in minutes—where the change of devices causes a lapse in time (minutes not contiguous), enter the next device number and the Pads on 'start time' of that device will be auto-filled from question 1. Times for subsequent minutes will be auto-filled from that edited 'Start time' after device number is entered into each row.

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

- Accelerometer/puck on first, pads on soon after—use same ‘Pads on’ time as used for Row 1 in item 4. Use same ‘Start time’ for Row 1 in Item 4 for the ‘Minute time’ in Row 1 of Item 5. Begin reporting minute epochs of CPR process measures from time ‘Puck on’.
- 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. For Item 5, the site must elect to either:
  - Not hand count compressions— enter time ‘Pads on’ for Item 1; that auto-fills row 1 of Item 4 and 5. Leave compression rate/depth/release blank and override associated error messages. 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.
  - Hand count compressions-- using the available impedance channel (generated when pads are on), hand count the compressions 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.
- Only accelerometer/puck on—in the rare instance where no pads are placed during the resuscitation, the site must elect to either:
- 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 5. If more than one device applied and CPR process measures provided by second device, enter the # for Device order, enter the start time for when CPR measures ensue; see device specific guidance for reporting of measures.
- 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 5 (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 rate’, and. This approach is strongly recommended during the course of the interventional trials.
- 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.

Unanalyzable: Mark this box for any minute that Compression rate (and Compression depth and Compression release, depending on device capability) are not generated by the CPR Process review software, or are not otherwise available. See device-specific guidance below for alternate means of providing Compression rate. When ‘unanalyzable’ is marked, no other data is entered to the right of that box for that given minute.

Compression rate: The device-calculated median rate at which chest compressions were performed during a given minute, either partial or whole. 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—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). NOTE: in some earlier versions of Zoll review software it was necessary to calculate the ROC defined ‘compression rate’ by taking Zoll reported ‘# compressions’ and dividing it by the reported CPR fraction; it was necessary to distinguish between ‘Compression rate’ for ROC data entry and a differently defined ‘compression rate’ reported by ZOLL RescueNet Code Review. This was resolved in more recent versions of software and appropriate values are reported for ROC definitions. This resolution is evident in at least clinical version 10.04.

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. The ROC-web detects if a device # entered is associated with Medtronic, and requires that no compression depth data be entered for that device #; leave the field blank, do not enter 0 or 00.

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. The ROC-web detects if a device # entered is associated with Medtronic, and requires that no compression release data be entered for that device #. Leave the field blank, do not enter 0 or 00.

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” (“Comp leaning” or “Comp release” depending on software version locally used) 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. The ROC-web detects if a device # entered is associated with Zoll, and requires that no compression release data be entered for that device #. Leave the field blank, do not enter 0 or 00.

Item 6 - (CCC only) CCC Compliance

Separate from asking what randomized therapy was *assigned* by the CTC (as asked on Patient Screening and Enrollment form), this Item 6 is intended to capture what the participating crew thought they were supposed to do; and, the site’s assessment of whether the CTC-assigned compression therapy was followed.

Item 6a - What did fire/EMS document as their intended randomization arm?

What did fire/EMS document as their intended randomization arm? Review the fire/EMS documentation and indicate which of the two CPR treatment arms the participating agency *intended* to deliver—either cycles of 30 compressions with pause for 2 ventilations OR cycles of continuous compressions with superimposed ventilations. This data element is what the crew 'said' they were supposed to do, or thought they did, as documented on the PCR/ACR or voice recording. This is not meant to capture what the crew actually did as confirmed on the continuous ECG—that is handled below in Item 6.b.

A similar, but different, question is asked on the Patient Screening and Enrollment form, item 4 regarding therapy assignment; that question asks what therapy was *assigned* by the CTC and the agency directed to provide, whether or not is was understood or delivered by the participating ROC agency.

Item 6b - Does continuous ECG show compliance with CTC-assigned therapy?

There are a number of data items related to monitoring of compliance with the CCC protocol. This specific data element relates only to the type of chest compressions that were generally administered during the study portion of the resuscitative effort, whether continuous or 30:2. Sites are being asked to assess general compression arm compliance so as to readily identify agencies that require a call-to-action for the site to provide reinforcement training and reminders of the assigned study therapy. Mark:

'Yes'—mark this if ECG is available; it provides a recording channel that displays chest compressions; AND it is evident that the therapy assigned by the CTC was provided. For either 30:2 or Continuous compressions, the first cycle of CPR is to be either 30 seconds or 120 seconds (as pre-specified for ROC by the local medical director) followed by a rhythm analysis and shock (if indicated).

Evidence of 30:2 (following the first cycle CPR, rhythm and shock) are second and third CPR cycles, each cycle comprised of two minutes or 150 compressions (bag-mask valve 2 ventilations for each 30 compressions). Each two minute cycle would be followed by a pause for rhythm check and shock (if indicated). A fourth cycle of CPR is conducted until either an advanced airway is successfully placed, or two minutes or 150 compressions (at 30:2) are completed, whichever is first, ending the study protocol and continuing standard ACLS care. ROSC at anytime in the sequence also signals the end of the study protocol.

Evidence of continuous compressions arm (CCC) (following the first cycle CPR, rhythm and shock) are second and third CPR cycles, each cycle comprised of two minute or 200 continuous chest compressions without a pause in compressions of ≥ 2 seconds. Each two minute cycle would be followed by a pause for rhythm check and shock (if required). A fourth cycle of CPR is conducted until either an advanced airway is successfully placed, or two minutes or 150 compressions (at 30:2) are completed, whichever is first, ending the study protocol and continuing standard ACLS care. ROSC at anytime in the sequence also signals the end of the study protocol.

It is recognized that the early ECG data may not be accessible (such as if pads not placed at start of CPR, or device not in the correct mode to see the compression channel)—with what ECG data is available, use your best judgment to assess if crews were compressing the chest continuously or with pauses for ventilation and report if the compression cycles were as randomized.

No, it did not show compliance—mark this if ECG is available, it provides a recording channel that

displays chest compressions; AND it is evident that the therapy assigned by the CTC was not provided (absence of evidence described in 'yes' above). It is recognized that the early ECG data may not be accessible (such as if pads not placed at start of CPR, or device not in the correct mode to see the compression channel). With what ECG data is available, use your best judgment to assess if crews were compressing the chest continuously or with pauses for ventilation, and report if the compression cycles were not as randomized.

No continuous ECG with compression channel during assigned therapy—mark this if no ECG download was provided; or if provided, it did not have a chest compression wave form during some portion of study period (approximate 6 initial minutes the resuscitative effort, from time CPR started or time Pads on to the end of CPR Cycle #3 or insertion of the advanced airway, whichever occurred last) that allowed site assessment of compliance with chest compressions. If no continuous ECG was available for the period of assigned therapy, review the fire/EMS patient care or research documentation for written or verbal indication (such as on a research message line; or defib voice recording) of whether the crew followed the CTC-assigned therapy.

' If not compliant, why not?—if 'no' is marked in Item 6.b. for items with '*', review the fire/EMS documentation for insight as to why the CTC-assigned therapy may not have been followed—select the response option that best logs the reason; freely mark 'Other/specify' to capture issues of importance (such as Union opposition, early advanced airway placement for airway protection, on-scene confusion, etc). This data element is intended to assist sites in reflecting on what actions might be taken to assist agencies in improving compliance with the assigned therapy.

Item 7 - ALPS drug information (ALPS Only):

Detailed information about ALPS drug dosage, route, and time administered are collected, along with shocks and rhythms before and after each of the first and second doses of study drug.

Indicate 'yes', 'no', or 'unknown' if any amount of any study drug syringe was given to the patient. Each ALPS study kit contains three syringes, labeled 1A, 1B, and 2. Numbering of syringes is for field and site convenience. All contain identical drug or placebo. Which of the three syringes given is not critical; rather, it is important to document how many syringes were given (whether partial or complete) for each dose.

If unknown if ALPS drug administered to patient—Complete the triggered alert form and explain the circumstances. Reserve marking 'unknown' for only when all measures have been exhausted to determine if ALPS drug was given.

If no (ALPS study drug was not administered)—indicate why—it is expected this will be an unusual circumstance. If any portion of any ALPS syringe was administered to the patient, do not here mark 'no'—instead, mark 'yes' ALPS dose 1 was given. Numbering of syringes is for convenience only; ALPS dose 1 may be any combination of two (or one if patient is < 100 lbs/45 kg) syringes from the study kit.

- *Rhythm not VF/Pulseless VT*—ALPS kit may have been opened in the presence of the patient that was not in cardiac arrest, or prematurely before the shock and/or qualifying rhythm were determined. See Item 7, question 3b for definition of VF/Pulseless VT.
- *Malfunction of syringe (explain)*— inability/difficulty pushing drug, cracking/breaking of glass syringes during use or effort to administer drug. Not intended to include packaging issues or evidence of cracked/broken glass syringes when kit is opened.
- *Syringes damaged (prior to or when kit opened)*—Intended to include evidence of cracked/broken glass syringes (barrel, tip, or plunger) when kit is opened and prior to efforts to assemble/connect system elements or to administer the drug.
- *Other, specify*—includes, but not limited to, no ALPS kit on rig, circumstances of fit/compatibility, lapse

in sterile technique,

- *Vascular access lost*—creating lost opportunity to administer any portion of any ALPS study syringe.
- *Unknown*—reserve marking 'unknown' for only when all measures have been exhausted to determine if ALPS drug was given.

If yes, ALPS study drug dose 1 given (either partial or complete) –If a syringe made contact with either the IV tubing or adaptor on the IV tubing the dose is considered as given. If given, also indicate whether ALPS study dose 2 was also given.

If unknown if second does ALPS drug administered to patient— Complete the triggered Alert form and explain the circumstances. Reserve marking 'unknown' for only when all measures have been exhausted to determine if ALPS drug was given.

If no (a second dose of ALPS study drug was not administered)—indicate why; it is expected this will be an unusual circumstance. Dose 2 is intended to be one ALPS syringe, given in sequence after dose 1 (two syringes, except for patients < 100 lbs/45 kg who are to receive one syringe) and another shock. Do not mark 'no' if any portion of a third ALPS syringe was administered to the patient (instead, mark 'yes' ALPS dose 2 was given). Numbering of syringes is for convenience only; ALPS dose 2 may be any numbered syringe from the study kit.

See Item 7, part a, for definitions for why no ALPS dose administered

If ALPS study drug dose 2 also given (either partial or complete) – indicate by responding yes.

Item 7a - Table of ALPS study dose information:

Study drug dose 1 information:

Number of syringes given for study drug dose 1 (whether partial or complete) - Dose 1 of ALPS is expected to be the contents of two study-kit syringes (whether labeled 1A, 1B, or 2). The exception is if the patient is considered by fire/EMS to be < 100 lbs (45 kg); then one syringe would be the expected first dose. Report the number of ALPS syringes actually given in the field for dose 1, as written in the ACR/PCR, or otherwise reported via drug or site-research or documentation. Count any given portion of a syringe as 'one' (for example if one complete syringe and ½ of another syringe was given for dose 1, mark '2 syringes' given; if only ½ of one syringe is given, mark '1 syringe'). Do not count syringes of open-label amiodarone or lidocaine that may have been separately given. Reserve marking 'unknown' for only when all measures have been exhausted to determine the number of syringes given for Dose 1.

Time study drug dose 1 given? Provide the documented time when dose 1 was given. If documentation is provided for each syringe for dose 1, enter the time documented for the first syringe.

Source for time study drug dose 1 given?—provide the source for the documented time (in order of preference, if more than one source available)—continuous ECG with voice (where the time documented is articulated on the voice channel and is used to determine or confirm); continuous ECG (where event markers have been used to annotate drug delivery); Snapshot ECG (where event markers have been used to annotate drug delivery; a short paper recording sometimes as brief as 6 seconds or an ECG snapshot file that captures a portion of the arrest period), or the ACR/PCR.

Route of study drug dose 1? Select the route of administration for both syringes for dose 1. The

protocol and FDA allow administration of ALPS drug via IV or IO routes. Administration via ETT (endotracheal or advanced airway) is not approved by the FDA—if delivered via this route, complete the Alert form that will be automatically triggered. Reserve marking 'unknown' for only when all measures have been exhausted to determine the route of administration.

Were syringe related issues reported with dose 1?—indicate if EMS providers reported difficulties administering ALPS drug because of difficulties pushing or pulling the plunger to deliver the contents of the syringe. This includes documentation of syringe or tip being 'plugged' or 'blocked'. Includes cracking/breaking of glass syringes during use or effort to administer drug. This does not include challenges connecting the adapter or leur connections to administer the study drug. The source for this information or clarification may be from the written record or from voice messages left on call lines—the site is encouraged to directly contact the provider when this is reported to understand the circumstances and to confirm if the required CLEARLINK adapter was used for connecting the study syringe to the IV tubing.

Shock before study drug dose 1: It is expected that at least one shock (either with a bystander AED, or by responding ROC or non-ROC providers) is delivered to the patient and VF/Pulseless VT persists prior to administration of ALPS study-drug dose 1. Indicate no, yes, or not noted, if at least one shock was given prior to administration of ALPS dose 1. Complete Alert forms that are triggered for responses other than 'yes'. It should be the very rare circumstance where no shock was given prior to ALPS drug or documentation of shock not made—in these circumstances, it is imperative to contact the agency/provider and provide feedback and re-training emphasis.

If yes, one or more shocks were given before ALPS study drug dose 1, provide the # of the shock that was closest to the time of administration of dose 1. Count of shocks includes those given by bystanders (PAD AED), non-ROC and ROC providers (for example, if 2 PAD shocks, 1 non-ROC, and 1 ROC provider shocks given prior to dose 1, enter shock # 4 as the shock # given before study drug dose 1. If PAD shocks were given, but the number is not known, count PAD as 1 shock and add to additional shocks delivered by field providers to calculate the shock #. Reserve 'Shock number not documented' for when all efforts to determine this have been exhausted. Provide the time of the entered shock #. This time must be earlier than the time for when study drug dose 1 given.

Indicate no, yes, or not noted, if a shock was given after administration of ALPS dose 1 (but prior to administration of ALPS dose 2). Reserve 'not noted' for when all efforts to determine this have been exhausted.

Shock after study drug dose 1: If yes, one or more shocks were given after ALPS study drug dose 1 (but before giving ALPS dose 2), provide the # of that shock. It would be expected that this shock # is sequential to the # of the shock given prior to ALPS dose 1 (unless multiple or stacked shocks were delivered). Count of cumulative shocks includes those given by bystanders (PAD AED), non-ROC and ROC providers (for example, if 2 PAD shocks, 1 non-ROC, 1 ROC provider shock prior to dose 1, and 1 shock after dose 1, enter shock # 5 as the shock # given after study drug dose 1. If PAD shocks were given, but the number is not known, count PAD as 1 shock and add to additional shocks delivered by field providers to calculate the shock #. Reserve 'not documented' for when all efforts to determine this have been exhausted. Provide the time of the entered shock #. This time must be after when study drug dose 1 given.

Indicate no, yes, or not noted, if a shock was given after administration of ALPS dose (but prior to administration of ALPS dose 2). Reserve 'not noted' for when all efforts to determine this have been exhausted.

Time of shock – Enter time that corresponding shock was given. Reserve 'Time not documented' for the rare cases in which ECG information is not available and time is not noted on PCR.

Study drug dose 2 information:

The series of questions for ALPS dose 2 mirror those for ALPS dose 1.

ALPS dose 2 is expected to be the contents of one study syringe (whether labeled 1A, 1B, or 2). Report the number of ALPS syringes actually given in the field for dose 2, as written in the ACR/PCR or otherwise reported via drug or site-research or documentation. Count any given portion of a syringe as 'one' (for example if ½ of one syringe was given for dose 2, mark '1 syringe' given). There may be instances where more than one syringe was given for dose 2—mark 'both syringes' if two were inadvertently given for dose 2. Do not count syringes of open-label amiodarone or lidocaine that may have been separately given. Reserve marking 'unknown' for only when all measures have been exhausted to determine the number of syringes given for the dose 2.

Time study drug dose 2 given?—Definition as for dose 1.

Source for time study drug dose 2 given?—Definition as for dose 1.

Route of study drug dose 2?—Definition as for dose 1.

Was syringe related issue reported with dose 2?—Definition as for dose 1.

Shock *before* study drug dose 2?—it is expected that at least one shock was delivered and VF/pulseless VT persists prior to administration of ALPS dose 2. Indicate no, yes, or not documented, if a shock was given prior to ALPS dose 2; this shock must have occurred between times for administration of dose 1 and dose 2. It is possible that a shock reported as given after dose 1 is the same shock reported as given before dose 2.

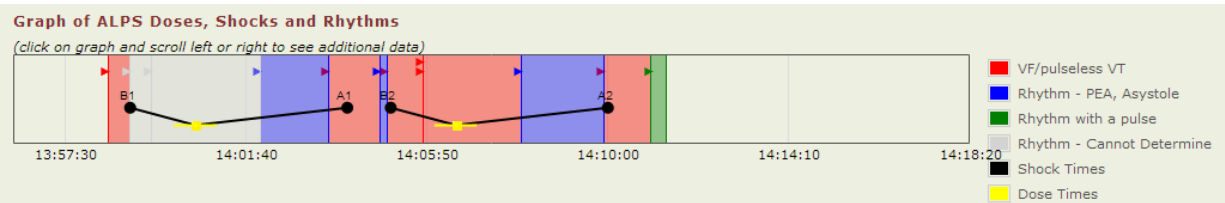
If yes, one or more shocks were given before ALPS dose 2, provide the # of the shock that was closest to (but not after) the time of administration of dose 2. Count of shocks includes those given by bystanders (PAD AED), non-ROC and ROC providers. If PAD shocks were given, but the number is not known, count PAD as 1 shock and add to additional shocks delivered by field providers to calculate the shock #. Reserve 'not documented' for when all efforts to determine this have been exhausted. The time for this shock # must be after time of dose 1 and earlier than time of dose 2.

Shock *after* study drug Dose 2?

If yes, one or more shocks were given after ALPS dose 2, provide the # of the shock that first follows dose 2. It would be expected that this shock # is sequential to the # of the shock given before ALPS dose 2 (unless multiple or stacked shocks were delivered). Count of cumulative shocks includes those given by bystanders (PAD AED), non-ROC and ROC providers. If PAD shocks were given, but the number is not known, count PAD as 1 shock and add to additional shocks delivered by field providers to calculate the shock #. Reserve 'not documented' for when all efforts to determine this have been exhausted.

Time of shock – Definition as for dose 1

Graph of ALPS Doses, Shocks and Rhythms



Legend-all data are obtained from tables a and b (hover over the events for more information)

B1/B2 –before dose 1/2

A1/A2 –after dose 1/2

>Arrows represent reported rhythm(s)

Item 7b - Rhythm Table:

Based on data provided in the preceding table (a), preferred rhythm times will be displayed. Provide rhythms closest to a shock or dose assuring that the rhythm occurs between events. For rhythms before a shock, enter a rhythm between the preceding event and the shock. For rhythms after a shock, try to enter a rhythm >30 seconds after the shock but before the next event. For rhythms before a dose, enter a rhythm between the preceding event and the dose. For rhythms after the dose, try to enter a rhythm closest to >90 seconds after the dose. We will accept rhythms outside of these preferred times when they occur between significant events (shock or dose). If no rhythm is available prior to another event mark 'cannot determine'.

Provide times as close to the event as possible when available. For all rhythms, it is preferred that the rhythms be obtained from a continuous ECG with either voice or event markers to annotate when drug was given. If a time is not provided, a rhythm is not required. However, if you do not like seeing a blank spot on the table and feel compelled to provide a rhythm, we will accept a rhythm assuring that it occurred between events. For example, we would like rhythm after ALPS dose >90 seconds and before next shock. If the shock after the dose occurs at 60 seconds, we will not provide a set of preferred times. While a rhythm after ALPS dose is not required in this situation, we will accept a rhythm. Be cautious that the rhythm entered occurs between events. In this case, it must occur after the dose and before the next shock.

For the 'before shock' rhythm, work backwards chronologically from the time of the reference shock # to the first documented rhythm prior to the shock, but after any earlier shock. Do not provide a rhythm with a time that is time-stamped (either electronically or otherwise) as occurring **after** the reference shock #. We will accept a rhythm as long as it occurs before the preceding event (dose or shock).

For the 'after shock' rhythm, work forwards chronologically from the time of the reference shock # to the first documented rhythm after the shock, but before any subsequent shock. We prefer that you first start looking for a rhythm ≥ 30 seconds after the shock was administered but before the next event (dose or shock) is given.

For the 'before dose' rhythm, determine the rhythm at or prior to ALPS administration. It is preferred that this rhythm be obtained from a continuous ECG with either voice or event markers to annotate when drug was given. If not available 'at' ALPS administration, work backwards chronologically to the first documented rhythm prior to ALPS dose (but after the preceding event (shock or dose). Do not provide a rhythm with a time that is time-stamped (either electronically or otherwise) as occurring after ALPS dose.

For the 'after dose' rhythm, it is preferred that you begin looking 90 seconds after the dose was given working forward chronologically, and before the next event. The next event could be either a shock or dose.

Enter the time when each rhythm was obtained. The times displayed are preferred times. If a rhythm is available with a time outside of the range, enter the time and rhythm assuring that the rhythm occurs between events (dose, shock). For example, we ask for a rhythm 30 seconds prior to a shock. If a rhythm is not available during that time frame and one is seen at 45 seconds before the shock enter that rhythm as long as it occurs after the preceding event (shock or dose).

If a time is not available and the rhythm is reported indicate by checking 'Rhythm time not documented'. This can be seen when the ECG is not available, however PCR documentation reports rhythms.

VF/Pulseless VT (includes AED shock)— ventricular fibrillation (VF)—an 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; this cardiac arrest rhythm documented in the prehospital PCR. Consider VT Pulseless if there is temporal evidence in the ACR/PCR, compression recording, or voice recording that CPR was performed or a shock delivered for this appearing rhythm.

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 documented by voice or in the ACR/PCR as being associated with perfusion (pulse, HR, a SBP either palpated or auscultated, or spontaneous respiration/movement). Assume such a rhythm is without pulse unless otherwise documented. Occasionally, EMS will note a rhythm (other than 'PEA' or 'VF/VT') in the ACR/PCR that is without pulse—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". Count or calculate (if rhythm strip < 60 seconds) the rate per minute; mark 'not available' if no ECG download and no temporal documentation of rate is stated in the ACR/PCR.

Rhythm with a pulse—this response option is intended to capture all rhythms that are temporally associated with a pulse (as documented in the ACR/PCR as pulse, HR, a SBP either palpated or auscultated, or spontaneous respiration/movement). This may include rhythms appearing to be NSR or wide complex tachycardia, junctional. Select this response option where a pulse is documented by voice recording or in the ACR/PCR. Count or calculate (if rhythm strip < 60 seconds) the rate per minute; mark 'not available' if no ECG download and no temporal documentation of rate in the ACR/PCR.

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)— AED is known to have been used, but did not deliver a shock after analysis, and no tracing is available.

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 rhythm. Includes rhythms for which the ECG documentation or indication of AED shock status is not available or missing from the PCR.

Provide the source for each of the rhythms (in order of preference, if more than one source available)—continuous ECG with voice (where voice was used to determine or confirm the data); continuous ECG; Snapshot ECG, or the ACR/PCR.)

Final rhythm when resuscitation stopped or at ED arrival (whichever is last): This data element seeks to establish the patient rhythm when prehospital care is completed, be that when resuscitation is stopped due to death or when the rig arrives at the ED (wheels stopped).

Time of final rhythm—24 hour clock.

Final rhythm and source--See Item 7, question b (above) for definitions of rhythm and sources

Situation—select one of two conditions that describes when final rhythm is captured. 'Resus stopped due to death' includes: death/pronouncements that occur in the field or in transit to the ED; the cessation of resuscitation efforts in absence of ROSC; patients who are without pulse or ongoing resuscitation efforts and whose body is transported to ED for pronouncement. 'At ED arrival' includes: patients for whom resuscitation efforts are ongoing at time of ED arrival; patients with ROSC at ED arrival. The preferred source for 'at ED arrival' is the prehospital ECG and ACR/PCR. If these are insufficient to determine final rhythm, the first documentation of rhythm in the ED may be used.

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 - ROSC at 1 st ED arrival? (ALPS only):

Mark ‘yes’ if ROSC (pulses) present at ED arrival (when EMS wheels stopped; per prehospital records and Pre-Hospital form, item 14 ‘Disposition’ is marked as Transported/ROSC present at ED arrival) or the patient developed pulses between the wheels stopped and first cared for in ED (such as ROSC obtained on the ramp), provide the first documented systolic blood pressure and pulse rate. It is intended that the pulse rate and SBP be temporally related. If only one of the values is first recorded (and the other is not also provided for the ‘vital signs’ set), provide that value and marked ‘not noted’ for the other pair component.

Mark ‘no’ if the Pre-Hospital form, item 14 ‘Disposition’ is marked Transported/ongoing resuscitation at time of transport ED arrival (wheels stopped), and when the ED staff first assessed the patient, he/she was without a pulse.

Item 4 - Did patient arrive at 1 st ED with a fire/EMS advanced airway in place? (CCC only):

This data element is to describe potential adverse events recognized in the ED associated pre-hospital placement of an endotracheal or supraglottal advanced airway by fire/EMS. This data element does not apply to advanced airways that were placed by other than fire/EMS (such as by healthcare bystanders in a clinic or surgery center; or a tracheostomy), but used by them (‘continuation of’) during the course of resuscitation. It does not include Cricothyrotomy.

Mark ‘no’ if an advanced airway (endotracheal or supraglottal) was not placed by fire/EMS providers. Mark ‘no’ if fire/EMS continued use of an airway that existed prior to their arrival or placed by other than them. This includes fire/EMS use of a tracheostomy tube. This includes use of airway access via Cricothyrotomy at ED arrival. Mark ‘yes’ if an advanced airway (either endotracheal or supraglottal) was placed by pre-hospital EMS providers, whether indicated as successful or unsuccessful. Or, mark ‘yes’ if ED notes indicate the patient arrived with a fire/EMS advanced airway in place, whether or not placed properly or needed repositioning.

If yes, patient arrived with a fire/EMS advanced airway in place, review notes of the first receiving emergency department (including those of respiratory therapy, physician, nurses, procedures) to discern if the EMS-placed airway was replaced or repositioned. Mark ‘not noted’ if ED documentation is silent on this. It is possible that a fire/EMS-placed advanced airway might be marked as both repositioned, then replaced depending on the clinical circumstances. If ‘yes’ the fire/EMS-placed advanced airway was repositioned in the first ED, review the available documentation and indicate the reason. The data abstractor should be looking for any indication that the tube is not in the trachea (placement in the trachea is the ‘correct’ location). Any mention in the report of ‘right main stem’ intubation (this means the tube is in the right bronchus branch instead of the trachea; ‘dislodgement’ of the advanced airway; and/or ‘esophageal’ intubation/airway location is an indication of an improper placement. Other reasons that may be documented for the repositioning might relate to high CO2 or low O2 sat or PaO2 prompts to reposition. **If there are any questions please contact the CTC to discuss.**

Item 5 - 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 6 - 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.

d. *Gender (check one)* — this data element is asked to help assure that ED/Hospital data being entered is for the same patient for which prehospital data was entered. It is important for sites with distributed data-entry to make all efforts to assure that data entered is for the same patient. Do not override age and gender crossform checks without verifying this.

Item 7 - 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 the date/time—when died, was discharged alive, admitted to the same or transferred to another hospital—from the second (or last) 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.

If Time of 'Discharge from final ED' is not documented in the ED patient record, use alternate references so as to provide an indication of how long the patient was there (prior to death or transfer to the hospital/ICU/CCU):

For death, provide latest time documented in ED for such things as vital signs, progress or nurses notes, admission administrative records, or disposition of body records. This provides some indication of whether the patient died after 10 minutes in the ED or 10 hours in the ED. Document in the RCC case file, the use of the alternate source for time of final ED status.

For transfer to hospital/ICU/CCU, enter time of final ED status as the time of admission to those locations, or the earliest documented vital signs, progress or nurses notes, admission administrative records, or other documented times. Document in the RCC case file, the use of the alternate source for time of final ED status.

Item 8 - Source for discharge status from final ED:

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 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 for cases not enrolled into CCC or ALPS is not approved.

HOSPITALIZATION

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 (1 st 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 form 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 five 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 five 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 11, 'Discharge status from final hospital'

Item 3 - No longer required for current Cardiac study

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).
- *Homeless/shelter:* Homeless denotes not having a regular dwelling and do not have 'fixed, regular, and adequate night-time residence' [US federal definition of homeless]. Homeless also includes those situations where the primary night-time residence is a shelter. Shelters are temporary 'homes' provided for those who have fallen on hard times and include those designated for homeless, or as warming or emergency/disaster shelters. *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 - First weight documented in hospital (ALPS only):

Indicate the first weight documented in the hospital, either in pounds or kilograms, or enter 'Not noted'. Patients admitted to the hospital due to a cardiac arrest are extremely ill and medication, especially diuretics, are titrated dependent on the patient's weight. It is unusual for a patient not to be weighed early in their hospital stay.

Item 6 - CCU/ICU days, initial continuous:

Indicate either the date **OR** 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. Do not enter both days and date. 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 - Ventilator days, initial continuous:

Indicate either the date **OR** number (integer) of calendar days in a row the patient was first on a ventilator. Do not enter both days and date. This includes time spent on ventilator in the ED. If the patient returns to the intensive care setting (and placed back on a ventilator) after previously having been removed from a ventilator, 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 (after ED arrival at 7 am), then is extubated at 7pm on Monday, that is ventilator day 1. If a patient arrives in the in the ED at 11am on Monday on a ventilator, then is extubated on Tuesday at 3am, that is 2 ventilator days. Also, a patient arrives to the ED with an advanced airway and receiving bag ventilations and he is extubated prior to placement on a ventilator, report that as 0 ventilator days.

Item 8 - Did patient awaken in ED or hospital? (obeys

verbal commands) (ALPS & CCC)

After reviewing the ED and hospital records, check the bubble 'yes', 'no' or 'Not Known' for whether the patient woke up in the ED or hospital. A patient can be awake without opening the eyes or speaking. A patient who is intubated, extremely lethargic or medicated may be unable to speak or open his eyes but may be able to move his fingers or squeeze his hand(s) when asked to do so. If documentation indicates the patient is able to follow commands, enter the date of the first awakening. If the records state the patient has been following commands but you are unable to determine when the patient first woke up, check 'Date not known'. ICU documentation often indicates GCS scores on a regular basis (such as every other day); this may be an indicator for where in the chart to review nurse/physician/neurologist consult progress notes to read for evidence of ability, or lack of ability, to follow commands.

Item 9 - 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. If no order for DNR is written, but comfort care (CC) measures are ordered, consider the date of that order to be a surrogate 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.

Epistry: Where more than one of the above is ordered, enter the date of the earliest order.

ALPS & CCC: Mark if DNR and/or care is limited/withdrawn. If marked, provide the associated date and time for each situation (or if only date available, mark 'time not noted.').

Item 10 - 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. In the event of live organ donation, report the time at which brain death is confirmed (usually by EEG with MD signature). If brain death was determined and live organ donation did not occur, report the time of cardiac death.

Interim Vital Status: (ALPS & CCC)

Vital status is the outcome measure for CCC and ALPS, thus it is important to document this data item in a timely manner. The DSMB also monitors the interventions studies for safety and timely data submission. Some cardiac arrest patients may spend months in the hospital due to the severity of their illness. For a patient who continues to be hospitalized consecutively for 30 days after admission, enter the date the coordinator last verified the patient was alive and receiving acute care treatment. The verification should be done at least every 30 days until the patient is deceased or is discharged from the hospital. The CTC will perform a vital status sweep prior to the bi-annual DSMB meetings and provide sites with a list of patients needing an interim status. An interim vital status can be updated as often as verification is

received about the patient's status.

Item 11 - Discharge status from final hospital:

Indicate patient status when the course of acute care associated with this cardiac arrest was completed. Disposition at discharge is reported for the latest (last) acute care hospital that the patient was admitted or transferred to during the course of care.

- Dead at discharge -> skip to Item 12
- Alive -> Complete disposition:
    - *Home* —A relative term, meaning the patient was discharged to their own home or a home like situation (e.g., with a relative). Indicate whether they were independent or needed assistance in their home, such as from a friend, relative, chore services. If it is not clear whether the patient was independent or needed assistance upon discharge to home, check "Unknown/Not noted".
    - *Rehabilitation* —defined as being discharged from an acute care hospital to either an adjoining rehab facility or admitted to a separate rehab facility, with the purpose of providing temporary care which would allow the patient to regain strength and function with the intent of returning home or to an assisted living facility. A hospital may have a separate unit within the building which is their rehabilitation center to which a patient moves after the acute care treatment is completed. Typically, the patient is considered discharged from the acute care and readmitted to the rehab unit for purposes of billing. It is important to clarify this situation when the patient is moved to a rehab unit but not moved outside the hospital walls.
    - *Assisted living* —includes a location where the patient assumes partial responsibility for their daily care on a long-term basis. This 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 can receive high-end nursing care on a short-term basis.
    - *Remain in acute care hospital, reclassified as non-acute patient awaiting placement or chronic care* —There are occasional situations in which a patient has been cleared for discharge by his or her physician but there are no beds available in a nursing home facility for the patient. If a patient is ready to be discharged but remains in the hospital only while awaiting a bed in a non-acute institution, check this bubble.

Item 12 - Source for discharge status from final hospital:

The intended and preferred source for *Discharge status from final Hospital* is the hospital patient care record. When a hospital 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 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 for that study is not approved.

Item 13 - 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.

Situations where the Discharge Summary may not be available, and what to do:

a. Hospital policy—some institutions require a discharge summary only if the ED/hospital stay is a minimum number of days. In this rare circumstance, if the stay was too short to require a Discharge Summary, review the entire chart and mark which conditions were documented.
b. Billing codes more robust—some institutions rigorously use billing codes to capture many conditions. For places where it is believed that billing code sheets might have additional or more extensive information, continue to use *only* the Discharge Summary to mark listed conditions. It is recognized that some local information may be lost, but across ROC, the tradeoff is to standardize the source so as to not bias information based on local practices.
c. Status changed from acute care to long-term care, but remains in same facility—in Canada, it is recognized that some patients remain in the same hospital, but are reclassified as 'non-acute' patients awaiting placement or chronic care. For these patients, use the documentation provided in the 'transfer note' written when the patient's care is reclassified; do not wait for the final Discharge Summary that might come much later when the patient is discharged from the non-acute care.

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)
- Acute liver failure—intended to capture acute onset of failure, not worsening of chronic pre-existing condition (such as cirrhosis). Includes jaundice, hepatitis, transaminitis, hyperbilirubinemia, hepatic failure.

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. This section is intended to capture anything else in this patient that seems unusual for this patient's underlyjng condition of post-resuscitation of a cardiac arrest. Use Item 14 to report complications of IO usage; do not here report related conditions.

Item 14 - Potential IO complications listed in Discharge Summary: (ALPS only)

Check all potential IO complications listed below that are identified on the discharge summary.

- *Not applicable, no IO marked successful by EMS providers*- Mark this if there is no indication the EMS providers marked IO insertion was successful and administered ALPS. If 'not applicable' marked, go to next question, item 15.
- *Compartment syndrome*- Compartment syndrome is a serious condition that occurs when nerves, blood vessels and muscle are compressed within a muscle compartment.
- *Abscess*-An abscess is a localized collection of pus commonly surrounded by swelling and inflammation, due to an infection. An abscess could occur at the IO infusion site.
- *Osteomyelitis*-Osteomyelitis is an infection of the bone.
- *Skin necrosis*-Necrosis is death of the tissue and it may occur at the site of an infection.
- *Loss of limb*
- *None of the above*

Check any of the above items noted in the final discharge summary. Terminology used to describe some of the potential IO complications may be unclear so consult your site PI or investigator if you are uncertain about an item listed on the discharge summary.

Item 15 - 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.

PROCEDURES/OBSERVATIONS

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 - Major 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 'Not Recorded') that they were not performed.

Where at least one procedure was done, all listed procedures must be marked as '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 'Not Recorded' 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 'Not Recorded' 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 'Not Recorded' 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.

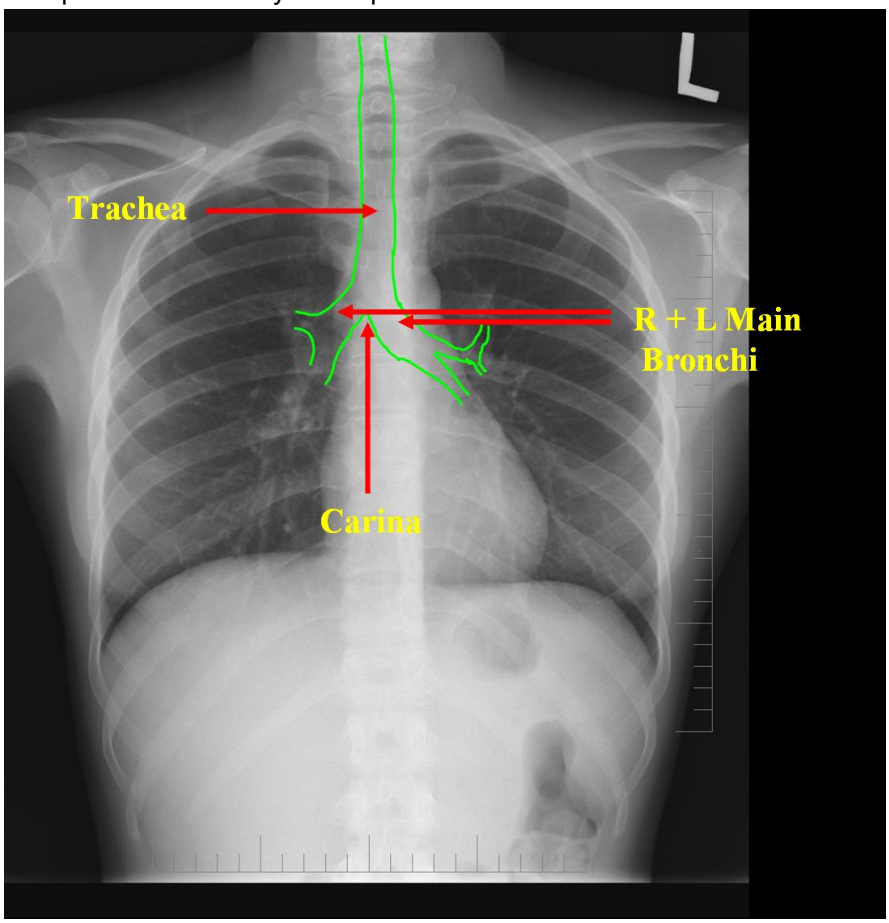
A. *1 st cardiac catheterization*— If patient had a cardiac cath, mark 'hospital' for where done. The cath lab is here considered part of the 'hospital' course of care, even if the patient is sent from the ED directly to the cath lab prior to admission to the hospital. If a cardiac cath is done within 24 hours of first ED arrival, indicate if the cath was either a diagnostic angiogram without any interventions or done for a percutaneous coronary intervention (PCI)

   If 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 the time of first balloon inflation is not in the report, mark 'time not noted'. 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. Also, indicate 'yes' or 'no' if the cath included rational atherectomy (Rotablator, RotaLink).

B. *1 st 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 the listed 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.
   - CCC only: The CCC protocol states that airway patency will be monitored in a number of

ways. The official report for the 1 st CXR done within 24 hours of ED arrival (as a matter of routine care, not ordered specifically for this review) will be read to assess if any of three specific mentions are made regarding the placement of the advanced airway at the time of the 1 st CXR—The data abstractor should be looking for any indication that the tube is not in the trachea (placement in the trachea is the 'correct' location). Any mention in the report of 'right main stem' intubation (this means the tube is in the right bronchus branch instead of the trachea); 'dislodgement' of the advanced airway; and/or 'esophageal' intubation/airway location is an indication of an improper placement. Other notations that might indicate an improper placement are 'ETT in too far', or include directions to pull back the ETT tube some number of cm, etc. **If there are any questions please contact the CTC to discuss**. Mark 'yes' or 'not noted' for each of the statements.

The picture below may be helpful



C. *1 st 12-lead ECG*—If a 12-lead electrocardiogram (ECG) was done within 24 hours arrival of first ED, determine the earliest date and time the first 12-lead ECG was done, and indicate if done in ED or hospital. This does not include rhythm strips. The following are intended to capture if there were indications that the patient was a candidate for prompt intervention and specific care pathways:

- Acute myocardial injury per physician notes?—for the first 12-lead ECG done, review the physician progress notes (whether ED or hospital, where ever the first ECG was done) and mark 'yes' if it is noted in their narrative that the first ECG showed evidence or possibility of 'myocardial injury'. 'Myocardial injury' includes STEMI, acute STEMI, ST elevation myocardial infarction, acute injury, acute MI, acute ST elevation. This does not include evidence of 'prior infarction'. This does not include myocardial ischemia or ST depression. The note need not detail the degree of ST elevation in which leads, nor the presence or absence of left bundle branch block (LBBB). Mark 'no' if the narrative states that a 12-ECG was reviewed and there is no evidence or possibility of the prior listed descriptors. Mark 'unknown/not noted' if the physician narrative is silent on the

impressions of the 12-lead ECG. This data element is captured to associate the doctor's recognition of the acute situation and subsequent procedures.

- Acute myocardial injury per final interpreted ECG?—for the first 12-lead ECG done with 24 hours arrival at first ED (the same ECG referenced above in question 1), locate the machine interpretation of results. If a machine interpretation is not provided for the ECG, use the interpretation/report generated by the cardiologist or physician. If neither can be located, mark 'Report not available.'

Reading the machine or physician generated report, select the one response option that best describes the results: Mark 'pacemaker' (includes intermittent or continuous pacing) if stated in report; this trumps all response options, as pacing affects the ability to interpret otherwise acute changes to the ECG and is outside the scope of this data element. Mark 'LBBB' (left bundle branch block) if stated in report (regardless if it is considered acute or old in nature); this trumps all response options except 'pacemaker'. Mark 'yes' if the formal interpretation of results states evidence or possibility of 'acute injury' (includes 'acute MI', acute myocardial infarction, 'acute ST elevation', 'STEMI', or ST elevation MI); this does not include evidence of an old/previous myocardial injury. Mark 'no' if the formal interpretation of results states that there is no evidence for these conditions, or they are 'ruled out'. Mark 'unknown/not noted' if report is silent on the subject. If the 12-lead print out or the physician's final report cannot be located, mark 'report not available.' If either the date or time of the very first 12-lead ECG is not available, mark 'time or date not noted' (enter what you do have).

D. *Fibrinolytics, 1 st 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), and Activase (alteplase). 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 acute myocardial injury or STEMI and/or when the patient goes to the cardiac catheterization laboratory. If either the date or time is not available, mark 'time or date not noted' (enter what you do have). Does not include antiplatelet or antithrombin agents such as heparins, clopidogrel, 2B3A inhibitors, or aspirin. Call the CTC if uncertain if a given agent is considered a fibrinolytic.

E. *Initial temp*—provide the date and time of the first documented temperature taken in either the ED or hospital, whichever was first. Provide the first documented temperature and indicate the units of measure. From the pull down menu, select the route or method of that first temp (axillary, esophageal, Foley, oral, pulmonary artery, rectal, temporal, tracheal, tympanic); select unknown/not noted if not otherwise documented. If 'other' method was used, specify. If either the date or time is not available, mark 'time or date not noted' (enter what you do have).

Within 72 hour hours of first ED arrival: This series of data elements are to be marked 'done' if performed within the 72 hours beginning at time of first ED arrival, whether done in the first ED, subsequent ED's, or the hospital. Review the 'Cut-off' date and time and assess if each of the listed items was done prior to 72 hour deadline. 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 'Not recorded' 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 'Not recorded' 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 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.

F. *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 that captures a full range of

cardiac parameters (such as cardiac output, heart valves, heart chambers, ejection fraction, etc.). Sonosites used for decisions to terminate resuscitation are not included.

G. *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. Mark 'yes' for evidence of pulmonary artery if patient's chart includes reports of cardiac output, cardiac index, pulmonary artery 'wedge' pressure, systemic or pulmonary vascular resistance. Mark 'yes' for evidence of arterial monitoring if patient's chart includes reports of mean arterial pressure (MAP). Does not include central venous pressure (CVP) monitoring or other forms of hemodynamic monitoring.

H. *Hemodynamic support, pressors*—indicate if pressor medication support was given during the initial 72 hours after arrival at ED. Includes bolus and drip administration. Includes whether pressors were given during th initial arrest, re-arrest, or post-resuscitation management. Examples of pressors are vasopressin, dopamine, dobutamine, epinephrine, norepinephrine (Levophed), phenylephrine (Neo-Synephrine). Does not include magnesium or calcium. This list is provided as examples and not an exhaustive list. If you find a potential other pressor at your site, contact CTC for guidance. Please note that epinephrine is separately identified on the prehospital form, but is grouped on the procedures/observations form as a pressor. Also, epinephrine given during cardiac arrest is considered a bolus of a pressor for the procedures/observations form. If given, indicate if such drugs given in the ED, the hospital, or both the ED and hospital.

I. *Hemodynamic support, devices*—indicate if devices were implemented to provide hemodynamic support within 72 hours of first ED arrival. Physician orders and ED/cath lab/critical care/intensive care progress notes, and procedure notes are to be reviewed to determine if the listed device methods were employed. These devices would not be initiated in the telemetry or step-down setting.

   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. It is intended that this table reflect procedures as 'Not recorded' 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 'Not recorded' 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 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.

J. ***EEG***—electroencephalogram; mark as done if either a standard diagnostic EEG done (a discreet 'test', 'spot' or 'snapshot') or continuous monitoring EEG was conducted. This data may be located within the physician's progress notes or sometimes within the 'Diagnostic Section' of (especially electronic) charts. Includes EEG bispectral index (BIS), EEG reduced leads (such as aEEG or 4leads), and EEG standard. Not to be confused with ECG (electrocardiography) or EMG (electromyography).

   ALPS & CCC: Further specify if EEG procedures that were 'done' were continuous or discreet tests. Continuous EEG may also be referred to as cEEG, DEEG (digitized EEG), or qEEG (quantitative EEG) and are used primarily to detect nonconvulsive seizures or cerebral ischemia/brain death; generally done for at least 24 hours continuous in the intensive care setting. Provide the date and time that either continuous discreet monitoring was initiated (may be noted on the official procedure report). If either the date or time is not available, mark 'time or date not noted' (enter what you do have).

K. *CCC only:* Anticonvulsant therapy. **Include anticonvulsant medication regardless of reason for administration. Other reasons may include sedation for ventilator support and preparation for cardiac catheterization**. These medications include only Dilantin (phenytoin) , Cerebyx (fosphenytoin), Phenobarbitol, Versed (midazolam), Ativan (lorazepam), benzodiazepines (see table 1 for list), Valium (diazepam), or Keppra (levetiracetam). This list does not include Precedex (dexmedetomidine hydrochloride), Etomidate, or Diprivan (propofol). Review drug documentation and indicate if these medications were given; does not include standing orders for 'as needed' medications that may have not been administered. This item includes any route or dose, regardless if given for acute or chronic (such as history of epilepsy prior to arrest) seizure disorders or sedation.

Table 1: List of Benzodiazepines	
Alprazolam	(Xanax, Xanor, Tafil)
Bromazepam	(Lexotan, Lexomil)
Chlordiazepoxide	(Librium)
Clobazam	(Frisium)
Clonazepam	(Klonopin, Rivotril)
Clorazepate	(Tranxene)
Diazepam	(Valium)
Estazolam	(ProSom, Nuctalon)
Flunitrazepam	(Rohypnol)
Flurazepam	(Dalmane)
Halazepam	(Paxipam)
Ketazolam	(Anxon)
Loprazolam	(Dormonoct)
Lorazepam	(Ativan, Temesta, Tavor)
Lormetazepam	(Noctamid)
Medazepam	(Nobrium)
Nitrazepam	(Mogadon)
Nordazepam	(Nordaz, Calmday)
Oxazepam	(Serax, Serenid, Serepax, Seresta)
Prazepam	(Centrax, Lysanxia)
Quazepam	(Doral)
Temazepam	(Restoril, Normison, Euhypnos)
Triazolam	(Halcion)

L. *ALPS & CCC:*Head CT scan: Noninvasive test using special X-ray equipment to detect anatomical changes to the brain. Includes 'CAT scan,' 'brain CT,' 'cerebral scan,' or computed tomography of the head. If done, provide the date of the first test (if multiple) done, or mark 'date not noted.' Likely done in radiology area.

M. *ALPS & CCC:* SSEP (Somatosensory Evoked Potential): Noninvasive test for assessing prognosis of comatose patients. Includes 'evoked potential' or 'evoked response'. Detects the response of the nervous system to a stimulus. If done, provide the date of the first test (if multiple) done, or mark 'date not noted.' Likely done at patient bedside.

N. *Hypothermia continued or started in the ED*—either internal or external methods that were done in the ED, whether a continuation of therapy started in the field, and/or or a different therapy started in the ED. For example, if cold fluid was initiated in the field and continued in the ED as the only form of hypothermia, 'Hypothermia continued or started in ED' would be marked as done. If a hypothermia method (such as cold fluid) was initiated in the field, continued in the ED, and then a different method applied (such as adjustable cooling pads), this item would also be marked as 'done'.

Were different methods started in ED?—mark ‘no’ if the only form of hypothermia therapy delivered in the ED was a continuation of the therapy started in the field. Mark ‘yes’ if a different form of hypothermia therapy, other than what was initiated in the field and continued in the ED, was initiated in the ED —mark if the different method(s) started in the ED were external (see applicable list) or internal (see applicable list). ‘Other/specify’ methods for Internal hypothermia includes intentional lowering of temperature via ventilator or hemodialysis settings. More than one method may have been initiated during the ED course of care; check all methods started in the ED. Provide the date and time that the first external and/or internal hypothermia therapy method was initiated in the ED. If either the date or time is not available, mark ‘time or date not noted’ (enter what you do have).

O. *Hypothermia continued or started in the hospital*—either internal or external methods that were done in the hospital, whether a continuation of therapy started in the ED and/or a different therapy started in the hospital (includes things done in the catheterization lab or operating room after leaving the ED). For example, if cold fluid hypothermia was initiated in the hospital, ’Hypothermia continued or started in Hospital’ would be marked as done. If a hypothermia method (such as cold fluid) was initiated in the ED, continued in the hospital, then adjustable cooling pads are instead applied, this item would also be marked as ‘done’ in hospital.

   Were different methods started in Hospital?—mark ‘no’ if the only form of hypothermia therapy delivered in the Hospital (includes the cath lab) was a continuation of the therapy started in the ED. Mark ‘yes’ if different hypothermia therapyies (other than those started in the ED)were initiated in the catheterization lab, operating room, or hospital. Mark if the hospital initiated therapy was an external (see applicable list) and/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 an external and/or internal method was first started in the hospital. If either the date or time is not available, mark ‘time or date not noted’ (enter what you do have).

   CCC only: If ‘internal’ hypothermia was started in the ED and the type marked is ‘endovascular’ (such as the Alsius IVTM system), indicate if the cooling catheter was inserted in the femoral or subclavian veins. If a different insertion site, mark ‘other’ and specify that location. If insertion site not indicated, mark ‘unknown/not noted’.

   CCC only: If hypothermia therapy was started in the hospital, indicate where that therapy was initiated, whether catheterization lab, the critical care unit (ICU, intensive care, coronary care or similar critical care setting), or another location (specify). Or, mark unknown/not noted.

P. *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 - 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.

FiO2 (fraction of inspired oxygen) is expressed in percentage form (%). If a patient is on a ventilator, report the % at which the system is set to deliver. Room air is about 21%. If an adult patient is receiving oxygen via nasal cannula, convert the delivered flow rate from liters per minute (such as 5 L/min) to % FiO2 using the below online resource. For patients < 18 years old, leave FiO2 blank if only nasal cannula flow rates are reported. Conversion of common adult flow rates are also provided in the below table for standard and high flow nasal cannula:

http://www .skyscape.com/archimedesonline/rchimedes.aspx?topicurl=h/tl2.htm&idx=_i2&alpha=E

Standard nasal cannula flow rate	Estimated FiO2	High flow nasal cannula flow rate	Mean FiO2
1 L	24 %	6 L	54 %
2 L	27 %	8 L	58 %
3 L	30 %	10 L	66 %
4 L	33 %	12 L	69 %
5 L	36 %	15 L	75 %
6 L	39 %		

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.

Item 4 - 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 any parenteral route (not by mouth), including subcutaneous, intramuscular,IV bolus or IV 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 is given by any parenteral route, 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 5 - Potential adverse events observed within 24 hours of 1 st ED arrival (ALPS only):

Check the bubble 'NR' for 'Not Recorded' or 'Yes' for any of the items documented during the first 24 hours of the patient's stay in the ED or the hospital, and complete the triggered Alert forms. If the patient is transferred from one ED or hospital to a second ED or hospital during the 24 hour period, any of the listed potential adverse events documented at either hospital should be checked:

- *Anaphylaxis cited in medical records:* Anaphylaxis is a serious allergic reaction which can be due to an allergy (known or unknown) to a medication. What distinguishes anaphylaxis from more mild allergic reactions (such as hives) is its severity. Anaphylaxis in its full-blown form can result in asthmatic-like bronchospasm with severe wheezing, swelling of the face tongue and throat resulting in upper airway obstruction, along with hypotension and tachycardia. Check anaphylaxis if noted on the EMS record. If symptoms consistent with anaphylaxis are noted on the PCR but anaphylaxis is not stated, further discussion is needed with the EMS providers and the site investigator. Anaphylaxis is not intended to capture the more mild allergic reactions (such as associated with hives or itching). Score the seriousness, severity and relation to study intervention (5a, 5b, and 5c) for this potential adverse event.
- *Pacing for bradycarida and/or heart block in patient without prior implanted pacemaker--* Check yes if the patient was paced with a temporary pacemaker during the first 24 hours of arriving at the ED or hospital records.
- *Potential seizure activity*—Check all that are noted in the ED or hospital records. Myoclonus may be also referred to as muscle twitching, jerks, or spasms. Seizure activity may als be referred to as grand mal, epileptic seizure, tonic/clonic movements, or convulsion.
- *Evidence of thrombophlebitis-Mild (no specific treatment, or only local such as hot packs); Moderate (requiring antibiotic treatment, either oral or IV); Severe (requiring surgical treatment, or indication of major concern such as a surgical consult)*—If evidence of thrombophlebitis at the ALPS administration site is checked, indicate whether it was mild, moderate or severe as the intent of this item is to determine the severity of the thrombophlebitis. Do not include thrombophlebitis occurring at a site other than the administration site for the ALPS drug.
- *IO complications-Compartment syndrome, Osteomyelitis Abscess, Loss of limb, Skin necrosis, or Other*—Check any of the items noted in the ED or hospital records that occurred at the ALPS IO administration site. If a complication occurred that is possibly related, check 'Other' and note the complication on the form. Do not include IO complications occurring at a site other than the administration site for the ALPS drug.

Item 6 - Antiarrhythmic drug therapy within 24 hours of 1 st ED arrival (ALPS only)

Check the bubble 'NR' for 'Not Recorded' or 'Yes' for any of the listed drugs documented during the first 24 hours of the patient's stay in the ED or the hospital. If the patient is transferred from one ED or hospital to a second ED or hospital during the 24 hour period, check any of the listed drugs for both hospitals. For amiodarone or lidocaine, indicate whether the drug was given by bolus or drip, or not noted. If a bolus was given, enter the total dose. Check if a beta blocker, magnesium or procainamide was given in the first 24 hours of ED/hospital arrival. Examples of beta blockers include atenolol (Tenormin), bisoprolol (Zebeta), carvedilol (Coreg, Coreg CR), esmolol (Brevibloc), labetalol (Normodyne), metoprolol (Lopressor), nadolol (Corgard), propranolol (Inderal) and sotalol (Betapace).

A ‘bolus’ of amiodarone would include a 10-minute ‘load’ or rapid infusion of amiodarone (the FDA-approved method for giving the initial loading dose of amiodarone). Documentation of this type ‘bolus’ amiodarone includes xxx mg ‘load’, or ‘bolus’, or ‘over 10 minutes’, or ‘IV push’, or ‘rapid infusion’. Lidociane may also be given as a rapid infusion (25-50 mg/minute, or a 2-4 minute infusion for a 100 mg dose).

CCC AND ALPS: ROSC AND HYPOTHERMIA THERAPY

The purpose of this form is to screen for patients that might have been eligible for ED or hospital initiated hypothermia therapy which is an important predictor of survival and neurologic function. And for those that received hypothermia therapy, it characterizes the depth and duration of that therapy, and related diagnostics and treatments. This form is required for all cases where the patient was transported to the ED.

Item 1 - Did the patient maintain pulses for at least one hour after either a) arriving at first ED [or first hospital if bypassed ED] with ROSC, or b) attaining ROSC within one hour of arrival?

If ‘no’ ROSC was not obtained and pulses sustained as below described, stop here and proceed to the next form. No further data is to be entered in this form.

Indicate ‘yes,’ if pulses were present for at least one hour after first ED arrival (where ROSC was present when patient arrived at ED), or if ROSC (return of spontaneous circulation) occurred within one hour arrival and pulses were present for at least one hour after ROSC. If the patient bypassed the first ED and was directly admitted to the hospital (includes the cath lab), mark ‘yes’ if, ROSC occurred in those settings and pulses were present for at least one hour after ROSC. If arrived with pulses, start the one hour clock at the time of arrival at first ED or hospital (if direct admit), not at time of 1 st ROSC documented (and entered in the Prehospital Time Record) for 1 st ROSC in the field.

Evidence of hour-long sustained pulses may be indicated in vital sign records (with pulse or measurable systolic blood pressure) or mention in nursing/physician notes of some level of consciousness. ‘Yes’ may be marked whether the patient subsequently lived or died in the ED or hospital.

Item 2 - Neurological status in the first ED or hospital:

The purpose of this item is to capture the patient’s earliest baseline level of consciousness or neurologic status documented in the ED or hospital. Assessment of baseline status can be affected by prior administration of medications that either sedate (a broad catch-phrase for drugs that calm, relieve anxiety, induce sleep) or paralyze the patient. Mark ‘yes’ if the patient medication record indicates that either a sedative drug (such as those listed on the form) or paralyzing agent (such as those listed on the form) were administered in the prehospital, ED, or hospital course of care prior to the time of the noted neurological status. Talk with your PI to clarify if unfamiliar medications are to be considered as either a sedative or paralytic.

If ‘Paralyzed’ is marked ‘not noted’, review the progress and nursing notes for comment on the

highest level of consciousness of the patient. The provided response options are listed from highest level of response (obeys verbal commands) to lowest (no response to stimuli). Where more than one response option is possible, select the one that best represents the status prior to receiving sedation or paralytics and/or prior to start of hypothermia.

Item 3 - Was hypothermia, other than continuation of prehospital method, started in first ED or hospital:

Indicate if a method of hypothermia was started in either the first ED or hospital (not just a continuation of a cooling method started in the pre-hospital setting). Hypothermia therapy started in the cath lab is considered as started in 'hospital'. The 'yes' or 'no' response should match that provided on the Procedure form, Item 2N or 2O. Many ED and hospitals have 1-2 page pre-printed standing orders for hypothermia that are signed to signal initiation of therapy, and intended to be initiated early in the course of care.

If 'no', hypothermia (other than continuation of field therapy) was started in the first ED or hospital, then indicate if there were concerns in the ED or during the first hour of hospitalization regarding uncontrolled or serious bleeding (including going to the operation room for hemorrhage control). Bleeding may be internal (such as intra-abdominal, intra-cranial, subarachnoid hemorrhage) or external (such as from an orifice). It may or may not require transfusion. Stop here and proceed to the next form (no other data is required or allowed.

Here forward, questions are related to the first instance of hypothermia therapy initiated in the ED or hospital. It is a rare circumstance that more than one instance of hypothermia is implemented—an example of which is is considered in the rare circumstance where a course of hypothermia is conducted for 20 hours, then stopped due to hemorrhage, then restarted and conducted for an additional number of hours. More than one instance of hypothermia does not include the continuation of hypothermia while transitioning from one type of therapy to another (such as switching form prehospital cold fluid therapy to inhospital adjustable cooling pad therapy); this transition would be considered one instance of hypothermia therapy. Where more than one instance of hypothermia, answer items 4-13 related to the first instance. ***Contact the CTC to discuss these unusual situations.***

Item 4 - Closest temperature prior to onset of ED or hospital hypothermia:

If hypothermia is initiated in the ED or hospital, provide the closest temperature that was documented **prior to** the onset of hypothermia. Enter the value and be sure to indicate the appropriate unit of measure, either degrees Celsius or Fahrenheit. Provide the date and time (indicating if either the time or date is not noted). If time of start of cooling is not known, then provide first temperature data documented prior to the physician's written order to provide hypothermia, or where written orders are not found, just prior to first documented efforts (in the nurses or progress notes) to initiate hypothermia.

Item 5 - No longer required for current Cardiac study:

Item 6 - Temperatures during cooling phase of hypothermia therapy:

The cooling phase of hypothermia is defined as including the induction of cooling, lowering the patient's temperature to the prescribed target (usually about 33 ° C/91.4 ° F), and the maintenance of the temperature within that range for a prescribed period (usually 24-72 hours, depending on local practice). The rewarming phase begins when efforts cease to maintain the cold target temperature and the patient is allowed to begin returning toward a 'normal' temperature.

This item seeks to capture only temperatures documented for the cooling phase. Starting with the first temp documented after the onset of the cooling phase, provide the date, time, and value (with unit of measure) for all temperatures documented during the first 24 hours of cooling. If numerous temperatures are documented, it is acceptable to provide only those taken approximately every two hours. This data is important to later assess the speed with which patients are cooled, the depth of cooling and the duration at given temperatures. If the patient is actively cooled for longer than 24 hours (such as 48 or 72 hours therapy), do not enter temperatures beyond those measured in the first 24 hours. Do not provide temperatures here with a date/time is documented during the rewarming phase (such as when the cooling device is put into stand-by or active rewarming).

- *If the patient dies during the cooling phase* (prior to completion of the prescribed period of cooling therapy), also provide the last documented temperature prior to death.
- *If no temperatures are documented during the cooling phase,* mark the provided box and enter no data in the table. This is anticipated to be an unusual event, such as when the patient was started on cooling therapy, died soon after, and no temperatures were documented, after the baseline pre-cooling temperature, prior to death.

Mark 'all available information entered' to indicate that no additional temperature data is documented for the first 24 hour period.

Item 7 - No longer required for current Cardiac study:

Item 8 - No longer required for current Cardiac study:

Item 9 - No longer required for current Cardiac study:

Item 10 - Cooling discontinued:

The cooling phase of hypothermia is defined as including the induction of cooling, lowering the patient's temperature to the prescribed target (usually about 33 ° C/91.4 ° F), and the maintenance of the temperature within that range for a prescribed period (usually 24-72 hours, depending on local practice).

Indicate the date and time the cooling phase ended, such as when cooling is put on stand-by and the patient is allowed to re-warm. If time is not known, leave it blank (do not enter '0' or '00') and override the resulting error message.

- *If the patient dies during the cooling phase* (prior to completion of the prescribed period of cooling therapy), mark the provided box indicating that. Do not enter the date/time the patient died as the date/time for discontinuation of cooling. Stop here and do not provide responses for **items 11** and **12**.
- *If the patient died during the re-warming phase of therapy*, provide the date/time that cooling was discontinued and respond to **item 12**.

Item 11 - No longer required for current Cardiac study:

Item 12 - Temperatures during re-warming phase of therapy:

The re-warming phase begins when efforts cease to maintain the cold target temperature and the patient is allowed to begin returning toward a 'normal' temperature. This item seeks to capture only temperatures documented for the re-warming phase.

Starting with the first temperature documented after the onset of the re-warming phase (cooling discontinued), provide the date, time, and value (with unit of measure) for all temperatures documented for the ensuing 12 hours or until the core temperature reaches 37 ° C (98.6 °F), whichever occurs earliest.

- *If no temperatures are documented during the rewarming phase,* mark the provided box and enter no data in the table. This is anticipated to be an unusual event, such as when cooling was discontinued and the patient allowed to begin rewarming, then died soon after, and no temperatures were documented for the rewarming period.
- *If the patient dies during the rewarming phase* (from discontinuation of cooling to 24 hours following), provide be sure to include the last documented temperature prior to death.

Mark 'all available information entered' to indicate that no additional temperature data, beyond what is entered in the table, is documented for the first 24 hour period.

Item 13 - Record highest temperature during the first 48 hours after cooling stopped:

The intent of this data variable is to capture if the patient became hyperthermic early after cessation of cooling therapy. Hyperthermia is thought to be associated with negative sequelae. Provide the value for the highest temperature that was recorded in the 48 hour period after cooling was stopped. This may, or may not, be a date/time/value recorded during the first 12 hours after cooling was stopped and recorded in Item 12. Enter the requested data for the highest temperature, whether or not included in **Item 12**.

PATIENT/FAMILY NOTIFICATION

The purpose of the Patient/Family Notification form is to document patient/family/LAR study notification practices for any patient who is enrolled in ALPS and/or the CCC trial. FDA and OHRP (Office for Human Research Protections) regulations regarding exception from informed consent and local IRB requirements must be followed regarding notification of patients/families/LARs of any patients who are enrolled in the trial regardless of whether they survived or not.

Study personnel must attempt to contact the patient or patient's family as soon as feasible as outlined by their local IRB/REB before they are discharged from the hospital in order to notify them of their participation in the trial. This notification attempt should allow time for discussion of questions about the study. Identifying oneself with the University or the local fire/EMS agency may help to alleviate patient or family concern about the study.

The procedures for notification will vary from site to site—as per local IRB/REB guidance. Depending on the status of the patient, it may be necessary to use more than one type of notification form. For example, if the patient is conscious and able to comprehend the study at the time of notification, the "Information sheet for patients conscious at time of initial notification" should be used. If the patient is unable, either physically or mentally, to understand the notification, the "Family/LAR of patient who has not regained consciousness or is unable to understand the informed consent" may be required. If and when, at a later

date, the patient recovers to the point where he or she would understand the notification, the “information sheet for patients who regain consciousness after family notification has occurred” should be used.

In all instances, the site must maintain documentation of all failed and successful attempts to notify the patient, family or LAR, including the dates of the attempts, the method(s) used and whether or not the attempt was successful.

The episode date, time, and episode ID will be pre-filled by the web data entry program, and it will be consistent with the data and time recorded on the Patient Enrollment form. Pre-filled data should be reviewed for accuracy. The incident ID and the site linking ID are optional.

Item 1 - Was patient and/or family and/or LAR notified that patient was in study?

Indicate ‘yes’ or ‘no’ whether the patient and/or the family and/or legal adult representative (LAR) were notified of the patient’s enrollment in the study. If ‘yes’, check one or more boxes to indicate who was notified, and the date each was notified. If a ‘family or LAR was notified, specify their relationship to the patient. Indicate whether the notification was completed for CCC, ALPS or both studies. If the patient was enrolled in both studies, separate notification forms are necessary for each study.

If notification was not completed, check ‘no’ and explain the reason for not notifying the patient, family, or LAR. *Under no circumstances should the “no” bubble be checked as a ‘placeholder’ if the site is deferring the notification or waiting to send out a notification.* The “no” bubble should be reserved for cases where no address of an LAR can be accessed or a returned letter (no known forwarding address). A reasonable effort should be made to notify, and the method used must be approved by the local IRB/REB. When ‘no’ notification was done, select the reason that best reflects why not.

- Documented attempts made by unable to reach patient or family—this includes return of unopened or certified mail and multiple documented attempts to reach the patient as soon as feasible. Documentation of attempts must be maintained at the site, or on the ROC-web as provided for on this form in Item 3.
- Patient or family/LAR refused in-person notification materials—such as when a coordinator locates the individuals, but circumstances cause them to not wish to discuss enrollment in the study. It is not anticipated that this occasion will occur very often over the course of the study. This response option does not include circumstances where the individuals wish to *defer* the discussion to a later time. This response option is *not* to be marked as a ‘place holder’ until the coordinator is able to arrange a time of mutual convenience to discuss. When a discussion is to be deferred, do not complete Item 1 until the course of notification effort has been completed.
- Not feasible to notify dead/unconscious—this is not intended to be marked when the coordinator, PI, or site has determined that notification should be delayed or withheld due to patient or family circumstances. ‘Not feasible’ is reserved for circumstances where it is not possible to locate the patient in the ED/hospital, or to determine contact information for the patient or family/LAR. ‘Not feasible’ also includes those circumstances that the site’s IRB/REB has specified in writing as not being feasible to contact the intended parties (such as might be specified for patients arrested in public and died in field; circumstances will vary between sites).
- Other/specify—response options will be periodically reviewed to determine the unusual circumstances that would lead to marking ‘other/specify’.

Item 2 - After notification did the patient (and/or family/LAR) withdraw from hospital record review?

Indicate ‘no’ or ‘yes’ or ‘other’ as to whether the patient, family or LAR withdrew from hospital record review at the time of notification or after notification of their participation in the study and enter the reason for the withdrawal and the date it occurred. If the family or LAR withdrew, enter their relationship to the patient. Remember that all records up to the time of withdrawal can be reviewed per the FDA and OHRP. For example, if the patient was entered into the study on June 1 and he was notified of his participation at 10:00 AM on June 3 but decided to withdraw from hospital record review, all records generated up until 10:00 AM on June 3 can be reviewed and entered on the ROC ALPS and CCC data forms. Unless the patient/family withdraws from the medical records review the site can continue to collect the data.

Item 3 - Document and explain attempts to notify the patient and / or family / LAR:

Sites are required to document all attempts made to contact the patient, family or LAR about their participation in the study and the attempt to obtain consent for follow-up. The site can elect to maintain the required documentation either locally at the site in a log or in individual patient files, or to maintain it on this ROC-web form.

Separate from the site’s decision where to document all attempts to notify the patient, ***the first attempt must be documented on the ROC-web form***. This is to allow the ROC Study Monitoring Committee (SMC) and DSMB to routinely monitor sites’ efforts to notify individuals of the patient’s enrollment in a clinical trial being conducted under exception from consent, and to allow them the opportunity to withdraw from further participation. In the circumstance where the first attempt to notify was successful or was the only attempt made, enter that attempt in this table and in Item 1 ‘Was the patient and/or family/LAR notified that patient was in study.’

Do not enter names, addresses, phone numbers or other identifiable information on this web-form; personal health information must instead be maintained securely at the RCC.

EPISTRY FINAL VITAL STATUS

The purpose of the Epistry final vital status form is to document information occurring during the Emergency Department (ED) course of care and/or Hospital course of care. It is to be completed for patients who were transported by EMS and were alive or for whom resuscitative efforts were ongoing.

Item 1 - Name of first ED/hospital 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. 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.

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

Provide the date (yyyy/mm/dd) and time (24 hour clock hh:mm) of patient arrival at the initial

emergency department or admission to the hospital (which ever occurred earliest). Sourced from hospital admission or patient care records. 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). In the event that time of arrival cannot be located in neither the hospital chart nor fire/EMS documentation, please mark “Unknown/Time not noted”.

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 acute care hospital before final discharge?

Indicate if the patient was transferred from the first ED/Hospital to a different acute care ED or 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 five 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 five 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 is the subject of the next question (#4).

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

Item 4 - Date 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. In the event that time of discharge or death is not known, please mark “Unknown/Time not noted”.

Item 5 - Final vital status:

Indicate patient status—dead or alive—when the course of care associated with this cardiac arrest episode was completed. Final status is reported for the latest (last) ED or acute care hospital that the patient was admitted or transferred to during the course of care. Indicate whether final status was obtained in the first ED/Hospital, after transfer to another hospital, or pt has been reclassified for non-acute care and remains in the acute care hospital awaiting placement.

Item 6 - Source for discharge status from final hospital:

The intended and preferred source for *Discharge status from final Hospital* is the hospital patient care record. When the data are abstracted from ED/hospital records, please indicate as such. In some cases a discussion with the hospital admissions department will result in discharge status (second preferred source). When a hospital record cannot be accessed, the 'social security death index' (SSDI) is the third preferred source. A date of death less than 14 days from the date of the 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 for that study is not approved.

CCC/ALPS ALERT CTC

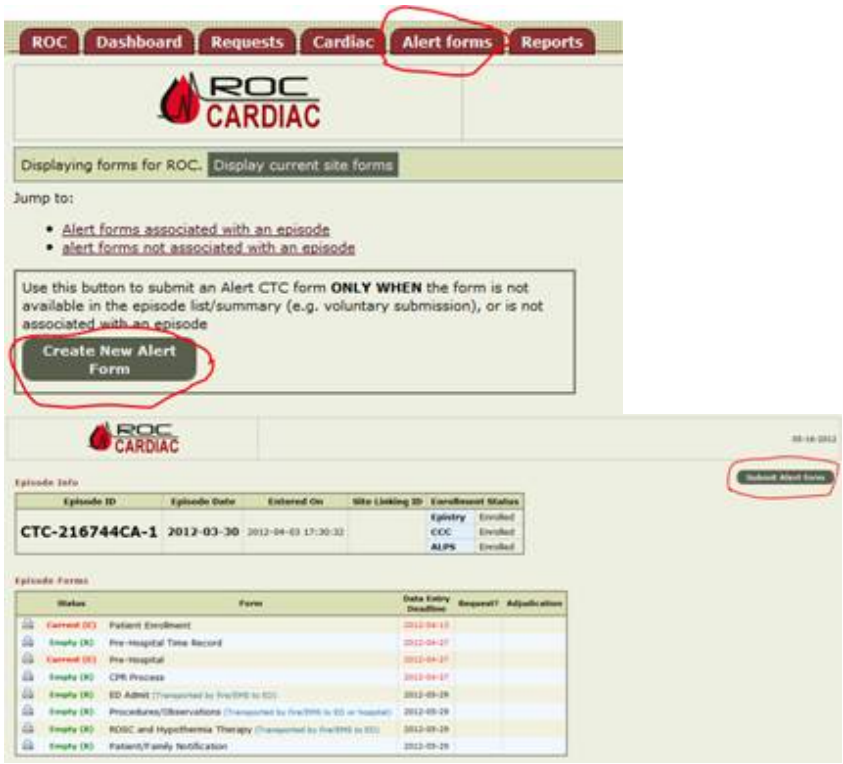
The purpose of the Alert CTC form is to notify the CTC regarding any potential adverse event, protocol violation/deviation, or unusual circumstance related to the study. A separate Alert CTC form is to be completed for each situation reported (one item/subject marked per form). An Alert CTC form is automatically triggered (and indicated on the Episode List and case Episode Summary) where response options are marked within the Enrollment, Time Record, Prehospital, ED, Procedure, or Hospital forms that suggest heightened attention should be given to discerning if the patient or protocol have been adversely affected. The auto-triggered Alert Form states the reason the form was triggered (as below, an alert auto-triggered for a case entered more than 30 days after episode).

The site is encouraged to use the triggered Alert for the stated reason it was generated, rather than to use for other things anticipated needing reporting. As additional data is entered into the web-forms, additional Alerts will be triggered for specific conditions; using a triggered form for other than it’s triggered purpose may create multiple forms for the same purpose.

While auto-triggered Alert CTC forms are generated for defined conditions, it is the site’s responsibility to assure that all potential adverse events and protocol violations are reported to the CTC and as required by the site’s local IRB. The site will self-generate an Alert CTC form to report situations that seem unusual for the patient’s underlying condition not otherwise captured by an auto-triggered Alert CTC form.

If an Alert CTC form is not triggered by data entry, but you become aware of an adverse

event or unusual circumstance that requires an Alert CTC form, access the ‘Create New Alert Form’ via the Alert Forms tab within the ROC Cardiac data entry section of the ROC-web. Or, on the Episode Summary page, click on "Submit Alert form" and a blank Alert CTC form with the episode ID will appear. Complete this form with the reason for the Alert. The completion (‘C’) or error status (‘E’) of the form is displayed on the Episode List.



Other Exclusion criteria marked ‘yes’ or Inclusion criteria marked ‘no’ are captured on the Patient Screening and Enrollment form and adequately there captured for reporting/tracking of the frequency of their occurrence. Sites are encouraged to separately trigger an Alert CTC form to report unusual circumstances associated with the marked criteria that cause concern for patient safety (such as when the CCC protocol may have caused a delay of therapy for an arrest that was EMS witnessed). Those concerns will be reported within one business day of their recognition.

A number of expected adverse event data (such as airway bleed or emesis before insertion of an advanced airway) are collected within the CCC data forms and are there captured for reporting/tracking of the frequency of their occurrence. Where data entry allows for reporting of certain situations, a separate Alert CTC form is not needed to duplicate that report. However, the site is encouraged to separately report circumstances related to that situation that it identifies as important for monitoring patient safety and study conduct.

Is this issue associated with an episode: This question is asked when an Alert form is site-generated via the ‘Alert forms’ tab, clicking on ‘Create New Alert Form’. Other avenues for generating an Alert form (via Episode Summary page or auto-generated as a result of data entered in case forms) recognizes the association of the reported issue with a specific case.

Where this question is asked, indicate ‘yes’ or ‘no’ if the circumstances to be reported are related to one specific episode. If ‘yes’, provide the CTC episode ID (format 123456; do not include the site letters, such as DAL or SKC, dashes, or the ‘CA-x’ suffix). The ID field will ‘auto populate’ the field as digits are typed, and will recognize if the entered number matches a case previously submitted by the site. Mark ‘no’ for any single circumstance that is being reported that affects more than one case (such as public formal objection to a trial).

Item 1 - Date:

Provide the date this form is first initiated, which may or may not be the same as the date of the situation that is being reported. The date of situation is either the date the reported circumstances occurred or the date the circumstances were first known by the site, whichever is earlier. It would be the rare situation where the site did not know the date the reported circumstances occurred.

Item 2 - General situations:

This section is intended to capture circumstances that affect the conduct of the trial for multiple patients or are related to situations other than individual patient safety or study conduct during the course of care for a particular patient (which would be reported as potential adverse events or potential protocol violations/deviations). Select the response option that best describes the general situation and provide an explanation of the circumstances. The CTC will review and discuss additional information or reporting that might be required.

Report only one situation per Alert form.

The site must self-generate an Alert form to report general situations (other than 'case entered more than 30 days after episode date; which is automatically triggered). A 'public formal objection to trial' might include the filing of a complaint (with a local IRB/REB, Office Human Research Subjects, or regulatory body) by a patient, family, or community person in opposition to conducting either/both the CCC or ALPS trial; of periodic community consultation leading to a conclusion of 'objection to a trial'. This does not include news paper or medical journal articles published in opposition or questioning the merits of either the CCC or ALPS trial.

An Alert form is triggered where a case is entered more than 30 days after the date of episode, and that response auto-filled. Provide a reason why the interventional trial case was identified and entered into the ROC-web with more than a 30-day lapse.

Item 3 - CCC only: Potential adverse events associated with CCC:

A potential adverse event is any untoward medical occurrence temporally associated with study therapy whether or not considered related to that therapy. Adverse events may be either expected or unexpected, vary in degree of seriousness or severity, and may or may not be related to the study intervention. Reporting of adverse events is required for monitoring the safety of the trial. Untoward signs or symptoms existing prior to study therapy are not considered adverse experiences unless they recur or are exacerbated after study therapy.

Report only one situation per Alert form.

CCC protocol caused delay or interruption of pre-hospital treatment —the site must create a new Alert form to report that course of prehospital care was adversely impacted by the conduct of the CCC protocol (whether continuous compressions or 30:2 study arms). Examples of potential delay in therapy might include: arrest is EMS witnessed and study therapy is delivered rather than standard therapy of assessing and delivering a shock as soon as feasible; or, crew is assigned to continuous compression arm and delivers 5-6 minutes of continuous compressions without out pause to assess rhythm for a shock; or there is confusion about the pattern of ventilations to be delivered. If therapy is reported to have been delayed, provide the approximate period necessary therapy was delayed (in minutes).

Complication associated with advanced airway (ET or other) placed by fire/EMS:

Other potential safety issue (complete 3a, 3b, and 3c): the site must create a new Alert form to report that prehospital or ED/hospital circumstances suggest a potential adverse event has occurred. When an alert is self-generated by the site to report a potential safety issue, it is required that the potential adverse event be assessed for its seriousness, severity, and relation to the study therapy. A pre-specified pattern of responses to this scoring system help to identify circumstances that require expedited reporting—either serious unexpected suspected adverse reactions (SUSAR) or serious unexpected adverse events.

Explain circumstances : For any item marked, provide details and/or context for the reported issue.

Timeframes for site reporting of CCC adverse events:

Unexpected serious adverse events : any adverse experience, the nature, severity or frequency of which is not consistent with the protocol or with the notification form. This includes events that are more serious than would be expected to occur. For CCC, this does not include neurological impairment.		
What	Site action	CTC action
Thought to be elated to study therapy and is fatal/life threatening	Site to contact CTC within 24 hours; within 3 working days of awareness site PI writes summary letter of circumstances, patient sequelae, whether related to study therapy, and agency remediation if related to study deviation or violation. Also within 3 days of awareness, site begins data entry for auto-triggered Alert form; or, if not auto-triggered, the site initiates an Alert form. Consult with the CTC to determine if a MedWatch form is required.	Contact regulatory/oversight groups (FDA, Health Canada, IRB, DSMB, Investigator), sites and NIH within 7 days of being made aware; CTC will respond to resulting queries within 15 days of their receipt from regulatory/oversight groups.
Thought to beelated to study therapy and is 'serious' (as defined below in 5.a. and 5.c)	Provide CTC with written notification within 7 calendar days. Consult with the CTC to determine if a MedWatch form is required.	Provide regulatory/oversight groups (FDA, Health Canada, IRB, DSMB), sites and NIH with written notification within 15 days of being made aware

Expected adverse events: any adverse experience disclosed as such in the protocol; the event may or may not be attributable to specific resuscitation therapies.		
What	Site action	CTC action
Thought to beelated to study therapy and is 'serious' regardless of 'severity' (as defined below in 5.a and 5.c)	Report on CTC Alert form within Prehospital (28 days) and ED/hospital (60 days) form completion benchmarks set by ROC Study Monitoring Committee.	Report in aggregate for status and annual summaries to regulatory/oversight (FDA, Health Canada, IRB, DSMB) groups. DSMB receives reports by treatment group.
Not related to study therapy		Report in status and annual summaries to regulatory/oversight groups.

IMPORTANT: Report to CTC anything that strikes you as being unusual for the expected clinical course of a patient treated or having been treated for out-or-hospital cardiac arrest and received study therapy. The CTC will help determine the appropriate course for reporting the reported circumstances.

Standard scoring of potential adverse events : Select the response option that best describes the effect or manifestation of the reported adverse event:

Item 3a - Seriousness of the potential adverse event (check one only)

As guided by US Department of Health and Human Services (http://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm). Marking of any response option, other than ‘none of the above,’ indicates the adverse event to be ‘serious’:

- Prolonged hospitalization, or required hospitalization—this adverse event extended the length of hospital stay.
- Life-threatening—in the view of the investigator, the occurrence of this adverse event places the patient at ‘immediate’ or ‘substantial’ risk of death. This does not apply to an event that, had it occurred in a more severe form, might have caused death.
- Fatal—mark this if it is suspected that death was an outcome of (caused by) the adverse event; this does not include death due to other causes though the adverse event was present.
- Led to permanent disability—this adverse event resulted in substantial disruption of the patient’s ability to conduct normal life functions.
- Required intervention to prevent permanent disability—this adverse event required medical or surgical intervention to preclude permanent impairment of a body function, prevent permanent damage to the body.
- Associated with congenital anomaly—exposure to the study therapy was during pregnancy and may have resulted in an adverse outcome in the child.
- None of the above

Item 3b - Severity of the potential adverse event (not to be confused with 'seriousness') (check one only)

Assessment of severity is subjective and the investigator must use medical judgment to compare the reported adverse event to similar types of events observed in clinical practice. Severity is not equivalent to seriousness of the event:

- Mild—symptoms are barely noticeable to patient; does not influence performance or functioning; prescription drugs not needed for relief of symptoms.
- Moderate—symptoms make the patient uncomfortable; influences performance of daily activities; treatment of symptoms may be needed.
- Severe—symptoms cause severe discomfort; may cause cessation of study treatment; treatment for symptoms may be given.

Item 3c - Relation to study intervention (check one only)

Select the one statement that best describes yours and the site PI’s judgment of the whether the reported issue is related to the study therapy. Marking of any response option, other than ‘not related’ or ‘unlikely related’ indicates the adverse event is to be reported as ‘related’ (whether definitely, possibly, or probably) to study therapy:

- Not related (clearly not related)
- Unlikely related (doubtfully related)
- Definitely related
- Possibly related (maybe related)
- Probably related (likely related)

Item 4 - CCC only: Potential protocol violation or deviation

Report ‘unplanned excursions’ from the protocol. Protocol ‘violations’ are generally defined as intentional acts in which the protocol was not followed and it potentially affects the patient. Protocol ‘deviations’ are generally defined as inadvertent acts in which the protocol was not followed, we ‘wished’ they had not been done, but the patient was not endangered. The ROC data-entry forms are programmed to capture a number of potential protocol violations and deviations and to automatically trigger an Alert form. The site is expected to self-generate an Alert form to report violations or deviations that do not otherwise have an auto-generated Alert form or may not be listed below.

Report only one situation per Alert form.

CCC protocol violations that require Alert form include, but are not limited to: a) protected population status known by field prior to study therapy and study therapy given (rather than standard of care as directed by agency medical director); b) opt out bracelet worn and study CPR given.

CCC protocol deviations that require Alert form include, but are not limited to: a) protected population status *not* known by field prior to study therapy and study therapy given; b) other inclusion/exclusion criteria not met and study therapy given (rather than standard of care as directed by agency medical director); c) mechanical compression device use during study-assigned therapy period.

CCC protocol deviations that are tabulated and later reported (do not require Alert form) include: a) Epinephrine or vasopressin not given < 10 minutes of ALS arrival; b) completion of 3 cycles study therapy < 5 minutes after fire/EMS arrival; c) advanced airway inserted < 5 minutes fire/EMS arrival.

Protected population status known during prehospital course of care: Here report if the patient was less than local legal age of consent, pregnant, or prisoner, and known to be so by field providers during the prehospital course of care (whether or not before or after study therapy given). This does not include fire/EMS learning of a protected status after wheels stopped at the ED. A known prisoner is a person who had cardiac arrest while incarcerated at a correctional facility or jail, or who was in police custody (not being pursued).

- Indicate if the protected status of the patient was known to fire/EMS providers before or after the initial period of CPR that would have otherwise been dedicated to study therapy (whether 30:2 or continuous compressions).
- Indicate which definition best describes what type of CPR was given to the protected patient during the initial period that would have otherwise been dedicated to study therapy. ‘Assigned therapy’ is the mode of CPR (either 30:2 or continuous compressions) that providers would have done for other patients enrolled the same day. ‘Local standard of CPR for this protected population’ is the form of CPR that the agency medical director has stipulated be done for this type protected patient—mark this if the medical director has stipulated that ‘study assigned therapy’ is the local standard of practice for this type protected patient during the course of the study—confirm with the main coordinator or agency medical director what is the directed standard and compare with what was delivered. If not either ‘assigned’ or ‘local standard’ of CPR, mark ‘other’ and describe (this is anticipated to be an unusual response option marked).

Protected population status learned during ED/hospital (not prehospital) course of care: Here report if the patient was less than local legal age of consent, pregnant, or prisoner, and it was not learned until the patient arrived in the ED or Hospital. An Alert form is triggered automatically if the ‘year of birth’ entered on the ED form suggests the patient may have been < local age of consent. The site must self-generate an Alert form to report if it is learned in the ED or Hospital that the patient was learned to be pregnant or prisoner.

- Indicate which definition best describes what type of CPR was given to the protected patient during the initial period that would have otherwise been dedicated to study therapy. The data abstractor will need to review prehospital source documents (including ECG) to assess which

option to select. ‘Assigned therapy’ is the mode of CPR (either 30:2 or continuous compressions) that providers would have done for other patients enrolled the same day. ‘Local standard of CPR for this protected population’ is the form of CPR that the agency medical director has stipulated be done for this type protected patient—mark this if the medical director has stipulated that ‘study assigned therapy’ is the local standard of practice for this type protected patient during the course of the study—confirm with the main coordinator or agency medical director what is the directed standard and compare with what was delivered. If not either ‘assigned’ or ‘local standard’ of CPR, mark ‘other’ and describe (this is anticipated to be an unusual response option marked).

Opt-out bracelet/indicator and study CPR given: Patients may have learned of ROC studies through local initial or ongoing community notification efforts made by the RCC. Patients have the right to indicate they are not to be enrolled in ROC trials. Local IRB’s provide/approve guidance on how a patient may indicate their unwillingness to be enrolled—most often that is via a medic-alert or similar bracelet or ‘dog tag’ saying this. This indicator might be noticed during the prehospital course of care or later in the ED/hospital. Mark this item if an indicator (likely described in the IRB application or approval) was present at any time, whether or not the EMS providers were aware of it prior to giving study therapy.

- Did CPR given [in the field during the initial resuscitation period during which study therapy would otherwise be given] conform with local standard of practice?—mark ‘yes’ if the type of CPR given during the initial period of resuscitation conformed with the type of CPR (whether 30:2 or continuous compressions) that the agency medical director has stipulated be done in this circumstance. Mark ‘no’ if it is known that the type CPR delivered during the initial period of resuscitation was different than what the medical director stipulated for this type of situation. The data abstractor will need to review prehospital source documents (including ECG) to assess which option to select. And, will need to know what the medical director’s local standard is.

Mechanical compression device used during study-assigned period of therapy: An Alert form is auto-triggered if the related exclusion criteria is marked on the Enrollment form, or the Time Record indicates a mechanical compression device was started in the early period of initial resuscitation efforts. Manual compressions are to be used to deliver either 30:2 or continuous compression study compressions for the initial four cycles of study therapy.

Other potential protocol violation or deviation: Report intentional or inadvertent acts that occurred during the prehospital course of care where the protocol was not followed, whether or not the patient was endangered. This might include delay or interruption of prehospital treatment caused by the CCC protocol (such as following an EMS witnessed arrest). After learning of the circumstances, the CTC will determine if the situation constitutes a deviation or violation for the protocol.

Item 5 - ALPS only: Potential adverse events associated with ALPS:

A potential adverse event is any untoward medical occurrence temporally associated with study therapy whether or not considered related to that therapy. Adverse events may be either expected or unexpected, vary in degree of seriousness or severity, and may or may not be related to the study intervention. Reporting of adverse events is required for monitoring the safety of the trial. Untoward signs or symptoms existing prior to study therapy are not considered adverse experiences unless they recur or are exacerbated after study therapy.

Report only one situation per Alert form.

Delay or interruption of prehospital treatment caused by ALPS protocol: The site must self-generate an Alert form to report this occurrence. Mark this, if in the judgment of the site coordinator and PI,

after reviewing prehospital source documentation and conferring with responders, that the protocol caused the course of care to be disrupted. This might include reported delays due to ability to assemble the syringe/adapters and administer the study drug; or confusion about eligibility criteria and definitive therapy delayed. Score the seriousness, severity and relation to study intervention (5a, 5b, and 5c) for this potential adverse event.

Anaphylaxis (complete 5a, 5b, 5c): Anaphylaxis is a serious allergic reaction which can be due to an allergy (known or unknown) to a medication. What distinguishes anaphylaxis from more mild allergic reactions (such as hives) is its severity. Anaphylaxis in its full-blown form can result in asthmatic-like bronchospasm with severe wheezing, swelling of the face tongue and throat resulting in upper airway obstruction, along with hypotension and tachycardia. Check anaphylaxis if noted on the EMS record. If symptoms consistent with anaphylaxis are noted on the PCR but anaphylaxis is not stated, further discussion is needed with the EMS providers and the site investigator. Anaphylaxis is not intended to capture the more mild allergic reactions (such as associated with hives or itching). Score the seriousness, severity and relation to study intervention (5a, 5b, and 5c) for this potential adverse event.

- An Alert form is auto-triggered with corresponding data entered into the Prehospital or ED/Hospital forms. Indicate if this was noted as occurring either during the prehospital course of care; or, within 24 hours of first ED/hospital arrival.

IO Complications (complete 5a, 5b, 5c): IO complications (specify)—Observations were made about the condition or integrity of the site in which, and after, ALPS drug was given. This does not include issues associated with placing the IO, such as might occur with process of assembling the device/needle, drilling, or missing the intended location. Score the seriousness, severity and relation to study intervention (5a, 5b, and 5c) for this potential adverse event. Observations might include, but are not limited to, compartment syndrome, abscess, skin necrosis, osteomyelitis, or loss of limb. In the situation where fire/EMS did not document which limb ALPS drug was given, but these type observations/circumstances occurred in the ED or hospital, do report the situation in the ED, Hospital and triggered Alert form. This will assure that safety monitoring is sensitive to an occurrence.

- An Alert form is auto-triggered with corresponding data entered into the Prehospital or ED/Hospital forms. Indicate if this was noted as occurring either during the prehospital course of care, within 24 hours of first ED/hospital arrival, or in the discharge summary.

Seizure acute (seizures, myoclonus, shivering) in prehospital within 24 hours (complete 5a, 5b, 5c): Any report by fire/EMS after ALPS drug given or in the ED/hospital within 24 hours will be reported as an expected adverse event. It is recognized that myoclonus (or muscle twitching jerks, spasms) and shivering are difficult to discern from one another and also difficult to differentiate from seizure activity (such as grand mal, epileptic seizure, tonic/clonic movements, convulsion). So, all are captured in the data forms if noted in the patient records, recognizing observer variability in documentation and in use of vocabulary.

- An Alert form is auto-triggered with corresponding data entered into the Prehospital, Hospital or Procedure/Observation forms. Indicate if this was noted as occurring either during the prehospital course of care; or, within 24 hours of first ED/hospital arrival. If documented as happening in more than one location, a separate Alert is required for each location (and will be automatically triggered).

Temporary pacing (complete 5a, 5b, 5c): Temporary pacing (either transcutaneous or external using adhesive pads or transvenous wire) was initiated by fire/EMS providers or after ALPS study drug was administered, either during the prehospital course of care or within 24 hours of ED/hospital arrival. This includes the rare circumstance where an arrest occurred in a clinic or other non-acute-care hospital setting and a bystander physician initiates pacing or inserts a pacemaker. This does

not include pacing provide by a pacemaker placed or implanted prior to ALPS study drug given. This does not include bradycardia reported for which atopine was given, but a temporary pacing was not initiated. Score the seriousness, severity and relation to study intervention (5a, 5b, and 5c) for this potential adverse event.

- An Alert form is auto-triggered with corresponding data entered into the Prehospital or ED/Hospital forms. Indicate if this was noted as occurring either during the prehospital course of care; or, within 24 hours of first ED/hospital arrival.

Thrombophlebitis (complete 5a, 5b, 5c): The Alert form is to be used to report only severe forms of thrombophlebitis (required surgical treatment or indication of a major concern). Less severe indications of thrombophlebitis are separately tabulated from the data forms and reported to DSMB and FDA. Score the seriousness, severity and relation to study intervention (5a, 5b, and 5c) for this potential adverse event.

- An Alert form is auto-triggered when the Procedure form is marked as 'yes' Evidence of thrombophlebitis within 24 hours first ED arrival *and* the condition is 'severe' (requiring surgical treatment, there is indication of major concern such as a surgical consult, or marked on Discharge summary. Indicate if this was noted as occurring either during the prehospital course of care (the site must self-generate an Alert form for this rare occurrence); within 24 hours of first ED/hospital arrival; or in the discharge summary.

Other potential safety issue: An Alert form is auto-triggered for other certain potential safety issue. The site is obligated to self-generate an Alert to report any potential safety issue that may not have been otherwise reported.

- Prehospital, syringe related issue with one or more ALPS syringes - The Alert is auto-triggered when this is marked on the Prehospital or CPR Process forms.
    - 'Non-functioning -- adapter used' should be selected when it is known that an adapter was used and it is reported that the syringe plunger cannot be pushed or pulled.
    - 'Non-functioning --adapter not used' should be selected when it is known that an adapter was not used and it is reported that the syringe plunger cannot be pushed or pulled.
    - 'Plunger expelled during use of rapid infuser' should be selected when contents of the syringe are expelled due to the pressure caused while using a rapid infuser.
    - 'Other, specify' is intended to capture (in text form) other reasons that arise that resulted in a syringe issue (such as break or crack in the syringe during the course of administration). This item is intended to capture issues with syringe performance that occurred during the course of drug administration. This item is not intended to capture difficulties removing the cap or connecting the CLEARLINK adapter or damage to syringes prior to or identified at opening of ALPS kit, go to item #9 'Broken/damaged ALPS kit'. Where a syringe related issue is also believed to have delayed or interrupted treatment of the patient, self-generate an Alert to report a 'Delay or interruption of prehospital treatment caused by ALPS protocol'.
- Prehospital, other (complete 5a, 5b, 5c)—the site is to self-generate an Alert form to report any circumstance that is a potential adverse event (regardless of seriousness or severity) that would not be expected during the usual prehospital course of care. For each 'other' prehospital potential safety issue reported, score it for seriousness, severity and relation to study intervention (5a, 5b, and 5c)
- Within 24 hours first ED/hospital arrival (complete 5a, 5b, 5c) —the site is to self-generate an Alert form to report potential adverse events that seem unusual for the patient's underlying condition. This includes only those events with an onset documented to have occurred within 24 hours of first ED arrival. For each 'other' potential safety issue that is reported to have onset within 24 hours of first ED arrival, score it for seriousness, severity and relation to study

intervention (5a, 5b, and 5c)

- Discharge summary (complete 5a, 5b, 5c) —this is intended to capture reporting of conditions listed on the hospital Discharge summary (other than any of the check list provided in item 13 of the Hospitalization form) that seem unusual for the patient's underlying condition. For these conditions, the site must self-generate an Alert CTC to report and score.

Explain circumstances : For any item marked as a potential adverse event, provide details and/or context for the reported issue.

Timeframes for site reporting of ALPS adverse events:

Unexpected serious adverse events : any adverse experience, the nature, severity or frequency of which is not consistent with the protocol or with the notification form and is more serious than would be expected to occur.		
What	Site action	CTC action
Thought to be related to study therapy and is fatal/life threatening	Site to contact CTC within 24 hours; within 3 working days of awareness, site PI writes summary letter of circumstances, patient sequelae, whether related to study therapy, and agency remediation if related to study deviation or violation. Also within 3 days of awareness, site begins data entry for auto-triggered Alert form; or, if not auto-triggered, the site initiates an Alert form. Consult with the CTC to determine if a MedWatch form is required.	Contact regulatory/oversight groups (FDA, Health Canada, IRB, DSMB, Investigator), sites and NIH within 7 days of being made aware; CTC will respond to resulting queries within 15 days of their receipt from regulator/oversight groups.
Thought to be related to study therapy and is 'serious' (as defined below in 5.a. and 5.c.), but is not fatal/life threatening	Provide CTC with written notification within 7 calendar days. Consult with the CTC to determine if a MedWatch form is required.	Provide regulatory/oversight groups (FDA, Health Canada, IRB, DSMB), sites and NIH with written notification within 15 days of being made aware

Expected adverse events: any adverse experience disclosed as such in the protocol; the event may or may not be attributable to specific resuscitation therapies.		
What	Site action	CTC action
Thought to be related to study therapy and is 'serious' regardless of 'severity' (as defined below in 5.a. and 5.c.)	Report on CTC Alert form within Prehospital (28 days) and ED/hospital (60 days) form completion benchmarks set by ROC Study Monitoring Committee.	Report in aggregate for status and annual summaries to regulatory/oversight (FDA, Health Canada, IRB, DSMB) groups. DSMB receives reports by treatment group.
Not thought to be related to study therapy		Report in status and annual summaries to regulatory/oversight groups.

IMPORTANT: Report to CTC anything that strikes you as being unusual for the expected clinical course of a patient treated or having been treated for out-or-hospital cardiac arrest and received study therapy. The CTC will help determine the appropriate course for reporting the reported circumstances.

Standard scoring of potential adverse events. Select the response option that best describes the effect or manifestation of the reported adverse event:

Item 5a - Seriousness of the potential adverse event: (check one only)

As guided by US Department of Health and Human Services (http://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm). Marking of any response option, other than 'none of the above,' indicates the adverse event to be 'serious':

- Prolonged hospitalization, or required hospitalization—this adverse event extended the length of hospital stay.
- Life-threatening—in the view of the investigator, the occurrence of this adverse event places the patient at 'immediate' or 'substantial' risk of death. This does not apply to an event that, had it occurred in a more severe form, might have caused death.
- Fatal—mark this if it is suspected that death was an outcome of (caused by) the adverse event; this does not include death due to other causes though the adverse event was present.
- Led to permanent disability—this adverse event resulted in substantial disruption of the patient's ability to conduct normal life functions.
- Required intervention to prevent permanent disability—this adverse event required medical or surgical intervention to preclude permanent impairment of a body function, prevent permanent damage to the body.
- Associated with congenital anomaly—exposure to the study therapy was during pregnancy and may have resulted in an adverse outcome in the child.
- None of the above

Item 5b - Severity of the potential adverse event (not to be confused with "seriousness") (check one only)

Assessment of severity is subjective and the investigator must use medical judgment to compare the reported adverse event to similar types of events observed in clinical practice. Severity is not equivalent to seriousness of the event:

- Mild—symptoms are barely noticeable to patient; does not influence performance or functioning; prescription drugs not needed for relief of symptoms.
- Moderate—symptoms make the patient uncomfortable; influences performance of daily activities; treatment of symptoms may be needed.
- Severe—symptoms cause severe discomfort; may cause cessation of study treatment; treatment for symptoms may be given.

Item 5c - Relation to study intervention (check one only)

Select the one statement that best describes yours and the site PI's judgment of the whether the reported issue is thought to be related to the study therapy. Marking of any response option, other than 'not related' or 'unlikely related' indicates the adverse event is to be reported as 'related' (whether definitely, possibly, or probably) to study therapy:

- Not related (clearly not related)
- Unlikely related (doubtfully related)
- Definitely related

- Possibly related (maybe related)
- Probably related (likely related)

Item 6 - ALPS only: Potential protocol violation: (check one and explain circumstances)

Protocol ‘violations’ are generally defined as intentional acts in which the protocol was not followed and it potentially affects the patient. Report only one item per Alert form.

Report only one situation per Alert form.

- *Opt-out bracelet/indicator and ALPS drug given:* The site will self-generate an Alert form to report the circumstance where there was indication (such as a bracelet, medic alert tag, family states such, written note) that the patient wished to not be enrolled into a ROC study. Patients have the right to indicate they are not to be enrolled in ROC trials. Local IRB’s provide/approve guidance on how a patient may indicate their unwillingness to be enrolled—most often that is via a medic-alert or similar bracelet or ‘dog tag’ saying this. Report this circumstance whether or not the EMS providers were aware of it prior to giving study therapy.
- *Protected population status known to fire/EMS prior to administration of ALPS drug (check all conditions known prior to administration):* Here report if the patient was less than local legal age of consent, pregnant, or prisoner, and known to be so by field providers prior to administration of any part of dose 1 ALPS drug. More than one protected status that was known prior to ALPS drug can be reported in this item. A known prisoner is a person who had cardiac arrest while incarcerated at a correctional facility or jail, or who was in police custody (not being pursued). An Alert form is auto-generated when it is marked on the Enrollment form that ALPS given and patient is a protected population.
- *Weight estimated to be < 100 lbs (45 kg) and > 1 syringe ALPS drug given for either dose 1 or dose 2:* An Alert form is auto-triggered if the number of syringes reported on the CPR Process form (item #7) for either dose 1 or dose 2 exceeds the limit required for patients < 100 lbs (45 kg). This item is not intended to capture the circumstance where EMS estimated the patient to weigh ≥ 100 lbs (45 kg), but ED/hospital documentation showed the patient’s weight to be different. This latter circumstance need not be reported on an Alert form; rather, it is separately captured from the data forms and tabulated for routine reporting to the DSMB.
- *Open label amiodarone or lidocaine administered by fire/EMS either before or after ALPS drug, prior to first ED arrival:* An Alert form is auto-triggered if ALPS drug was given and it is marked on the Enrollment form that open label amiodarone or lidocaine (including any given to numb the site for IV or IO insertion) was given prior to administration of ALPS drug and during the course of prehospital care. An Alert form is also auto-triggered if data entered on the Prehospital form indicates that open label amiodarone or lidocaine were given during the course of care, whether or not directed to do so by EMS medical control following an unblinding. At the time the CTC adjudicates the Alert, the distinction will be established and adjudication of the Alert made to reflect this.
- *Ineligible rhythm (such as asystole, PEA, atrial fibrillation, VT with pulse) and ALPS drug administered:* An Alert is auto-triggered if ALPS drug was given and the Enrollment form inclusion criteria indicates VF or pulseless VT was not present after at least one shock. An Alert form is also triggered if ‘no’ is marked on the CPR Process form (Item 7) for ‘was shock given before study drug dose 1’.
- *Study drug dose 1 given via ETT:* Dose 1 includes any portion of either of the first two syringes given back-to-back (one syringe if patient’s estimated weight was < 100 lbs/45 kgs and EMS appropriately gave only one syringe for dose 2) via the endotracheal tube or other advanced advanced airway.
- *Study drug dose 2 given via ETT:* Dose 2 includes any portion of the one syringe given via an

endotracheal tube or other advanced airway.

- *Explain circumstances* : For any item marked as a potential protocol violation, provide details and/or context for the reported issue.

Item 7 - ALPS only: Potential protocol deviation: (check one and explain circumstances)

Protocol ‘deviations’ are generally defined as inadvertent acts in which the protocol was not followed, we ‘wished’ they had not been done, but the patient was not endangered.

Report only one situation per Alert form.

- *Protected population status not known to fire/EMS prior to administration of ALPS drug (check all conditions known prior to administration):* Here report if the patient was less than local legal age of consent, pregnant, or prisoner, and the status was not known to be so by field providers prior to administration of any part of dose 1 ALPS drug. More than one protected status that was known prior to ALPS drug can be reported in this item. A known prisoner is a person who had cardiac arrest while incarcerated at a correctional facility or jail, or who was in police custody (not being pursued). An Alert form is auto-generated when it is marked on the Enrollment form that ALPS given and patient is a protected population (whether or not it was later learned during the prehospital course of care or in the ED/hospital).
- *Weight not known by field to be < 100 lbs (45 kg) and > 1 syringe ALPS drug given for either dose 1 or dose 2:* An Alert form is auto-triggered if the number of syringes reported on the CPR Process form (item #7) for either dose 1 or dose 2 exceeds the limit required for patients < 100 lbs (45 kg). At adjudication of the Alert form, it will be sorted out if documentation of estimated weight in the field was before or after administration of ALPS drug. This item is not intended to capture the circumstance where EMS estimated the patient to weigh ≥ 100 lbs (45 kg), but ED/hospital documentation showed the patient’s weight to be different. This latter circumstance need not be reported on an Alert form; rather, it is separately captured from the data forms and tabulated for routine reporting to the DSMB.
    - Indicate the total number of syringes given for doses 1 and 2 (any portion given of a syringe is counted as 1 syringe).
- *Inclusion/exclusion criteria (other than protected population) not met and ALPS drug given:* An Alert form is auto-triggered if the Enrollment form is marked to indicate ALPS drug given and any exclusion criteria marked (other than protected populations, which are separately handled). Administration of any portion of any syringe constitutes ‘ALPS given’.
- *ALPS kit opened other than in presence of patient:* The site will self-generate an Alert form to report this circumstance. This includes opening of an ALPS kit in a rig on its way to attend to a cardiac arrest; or, tamper seals found broken prior to opening in presence of patient (whether intentional or not). Provide the serial number for the kit. Entering the kit number here will change its status in the ROC inventory system and separate bar-code scanning of the kit is not required. Do not enter a kit # on an Enrollment form for an ALPS kit that was entered other than in the presence of a patient.
- *ALPS kit opened in presence of patient and not given:* An Alert form is auto-generated when the Enrollment form is marked to indicate that an ALPS kit was opened in the presence of a patient, but no amount of study drug was administered. This does not include the situation where more than one ALPS kit was opened (for whatever reason) Provide the study kit # involved and mark which reason best describes the circumstances. Report if the kit was disposed of according to local policy. Describe the circumstances if ‘other’ is selected.
- *More than one ALPS drug kit opened in presence of patient:* An Alert form is auto-generated when the Enrollment form is marked to indicate that more than one ALPS kit was opened in the presence of the patient. Participating rigs are required to carry only 1 ALPS kit at a time.

Opening of more than one kit may (but, should not) occur if a second rig arrives with ALPS stock and mistakenly opens it. If a syringe(s) is cracked/broken or malfunctions, providers are to 'shut the lid and move on'; they are not to open a second kit to start or continue dosing of ALPS. Here provide the kit # of the 'extra' ALPS kit that was opened, but was not given, and provide the reason. Contact the CTC for any other circumstances that involve the opening of more than one ALPS kit in the presence of a patient. The CTC is working to modify/clarify the response options for this Alert form item.

- *Explain circumstances* : For any item marked as a potential protocol deviation, provide details and/or context for the reported issue.

Item 8 - ALPS only: Other potential violation or deviation: (check one and explain circumstances)

Protocol 'deviations' are generally defined as inadvertent acts in which the protocol was not followed, we 'wished' they had not been done, but the patient was not endangered. Protocol 'violations' are generally defined as intentional acts in which the protocol was not followed and it potentially affects the patient. Report only one item per Alert form.

The site is to self-generate an Alert form to report any inadvertent or intentional acts that are not consistent with the ALPS protocol and constitute a violation or deviation as above defined, and for which an Alert form has not been automatically generated by virtue of complete data entry.

Report only one situation per Alert form.

Item 9 - Document ALPS only: Other situation not listed: (check one and explain circumstances)

Report only one situation per Alert form.

- *Study therapy unblended:* If unblinding of study therapy has been provided by the Unblinding Center at the request of a treating physician, provide the date of unblinding. Provide the name of the treating physician that made the request and received the unblinding results.
- *Missing ALPS kit #:* Here enter (with site-generated Alert form) the ID of an ALPs kit that is known to believed to be 'lost and gone forever' and there is little reason to believe it will be found. Submitting that kit ID # will adjust the status of the kit in the ROC inventory and remove it from lists of kits expected to be barcode scanned. Also here enter the ID of ALPS kits for which an Alert form has been auto-triggered for each kit that has not been barcode scanned for more than 120 days. If and when a previously reported missing kit is found, return to the same Alert form where it was reported lost, and enter the date the kit was found. This will return the kit to ROC inventory.
- *Broken/damaged ALPS kit:* Here report the ID of ALPS kits that are damaged outside (crushed, seals broken) or that inside contain one or more damaged syringes. This includes those syringes with cracked tips or barrels, or other external damage visible to the eye. This does not include the situation where the plunger cannot be pushed or pulled and an occlusion of the tip is suspected (this situation is instead to be reported elsewhere as a malfunction). This includes those kits with 3 seals broken due to shearing; If 3 seals opened by EMS intentionally (not on a case), complete self-generated alert for ALPS kit opened other than in presence of a patient. Additionally, this alert applies to kits where the physical barcode will not scan or peel-off labels are missing (and it affects site tracking of kits). Additional details can be found on the Inventory FAQ website (https://roc.uwctc.org/tiki/ROCInventory). Contact the CTC to discuss kit-related situations that arise for which the avenue for reporting is not clear.

- *Other situation:* The site will self-generate an Alert form to here report a situation that is not an 'other protocol violation/deviation' or 'other potential safety issue. If related to an ALPS kit, provide the kit #. Explain the circumstances.
- *Explain circumstances* : For any item marked as a potential protocol deviation, provide details and/or context for the reported issue.

APPENDIX A: History of changes to Manual of Operations

Summary of changes made with each edition of the MOO.

1. **Screening and Enrollment Form**

   June 29, 2011

   a. CTC episode ID—change to format
   b. EMS Response—change to indication of study participation; change to use of 'unknown' and 'non-ROC' rigs for saving a form without errors
   c. Epistry Enrollment—explanation of co-enrollment
   d. CCC Screening—explanation, therapy assignment, inclusion and exclusion criteria

   August 26, 2011

   e. Item 3.c. added—ALPS only, response option added ('Not a cardiac arrest')
   f. Item 6 CCC exclusion criteria—'written' advance directive' clarified
   g. Items 7, 8, 9—ALPS screening criteria titles added

   May 29, 2012

   h. Item 1—EMS Response—Table 2 and narrative updated to include Agency and Vehicle combination (non-participating agency with non-ROC rig) allowed without error.
   i. Item 1 (ALPS only)—ALPS ALPS Drug kit opened or given—distinction what to complete if opened in presence of patient, not in presence of patient, or if more than one kit opened.
   j. Item 3—Episode characteristics—'Treated by EMS' clarified for bystanders.
   k. Items 4-6 (CCC only)—Inclusion/exclusion criteria clarified
   l. Items 7-8 (ALPS only)—Inclusion/exclusion criteria defined

2. **Time Record**

   June 29, 2011

   a. 1st mechanical compression device (CCC only) added
   b. Miscellaneous changes, including renumbering of items

   August 26, 2011

   c. Items 13, 14—ALPS data element titles added ('1st dose ALPS study drug, 2nd dose ALPS study drug)

   May 29, 2012

   d. Time of event—role of electronic chart time clarified as watch or defib times
   e. Time 1st successful IV/IO access—definition clarified
   f. Time 1st and 2nd dose ALPS study drug (ALPS only)—defined

3. **Prehospital Form**

June 29, 2011

a. Item 5, Bystander resuscitation—added dispatch CPR and type bystander performed
b. Item 7, Evidence of bloody fluid in airway—changed from Epistry to 'CCC only' element
c. Item 9, Pre-hospital interventions—type mechanical devices used (CCC only)
d. Item 9, Pre-hospital interventions—advanced airways, documentation of 'success' (CCC only)
e. Item 9, Pre-hospital interventions—IV/IO placements successful, site changed from Epistry to 'CCC only' element
f. Item 9, Pre-hospital interventions—Monitor/advanced clarifications
g. Item 10, Was emesis noted before advanced airway (CCC only) added
h. Miscellaneous changes, including renumbering of items

August 26, 2011

i. Item 4 Cardiac arrest occurred—ALPS only, 'Patient not in cardiac arrest in the presence of fire/EMS' added
j. Item 9 Procedures—corrected location of IV/IO form CCC, to ALPS only

September 21, 2011

k. Item 9, Prehospital intervention by fire/EMS—'Continuation of IV' made independent of 'IV successful'; was fluid given included; ALPS only, location of IV, included.

May 29, 2012

a. Item 9—Prehospital interventions—assessment of successful advanced airway placement (ET and supraglottal) revised to conform with protocol amendment 1.
m. Item 9—IV/IO line—clarified
n. Item 10 (CCC only)—Was emesis noted before advanced airway inserted—clarified if no airway
o. Item 11 (ALPS only)—Possible related adverse events defined
p. Item 12—Drug therapies noted augmented with ALPS only changes

4. **CPR Process Form**

June 29, 2011

a. Change from minute epochs to compression segments and unanalyzable segments
b. Site assessment of CCC compliance

August 26, 2011

c. Item 1 Device info and ECG data—clarification of 'device type'
d. Item 1 ECG recording exists—clarification for marking 'yes'
e. Item 1 File upload—clarification to not upload snapshot ECG files; Note to not upload Philips Event Review Pro 4.0 files
f. Item 2 Were any shocks delivered by fire/EMS responders—pediatric defib placeholder added (will launch with ALPS, though Epistry item)
g. Item 4 Did ECG provide CPR process measurements:
    - pause in compressions changed from > 3 seconds to ≥ 2 seconds (announced previously, effective August 17, 2011) throughout the section;
    - clarification of minutes required for Epistry and CCC/ALPS; directions how to set defaults for Medtronic Codestat 9 to provided required compression segments;
    - voice recording recognized as source for segment Start and Stop Times
    - Scenarios for Start and Stop Times clarified

- Time of shock, if more than two, clarified
- Primary reason for stopping—response options clarified; Mechanical comp device placed, Other, and Compression signal lost added to list (previously announced, effective August 17, 2011)

h. Item 5 Rate and depth compression—'unanalyzable' response option added for minute epochs
i. Item 6.b. CCC compliance—descriptions of 30:2 and CCC conformed to training slides
j. Item 7 ALPS compliance—title added

<u>September 21, 2011</u>

k. Item 4, CPR process measures?—directions modified for how to document the interruption of signal due to change of devices; so as not to unintentionally indicate a prolonged 'pause' in compressions where the gap is due to a loss of ECG signal. Clarification of 'Reasons for Stopping'—'Device change' and 'Compression signal lost.'

<u>December 7, 2011</u>

a. Item 2, "Were any shocks delivered by fire/EMS responders?"—shock details added at request by AHA for patients < 18 years old (joules, source, attenuated cables used).
m. Item 3, "Initial rhythm"—response options for 'Source' expanded to include 'ECG with voice'.
n. Item 4, "CPR process measures"—pick-list for 'Primary reason for stopping' modified: deleted 'Rhythm check', 'Advanced airway',' Moving patient', 'Device change', 'Mech comp device placed'; added 'Shock delivered', 'ROSC'; retained 'Ventilations', 'Shock delivered', 'ROSC', 'Resus stopped', 'Reached ED', 'Other', and 'Compression signal lost'.
o. Item 4, "CPR process measures"—removed column labeled 'rhythm at check or before shock'.
p. Item 4, "Reason determined by?"—added 'ECG with voice' response option.
q. Item 4, "CPR process measures"—directions clarified for how to enter a change of devices.

<u>May 29, 2012</u>

r. Item 7 (ALPS only)—Was any ALPS study drug given?—defined

5. **ED Admit Form**

<u>June 29, 2011</u>

a. Item 4, Did patient arrive at 1st ED with fire/EMS advanced airway in place (CCC only) added
b. Miscellaneous changes, including renumbering of items

<u>August 26, 2011</u>

c. Item 7 Discharge status from final ED—clarification what to do when no discharge time for patients died or transferred

<u>May 29, 2012</u>

d. Item 3 (ALPS only)—ROSC at ED arrival?—defined
e. Item 4—Did patient arrive at 1st ED with advanced airway?—clarified
f. Item 6—Demographics—gender

6. **Hospitalization**

<u>June 29, 2011</u>

a. Item 3, History prior to arrest added (ALPS & CCC)

b. Item 5, First weight documented in hospital added (ALPS only)
c. Item 8, Patient awaken in ED or hospital added (ALPS & CCC)
d. Item 9, Order written for DNR or limited/withdrawn care, more detail (ALPS & CCC)
e. Interim vital status added (ALPS & CCC)

May 29, 2012

f. Item 11—Discharge summary listed conditions—acute liver failure added; 'other' defined; directions for what to do if no Discharge Summary.
g. Item 14 (ALPS only)—Potential IO complications listed in Discharge Summary—defined

7. **Procedures/Observations**

June 29, 2011

a. Item 2B, 1st CXR, assessment of advanced airway placement (CCC only)
b. Item 2C, 1st 12-lead ECG, change from STEM to myocardial injury
c. Item 2J, EEG, specified continuous or discrete test (ALPS & CCC)
d. Item 2K, Anticonvulsant therapy added (CCC only)
e. Item 2L, Head CT added (ALPS & CCC)
f. Item 2M, SSEP added (ALPS & CCC)
g. Item 2N, Hypothermia in ED, reference adjusted
h. Item 2O, Hypothermia in Hospital, reference adjusted
i. Item 2O, Hypothermia in Hospital, internal method specify insertion site (CCC only)
j. Item 2O, Hypothermia in Hospital, location in hospital where started (CCC only)
k. Miscellaneous changes, including renumbering of items

May 29, 2012

a. Item 2D—Fibrinolytics—list of examples revised
m. Item 2 'within 72 hours of first ED arrival'—period clarified
n. Item 2K (CCC only)—Anticonvulsants—list of examples revised
o. Item 2N—Hypothermia in ED—methods clarified
p. Item 4—Glucose control—routes clarified
q. Item 5 (ALPS only)—Potential adverse events—defined
r. Item 6 (ALPS only)—Antiarrhythmic drugs within 2 hours—defined

8. **ROSC and Hypothermia Form—changed from CCC only, to CCC and ALPS**

June 29, 2011

a. Form added (CCC only)

August 26, 2011

b. Item 6 Temperatures during cooling phase of hypothermia—clarification how to respond when patient dies during therapy
c. Item 11 Cooling discontinued prior to assigned time—clarification of how to respond when patient dies during therapy

September 21, 2011--- changes effective in forms as of September 28, 2011

d. Item 5, Time temperatures first documented—rewarming phase threshold temperature changed from ≥ 96.8 F (36 C) to ≥ 98.6 F (37 C)
e. Item 6—Temperatures during cooling phase—response options for 'no temperature data during cooling phase' and 'all available information entered' added. Table expanded from 10

to 12 lines.

f. Item 10—Cooling discontinued—response option ‘patient died prior to completion of cooling therapy’ added. Instructions to ‘stop here’ for further data entry on this form.
g. Item 11—Cooling discontinued prior to assigned time—response option ‘unknown/not noted’ added.
h. Item 12—Temperatures during rewarming phase of therapy—response options ‘no temperature data for rewarming phase’ and ‘all available information entered’ added. Table expanded from 6 to 8 lines

May 29, 2012

i. Item 1—Did the patient have sustained ROSC for at least one hour of first ED arrival?—defined
j. Item 3 –Was hypothermia, other than continuation of prehospital method, started in first ED or hospital?—clarified
k. Item 5—Time temperature targets are first documented—removed, no longer required
l. Item 6—Temperatures during cooling phase of hypothermia therapy—changed from every 6 hours to all temperatures in first 24 hours
m. Item 7—Seadation used during cooling phase of hypothermia—removed, no longer required
n. Item 8—Paralytics used during cooling phase of hypothermia therapy—removed, no longer required
o. Item 9—Diagnostic or monitoring done during cooling or re-warming phase of hypothermia—removed, no longer required
p. Item 11—Cooling discontinued prior to assigned time—removed, no longer required
q. Item 12—Temperatures during re-warming phase of therapy—changed from every 6 hours to all temperatures in first 12 hours of rewarming or reaches 37° C
r. Item 13—Record highest temperature during first 48 hours after cooling stopped—defined

9. **Patient/Family Notification**

June 29, 2011

a. Form added (ALPS & CCC)

November 1, 2011

b. Item 1—Was the patient and/or family/LAR notified that patient was in study?—Response options added. If ‘no’ marked, response options for ‘why not?’ options specified (documented attempts made but unable to reach patient; patient or family/LAR refused in-person notification materials; not feasible to notify dead/unconscious; other/specify).
c. Item 2—After notification did the patient and/or family/LAR withdraw from hospital record review?—Response option deleted. ‘Other/explain’ deleted. Response options limited to ‘no’ or ‘yes’ without contacting the CTC.
d. Item 3—Document and explain attempts to contact patient and/or family/LAR—Caution added for site to not provide personal identifying information where ROC-web documentation of attempted contact is maintained.

May 29, 2012

e. Item 3—Document and explain attempts to notify the patient and/or family/LAR—requirement to document on the ROC-web form, attempts to notify patients or others of enrollment in CCC or ALPS

10. **Alert CTC**

June 29, 2011

a. form added, directions partly complete

May 29, 2012

b. Item 1—Date—defined
c. Item 2—General situations—defined
d. Item 3 (CCC only)—Potential adverse events associated with CCC—defined
e. Item 4 (CCC only)—Potential protocol violation or deviation—defined
f. Item 5 (ALPS only)—Potential adverse events associated with ALPS—defined
g. Item 6 (ALPS only)—Potential protocol violation—defined
h. Item 7 (ALPS only)—Potential protocol deviation—defined
i. Item 8 (ALPS only)—Other potential protocol violation or deviation—defined
k. Item 9 (ALPS only)—Other situation not listed—defined

11. **Attachment D – De-identification, Philips Event Review Pro 4.1**

August 26, 2011

a. Section D added—directions for how to perform de-identification

12. **Miscellaneous changes**

June 29, 2011

a. Overview Cardiac Studies replaces sections for Epistry Overview, Patient Enrollment, Cardiac Arrest Inclusion Criteria, Human Subjects, and Regulatory—readers are referred to individual protocols.
b. Linkage, Multiple Episodes, Site Audit, Closing Case without Discharge Status—miscellaneous.

APPENDIX B: 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)	**Main Coordinator / Principal Investigator**
Name:	Name:
Signature:	Signature:
Date:	Date:

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

APPENDIX C: De-identification, Medtronic CODE-STAT Software

ROC Site Instructions for using Medtronic CODE-STAT soft ware

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.

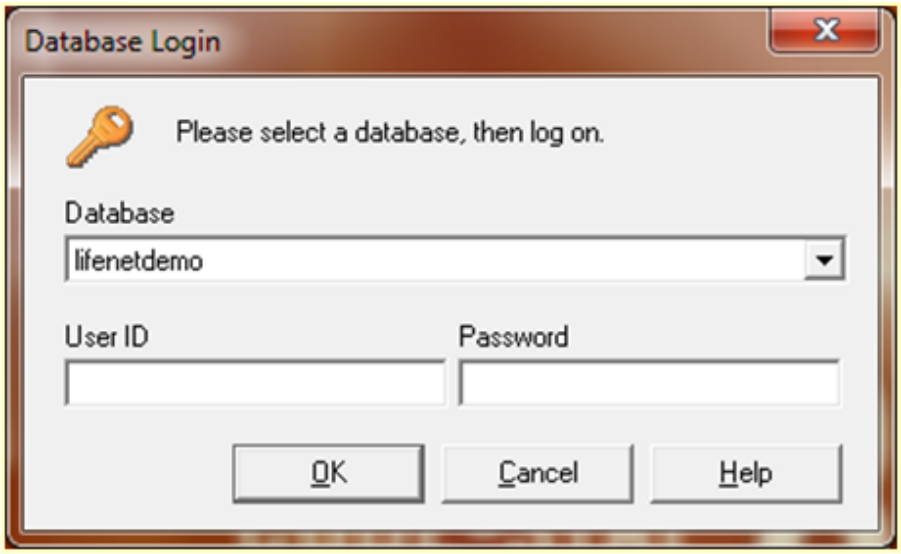
Configuring the Exporter

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:



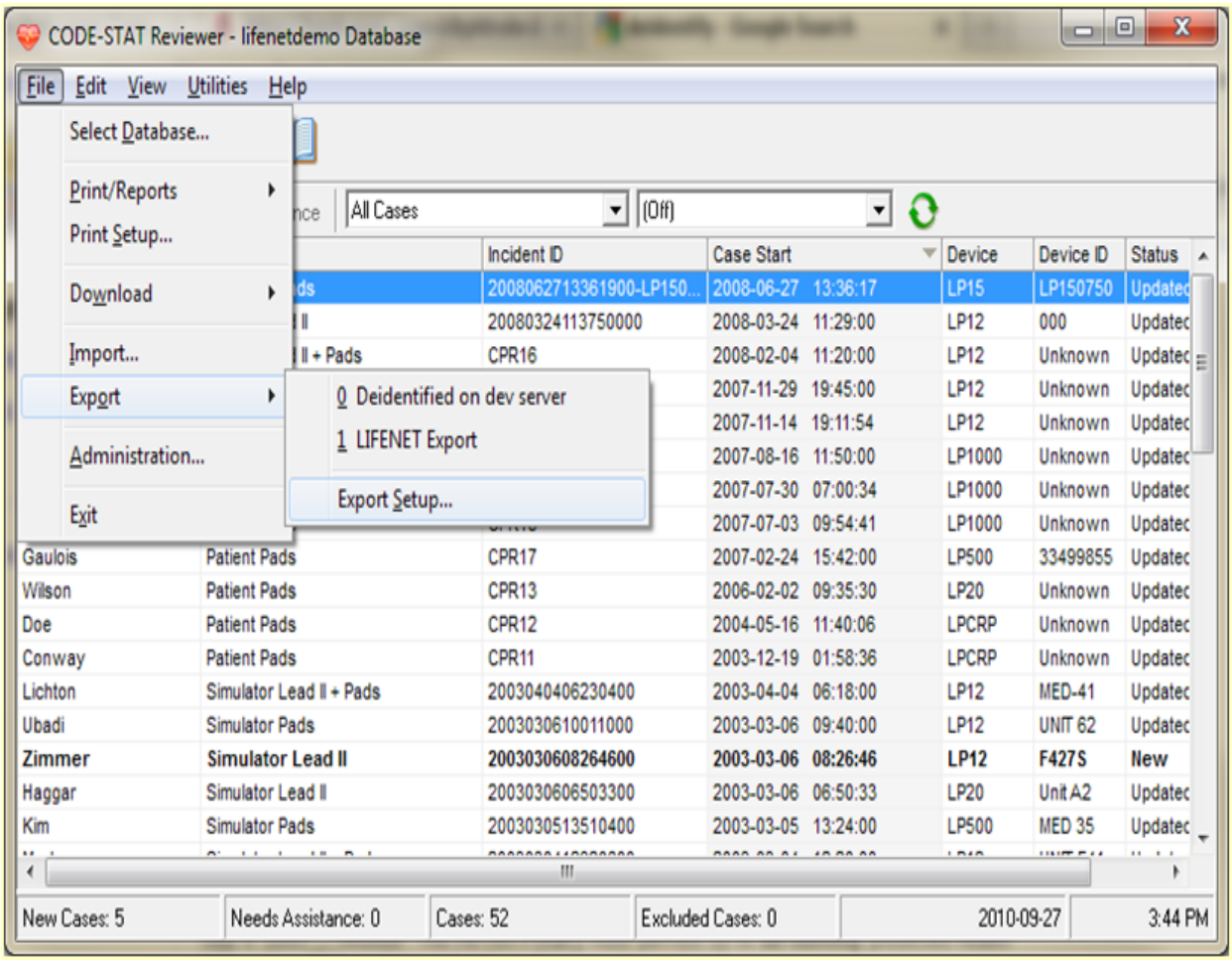
  At the prompt you must select the database that holds the files you will be attaching to ROC cases. This may be different for each site depending on how your site manages ECG files. (The examples here use the ‘lifenetdemo database’ that contains sample cases)

  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
medtronic	ers

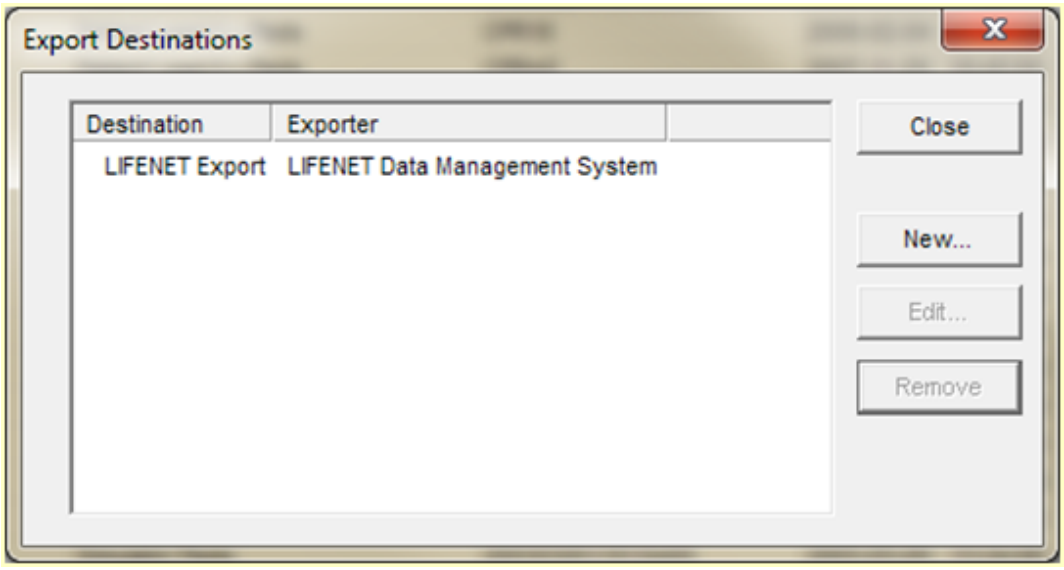
- ***Open the Export Destinations Window***

  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:



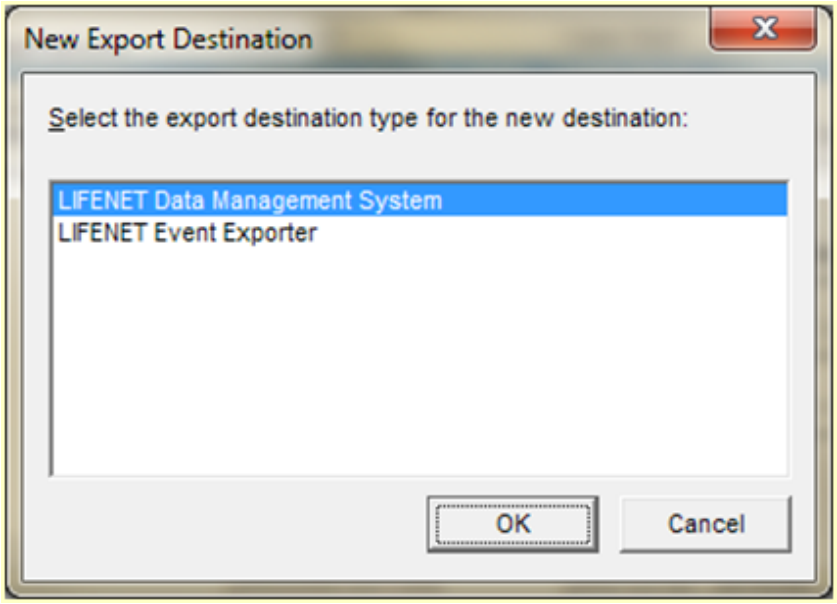
- ***Open the New Export Destination Window***

  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*:

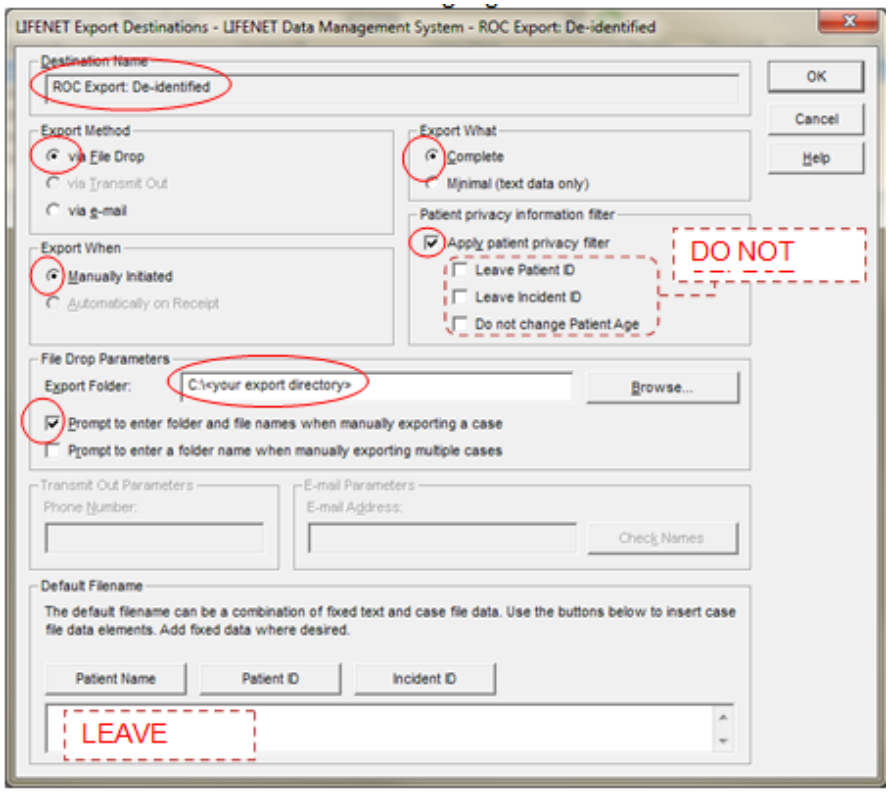


- ***Configure the New Destination***

  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	*Export Folder*: 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. *Prompt to enter folder and file names when manually exporting a case:* 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.) *Prompt to enter a folder name when manually exporting multiple cases:* 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.)
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:

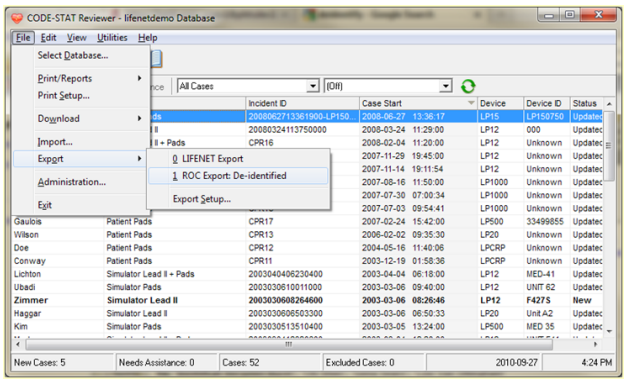


Exporting Files with the ROC Exporter

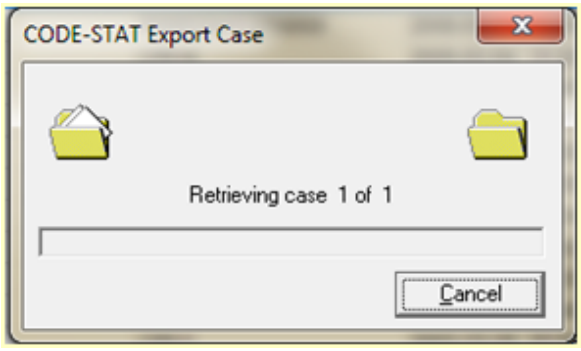
To export a case with the de-identifier configured as above follow these steps:

- ***Open the Case with CODE-STAT Reviewer***

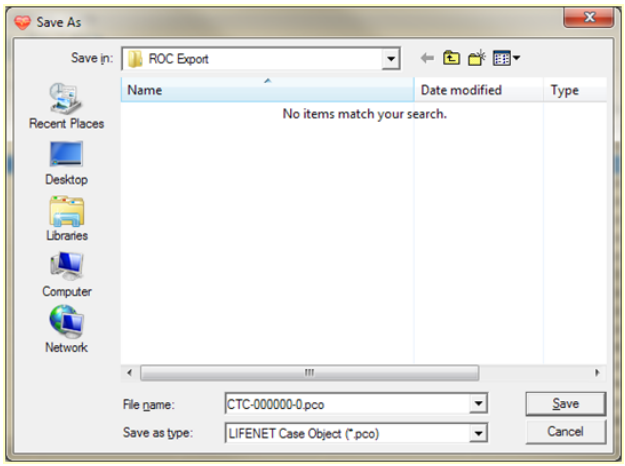
  Open CODE-STAT Reviewer and select the database that holds the ROC case you wish to export. Log in using your normal CODE-STAT Reviewer account. This may be the same as the administrative account that you used in step 1 or it may be different. As mentioned in step 1 your site most likely has its own 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

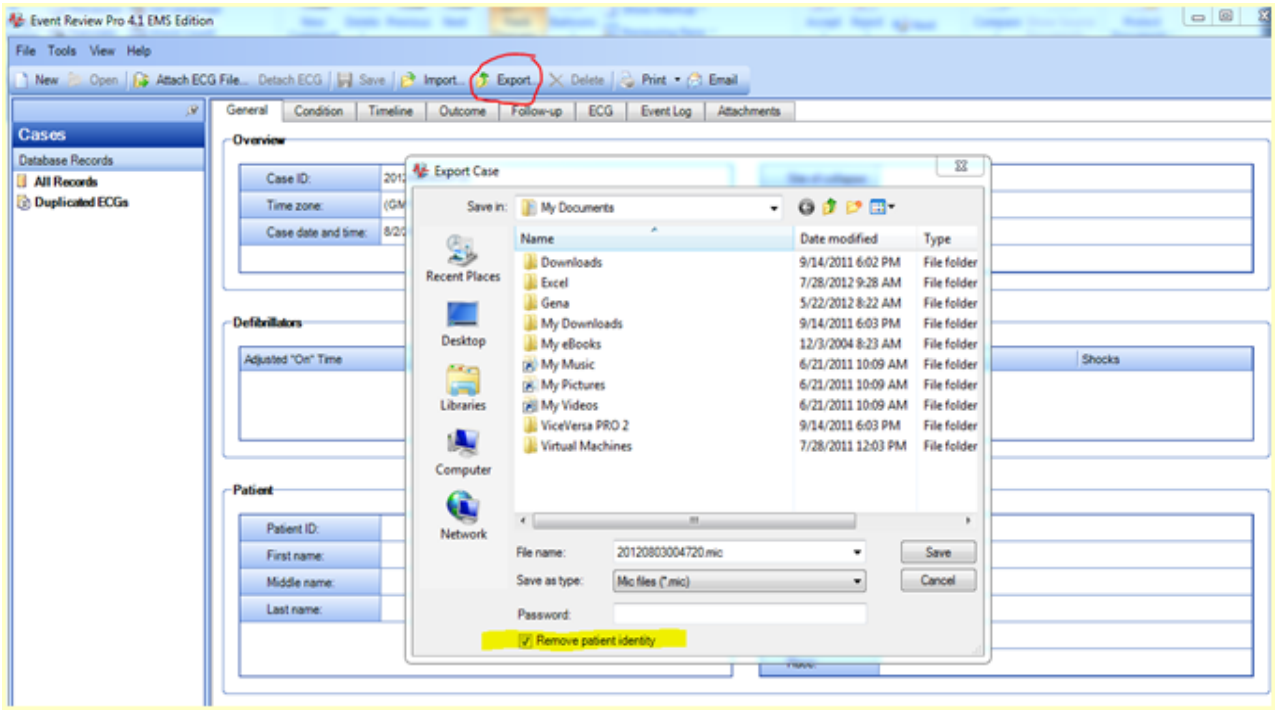
APPENDIX D: De-identification, Philips Event Review Pro, version 4.1 or higher

NOTE for Philips recordings: Do not upload Philips ECG files exported from Event Review Pro, version 4.0. Only QCPR files and files created by Event Review Pro version 4.1 (and higher) are to be uploaded to the ROC-web. When exporting an ECG file from Event Review Pro 4.1 or higher (see below excerpt from Philips operators' manual), select 'Export' (circled) in the top menu bar. The location options for saving the file are displayed (as would occur to save a file of any type to your computer). Select the location to save the file. Check the box titled 'Remove patient identity' located at the base of the file window (highlighted).

With the box checked and the file saved, the file will have been altered as follows (as stated in the Event Review Pro Operator's Manual posted to the Philips website (accessed 2012-8-3):

http://www.healthcare.philips.com/us_en/products/resuscitation/products/event_review_pro_ems/documents.wpd

a. First, middle, and last name are replaced with *** (asterisk)
b. Patient ID is replaced with *** (asterisk)
c. If age > 90, date of birth and age fields are made blank



Event Review Pro User Guide—excerpt on how to export a file:

Exporting a Case

The **Export** option is available on the File menu or toolbar when a case is open. For more information, see Displaying Case Details.

Use **Export** to share information with other Event Review or Event Review Pro users. You can also use **Export** to back up information.

Export does not save the case to the database. Export creates a file outside the application.

You can export a file with encryption or without encryption. If you plan to import a case with the *cod* file extension that you exported from Event Review or Event Review Pro, versions 3.x, Philips Healthcare recommends that you do not encrypt the export file with a password. If you do encrypt a file, anyone attempting to open the file must have the password to open it.

CAUTION

Philips recommends that you record the encryption password and save it in a secure location. If you forget the password, Customer Support cannot "unlock" the file.

To export a case file ▾

1 On the navigation pane, click the **Cases** navigation button.
For more information, see Creating a Case.

2 On the File menu or toolbar, click **Export.**

Event Review Pro displays the Export Case window.

Export displays the last folder you used to export a file. If you want a different location, open the **Save in** list and navigate to the file location.

Event Review Pro limits the list to the supported file types.

3 If you want to remove patient data from the exported file, select the **Remove patient identity** check box.

4 If you accept the default settings, click **Save** and Event Review Pro completes the export.

5 If you need to change the defaults, you make the following changes:

- To save the file in a new location, open the **Save in** list and navigate to the new location.
- To change the default file name, type a name in the **File name** field.
- To encrypt the file with a password, type the password in the **Password** field. Passwords must have a maximum of 16 characters. Passwords are case sensitive.

Event Review Pro saves the file to the My Documents folder or the last visited folder. Event Review Pro uses the case ID as the file name and adds the selected extension. An example of an exported file name is *021804110313.mic*.

6 If you encrypt the file with a password, remember to notify the recipient that the file was encrypted and to provide the password.

7 Click **Save.**

To modify text notes in the Events pane or on the ECG on the Overview or Channels pane, the Philips Event Review Pro Users Guide indicates:

To modify a note in the Events pane

1. Click the note you want to modify.
2. On the toolbar, click Edit Note  .
3. In the Note window, modify the note.
4. Click OK.

To delete a note in the Events pane

1. Click the note you want to delete.
2. On the toolbar, click Delete Note  . The note disappears from the Event pane, the ECG waveform, and the Timeline tab.

It is recommended that after modifying notes and exporting the ECG file (having checked the 'Remove Patient Identity' box), that the site open the exported file and confirm the intended changes to the file

transpired, prior to uploading the ECG file to the ROC-web.

Managing notes on the waveform

You can add, edit, and delete notes on the waveform. You can also use the application toolbar to add notes.

If you want to add a note that is "fixed" on the ECG waveform--that is, its time and date do not change--use the Timeline tab. If you want to add a note whose time and date move according to the Adjusted "On" time, set on the Defibrillators section of the Overview tab, use the ECG menu.

To add a note

1. Click the waveform where you want the note to appear.

   The sweep bar moves to the pointer location.

2. Use one of the following methods:

   - On the ECG menu, click Add Note.
   - On the Events pane toolbar, click Add Note  .
   - Right-click the waveform to display the shortcut menu, and click Add Note.

   The Note window opens, with a table similar to the table on the Timeline tab.

3. Click the Event Name field.
4. On the list of events, click and complete an event from the list the same as when you add events on the Timeline tab.

   For more information, see Documenting events on page 60.

5. Complete the fields, as appropriate.
6. Click OK.

   The note now appears on the waveform, the event tree, and the Timeline tab.

To modify a note

1. On the event tree, click the note that you want to modify.
2. Use one of the following methods:

   - On the Events pane toolbar, click Edit Note  .
   - Right-click the waveform to display the shortcut menu, and click Edit Note.

3. In the Note window, make your modifications to the note.
4. Click OK.

To delete a note

1. Click the note that you want to delete.
2. Use one of the following methods:

   - On the Events pane toolbar, click Delete Note  .

- On the Events pane toolbar, click Delete Note.
- Right-click the waveform to display the shortcut menu, and click Delete Note.

The note disappears from the waveform.

APPENDIX E: Ordering and receiving ALPS inventory

Requests for ALPS study kits are communicated by the site to the CTC (via email or in person) specifying the number of kits needed, the intended agency, and anticipated timeframe of need. CTC will then review the site's inventory status (per the ROC-web), the rate of enrollment, and other circumstances to determine the number of kits that will be shipped. CTC will then place the order directly with Almac Clinical Services (the third-party inventory depot).

Quantities are shipped in 'factors of three' (that is, when kits are shipped, they will be comprised of equal numbers of kits containing either amiodarone, lidocaine, or placebo); this is to maintain 'balance' of study design. All kits are identically packaged and the contents are blinded to everyone (with a very few exceptions at the CTC or when unblinded at the request of a treating physician).

Shipping schedules: Study kits are sent to sites by Fed Ex next-day delivery. Orders are shipped on Monday-Thursday for US orders, and Monday-Wednesday for Canada orders. No shipments leave Almac on Fridays or weekend days. Otherwise, orders are processed for shipment the following Monday (depending on country-specific shipping schedule). Orders received at Almac (via the CTC) prior to 9:00 AM PST (12:00 EST) on a US or Canada shipping day-of-the-week can ship the same day for delivery the next. An advanced request can be made to arrange for shipping to be done on a specific day (such as arrange on Monday to have kits shipped the following Monday). Sites must be prepared to receive shipment on the anticipated date. Automatic email is sent to the site and CTC when Almac ships an order.

Shipping containers and temperature monitoring: ALPS study kits are shipped in special containers that are intended to maintain the temperature inside the package at 15-30 degrees C for 48 hours. A TempTale 4 monitor is included in each package to record temperature excursions including any temperatures above or below 15-30 degrees C, and the length of time out of range. Though the TempTale 4 monitor will indicate if the temperature was out of range during transit, an out-of-range reading does not necessarily mean the ALPS kits cannot be used at your site. It is important to contact the CTC for instructions if the TempTale monitor alarmed (the 'bell' icon is displayed) during shipment. The CTC will confer with Almac to determine if the out-of-range reading precludes clinical use of the associated study kits.

Each container ('shipper') holds a maximum of 32 study kits. Each container weighs approximately 40 lbs (18 kg) with outside dimensions of 27.8 x 23.1 x 22.8 inches (70.6 x 58.7 x 57.9 cm).

Documentation for receipt of ALPS kits: The following steps are to be completed by the site on the day of receipt of ALPS kits from Almac. Each shipping container has a separate Temp Tale monitor and reporting form (one Packing List may include more than one shipping container):

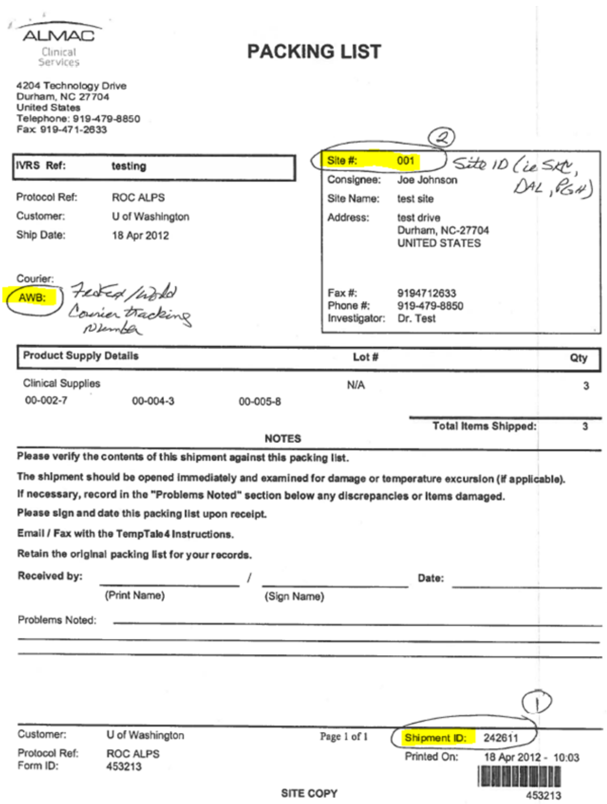
1. Packing list (see below sample)
    a. Compare the ALPS kit ID's listed on the Almac packing list with the contents of the shipment.
    b. Note any discrepancies or damaged kit ID's in the designated field ('Problems noted') at the end of the packing list. If there are any discrepancies or damaged kits, enter the information at the bottom of the packing list under 'Problems Noted.' Sign and date.
    c. If all kit IDs noted on the packing list are contained in the shipment, sign and date.
2. Temp Tale Instructions (see below sample)
    a. Record the information from the TempTale 4 monitor as per the instructions on the form.
    b. If the TempTale4 indicates that it alarmed (the 'bell' icon is displayed) during shipment, return

the monitor to Almac in the provided envelope. If no alarm is indicated, retain the monitor at the site until instructed by CTC that it is no longer needed (do not send the monitor back to Almac).

3. Email documentation to Almac and CTC
    a. Scan both the signed/dated Packing List and the completed TempTale 4 Instructions form and email them to Almac at coldchaindu@almacgroup.com. When emailing to Almac, also ‘cc’ Susan Fisher (jcarson@uw.edu) and Heather Herren (hherren@uw.edu) at the ROC CTC.
4. Retain the original TempTale 4 form and packing list for site inventory records.
5. Scan all ALPS study kits into ROC-inventory system as final confirmation of receipt

Disposition of shipping materials: TempTrack4 monitors are single use items; once the ‘stop’ button is pressed and temperature data displayed, the monitor will not collect further temperature information. Shipping containers are not to be returned to Almac; they may be reused by the site to distribute or store ALPS inventory; or, they may be discarded. The thermal contents of the containers cannot be recycled.

SAMPLE ALPS PACKING LIST



ALMAC
Clinical Services

PACKING LIST

4204 Technology Drive
Durham, NC 27704
United States
Telephone: 919-479-8850
Fax 919-471-2633

IVRS Ref: testing

Protocol Ref: ROC ALPS
Customer: U of Washington
Ship Date: 18 Apr 2012

Courier:
AWB: FedEx/World Courier tracking Number

Site #: 001 (2) Site ID (ie SKC, DAL, PGH)
Consignee: Joe Johnson
Site Name: test site
Address: test drive
Durham, NC-27704
UNITED STATES

Fax #: 9194712633
Phone #: 919-479-8850
Investigator: Dr. Test

Product Supply Details			Lot #	Qty
Clinical Supplies			N/A	3
00-002-7	00-004-3	00-005-8		
			Total Items Shipped:	3

NOTES

Please verify the contents of this shipment against this packing list.
The shipment should be opened immediately and examined for damage or temperature excursion (if applicable).
If necessary, record in the "Problems Noted" section below any discrepancies or items damaged.
Please sign and date this packing list upon receipt.
Email / Fax with the TempTale4 Instructions.
Retain the original packing list for your records.

Received by: ____________ / ____________ Date: ____________
(Print Name) (Sign Name)

Problems Noted: ____________

Customer: U of Washington
Protocol Ref: ROC ALPS
Form ID: 453213

Page 1 of 1

(1) Shipment ID: 242611
Printed On: 18 Apr 2012 - 10:03
453213

SITE COPY

SAMPLE TEMPTALE4 INSTRUCTIONS

ALMAC

University of Washington – Protocol: ROC ALPS
TempTale4 Instructions

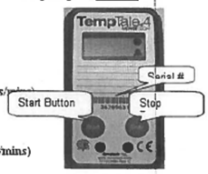
Step 1 – VERIFY and RECORD below the information for the shipping container.
Note: There will be 1 device per shipping container.

Shipment ID #:	(1)	Quantity Received in the Shipper (# of kits):	
TempTale4 Serial #: (located under bar code)		Investigator/ Site #:	(2)
Date Received: (DD/MMM/YYYY)		Time Received: (24-hour format)	
Site Contact Person:		Site Telephone/ Fax:	

Step 2 – STOP the TempTale4 device.
Remove the device from the shipping container. Close the shipping container until readings are taken. Immediately press the red STOP button for 3 seconds until the stop icon appears.

Does the device display a "Bell" icon?	(Please circle one):	NO	YES

Step 3 – RECORD the information from the TempTale4 device display.
Press the green START button for about 5 seconds. The following information will cycle through on the LCD screen of the device. Record the information in the corresponding line below. Pressing the green START button again for about 5 seconds will repeat the cycle of information.



_____ **Average temperature (°C)**

_____ **Highest temperature reached (°C)**

_____ **Cumulative amount of time above the high limit alarm (hrs/mins)**

_____ **Lowest temperature reached (°C)**

_____ **Cumulative amount of time below the low limit alarm (hrs/mins)**

Step 4 – Within 48 hours scan and email the Packing List to coldchainteamdu@almacgroup.com and sfisher@uw. edu and gkroeze@uw.edu OR fax to U of Washington at 206-543-0131 and Almac at 919-471-2633. HHERREN@UW.EDU

Step 5 – Immediately TRANSFER the kits to controlled room temperature storage.

Step 6 – If the monitor ALARMED (bell icon will be displayed), the product must be QUARANTINED in a controlled room temperature environment and approval obtained from Almac Clinical Services in order to utilize the product. Return the temperature monitor with the Return Airway bill and Envelope provided with the shipment. If the monitor did NOT alarm do not send the monitor back but retain it at the site until you receive instructions from the CTC to dispose of the monitor.

Contact: 1107 NE 45th St, Suite 505, Seattle, WA 98105-4680 800-332-0586, 206-685-1302 Fax 206-543-0131 rochelp@uwctc.org