ECLS Registry Form

Extracorporeal Life Support Organization (ELSO)

Please refer to the ELSO Registry Data Definitions Document for Details

Unique ID: _____ Birth Date: _____
(include time for neonates)

Sex: _____ (M, F, unknown) Race: _____(Asian, Black, Hispanic, White, Middle Eastern or North African, Native American, Native Pacific Islander, Other, Unknown)

Run Information

Date/Time On: _____ Date/Time Off: _____ Support Type: ☐ Pulmonary ☐ Cardiac ☐ ECPR
Run No: _____
Weight (kg): _____ Height (cm): _____

Intubation:
☐ Yes, Date Known: _____
☐ Pre-existing Trach: _____
☐ Yes, Date Estimated: _____
☐ Yes, Date Unknown
☐ No

Invasive Ventilation:
☐ Yes,New Date/Time: _____
☐ Pre-existing Ventilation: _____
☐ Yes, Date/Time Estimated: _____
☐ Yes, Date/Time unknown
☐ No

Neonatal patients only:

Birth weight (kg): _____ Gestational age: _____
Apgar (1 min): _____ Delivery: _____ (Vaginal, ER or Elective C-section, Unknown)
Apgar (5 min): _____ Maternal age: _____
CDH: ☐ Y ☐ N ☐ Unknown CDH Prenatal diagnosis: ☐ Y ☐ N ☐ Unknown
CDH Side: _____ (Right,Left,Bilateral, Unknown)
Repair: _____ (None, Pre-ECLS,On ECLS, Post-ECLS)

Pre-ECLS Assessment

ABG: Closest to/before ECLS, no more than 6 hours before ECLS

Date/Time: _____
FiO2 (at ABG draw): _____(%)
Lactate: _____
pH: _____ Unknown? ☐
PaCO2: _____
PaO2: _____
HCO3: _____Unknown? ☐
SaO2(%): _____
SpO2 (%): _____

Vent Settings: Closest to/before ECLS, no more than 6 hours before ECLS

No Ventilator in use: ☐
Date/Time: _____
Vent Type: _____
Rate/Hz: _____
PIP/Ampl: _____
PEEP: _____
MAP: _____
Hand bagging: ☐ Y ☐ N ☐ Unknown
(Select if hand bagged beginning in the 6hrs pre ECLS AND continuing to the time of cannulation)

Hemodynamics (Closest to and before ECLS start, ideally no more than 6 hours before ECLS start)

Date/Time: _____ SBP Unknown? ☐

BP: _____ _____ _____ SvO2: _____ PCWP: _____
Systolic Diastolic Mean

PAP: _____ _____ _____ CI: _____
Systolic Diastolic Mean

Pre ECLS Support

Hospital Admit Date/Time: _____

☐ Transported on ECMO ☐ Transported not on ECMO ☐ Not Transported ☐ Unknown

Pre-ECLS cardiac arrest: ☐ Y ☐ N ☐ Unknown

Bridge to transplant: ☐ Y ☐ N ☐ Unknown

Is Trauma the underlying reason for ECLS? ☐ Y ☐ N ☐ Unknown

Mechanical Cardiac Support (Select those used or in place within 24 hours pre ECLS)

☐ Berlin Heart ☐ BiVAD ☐ Cardiac pacemaker ☐ Cardiopulmonary bypass (CPB) ☐ Intra-aortic balloon ☐ LVAD
☐ Perc Ventricular Assist Device ☐ RVAD

Renal, Pulmonary and Other Support (Select those used or in place within 24 hours pre ECLS)

☐ Inhaled Anesthetic ☐ Inhaled Epoprostenol (>6 hours) ☐ Inhaled Nitric oxide (>6 hours) ☐ Liquid ventilation ☐ Plasmapheresis
☐ Prone Positioning (>16 hours) ☐ Renal Replacement Therapy ☐ Surfactant ☐ Therapuetic Hypothermia < 35 degrees C

Medications Excluding Vasoactives (Select those used or in place within 24 hours pre ECLS)

☐ Alprostadil ☐ IV Bicarbonate ☐ Epoprostenol (all synthetic prostacyclin analogues) ☐ Narcotics ☐ Neuromuscular blockers
☐ Sildenafil ☐ Systemic Steriods ☐ THAM

Vasoactive Infusions (Select those used within 24 hours AND continuously for 6 hours pre ECLS)

☐ Dobutamine ☐ Dopamine ☐ Enoximone ☐ Epinephrine ☐ Esmolol ☐ Levosimendan ☐ Metaraminol ☐ Metoprolol
☐ Milrinone ☐ Nicardipine ☐ Nitroglycerin ☐ Nitroprusside ☐ Norepinephrine ☐ Phenylephrine ☐ Tolazoline ☐ Vasopressin

ECLS Assessment

Arterial Blood Gas

Closest to 24 hours after ECLS start, but no less than 18 hours and not more than 30 hours after ECLS start

Date/Time: _____
FiO2 (at ABG draw): _____(%)
Lactate: _____
pH: _____ Unknown? ☐
PaCO2: _____
PaO2: _____
HCO3: _____ Unknown? ☐
SaO2(%): _____
SpO2 (%): _____

Ventilator Settings

No Ventilator in use: ☐
Date/Time: _____
Vent Type: _____
Rate/Hz: _____
PIP/Ampl: _____
PEEP: _____
MAP: _____
Hand bagging: ☐ Y ☐ N ☐ Unknown

Hemodynamics Closest to 24 hours after ECLS start, but no less than 18 hours and not more than 30 hours after ECLS start

Date/Time: _____ (Select option if SBP/DBP is unavailable or unknown)

BP: _____ (Systolic) _____ (Diastolic) _____ (Mean) SvO2: _____ PCWP: _____

PAP: _____ (Systolic) _____ (Diastolic) _____ (Mean) CI: _____

Blood Pump Flow Rates (L/min)

Pump flow at 4 hours: _____ Pump flow at 24 hours: _____

ECLS Care

Unit Where Majority of ECLS Care Received

☐ Adult Medicine ICU ☐ Adult Surgical ICU ☐ Adult Cardiac ICU ☐ Adult Cardiovascular ICU ☐ ECLS ICU ☐ Emergency Department
☐ Mixed ICU ☐ Neonatal ICU ☐ Pediatric ICU ☐ Pediatric Cardiac ICU ☐ Operating Room/Cath Lab ➡ Initiated for procedure? Yes No

Nutrition and Mobility

Enteral Feeding Date/Time (started and continued for at least 2 days) _____

Level of Mobilization at day 7 of ECLS (>8 years)	Maximum Level Achieved During ECLS (>8 years)
☐ 0 Nothing (lying in bed)	☐ 0 Nothing (lying in bed)
☐ 1 Sitting in bed, exercises in bed	☐ 1 Sitting in bed, exercises in bed
☐ 2 Passively moved to chair (no standing)	☐ 2 Passively moved to chair (no standing)
☐ 3 Sitting over edge of bed	☐ 3 Sitting over edge of bed
☐ 4 Standing (with or without assist)	☐ 4 Standing (with or without assist)
☐ 5 Transferring bed to chair	☐ 5 Transferring bed to chair
☐ 6 Marching on spot (at bedside)	☐ 6 Marching on spot (at bedside)
☐ 7 Walking with assistance of 2 or more people	☐ 7 Walking with assistance of 2 or more people
☐ 8 Walking with assistance of 1 person	☐ 8 Walking with assistance of 1 person
☐ 9 Walking independently with a gail aid	☐ 9 Walking independently with a gail aid
☐ 10 Walking independently without a gait aid	☐ 10 Walking independently without a gait aid

Mode and Cannulations

Initial Mode of ECLS

ECLS Start Date/Time: _____ ECLS/Mode Stop Date/Time: _____

ECLS mode: ☐ V-A (Venoarterial) ☐ V-V (Venovenous) ☐ V-VA (Veno - venoarterial) ☐ A-VCO2R
☐ VV-ECO2R ☐ Other ☐ Unknown

Cannulas Placed for the Initial Mode of ECLS

	Cannula #1	Cannula #2	Cannula #3	Cannula #4	Cannula #5
	Note: Times will autopopulate with time on and off ECLS. Only note new date/time for cannulas placed/removed during the run.				
Start Date/Time					
End Date/Time					
Manufacturer					
Cannula Model/Size					
Pre-Existing?					
Percutaneous?					
Site (Note if Drain Y/N)					
Replaced?					
Reason?					

Please see the Data Definitions document for specific fields' definitions.

Equipment

Membrane Lung	#1	#2	#3
Start Date/Time			
End Date/Time			
Manufacturer			
Device			
Membrane Replaced? Reason?			
Blood Pump	**#1**	**#2**	**#3**
Start Date/Time			
End Date/Time			
Manufacturer			
Device			
Pump Replaced? Reason?			

Other Equipment	Manufacturer	Device
Heat Exchanger		
Hemofilter		
Temp Regulation Device		

Membrane Lung	#4	#5	#6
Start Date/Time			
End Date/Time			
Manufacturer			
Device			
Membrane Replaced? Reason?			
Blood Pump	**#4**	**#5**	**#6**
Start Date/Time			
End Date/Time			
Manufacturer			
Device			
Pump Replaced? Reason?			

Other Equipment	Manufacturer	Device
Heat Exchanger		
Hemofilter		
Temp Regulation Device		

Duplicate this page as required for multiple changes

Add New Mode Conversion (this section to be used only for mode conversions – must enter a Stop Date/Time for the initial mode)

ECLS Start Date/Time: _____ ECLS/Mode Stop Date/Time: _____

ECLS mode: ☐ V-A (Venoarterial) ☐ V-V (Venovenous) ☐ V-VA (Veno venoarterial) ☐ A-VCO2R
☐ VV-ECCO2R ☐ Other ☐ Unknown

Cannulas Placed for this Mode of ECLS

	Cannula #1	Cannula #2	Cannula #3	Cannula #4	Cannula #5
	Note: Times will autopopulate with time on and off ECLS. Only note new date/time for cannulas placed during the run.				
Start Date/Time					
End Date/Time					
Manufacturer					
Cannula Model/Size					
Pre-Existing?					
Percutaneous?					
Site (Note if Drain Y/N)					
Replaced?					
Reason?					

Add Another Mode Conversion (this section to be used only for mode conversions – must enter a Stop Date/Time for the previous mode)

ECLS Start Date/Time: _____ ECLS/Mode Stop Date/Time: _____

ECLS mode: ☐ V-A (Venoarterial) ☐ V-V (Venovenous) ☐ V-VA (Veno venoarterial) ☐ A-VCO2R
☐ VV-ECCO2R ☐ Other ☐ Unknown

Cannulas Placed for this Mode of ECLS

	Cannula #1	Cannula #2	Cannula #3	Cannula #4	Cannula #5
	Note: Times will autopopulate with time on and off ECLS. Only note new date/time for cannulas placed during the run.				
Start Date/Time					
End Date/Time					
Manufacturer					
Cannula Model/Size					
Pre-Existing?					
Percutaneous?					
Site (Note if Drain Y/N)					
Replaced?					
Reason?					

Duplicate this page as required for multiple mode changes

ICD-10 Diagnoses

Primary Diagnosis: _____(check box as primary)

Secondary Diagnoses: (unlimited)	

CPT Procedure Codes (List all relevant procedures related to the patient even if preceding this admission)

Date/Time	Estimated? Y/N	Code/Procedure

ECLS Complications (Refer to ELSO Data Definitions for Specific Details)

Enter multiple complications of the same type by 'add new complication' with new date/time.
Complications that 'continue' for several days only need the first date of occurrence.

Date/Time	Mechanical	Definition
	Oxygenator Failure	*Requiring change due to clot formation or gas exchange failure or blood leak*
	Pump Failure	*Requiring hand cranking or pump exchange*
	Raceway Rupture	*In a roller pump rupture of the raceway tubing*
	Other Tubing Rupture	*Rupture of ECLS tubing*
	Cannula Problems	*Requiring intervention (reposition or exchange) for misplacement, dislodgement, replacement due to clots/fibrin, mechanical failure or inappropriate position*
	Circuit Change	*Entire circuit (with exception of cannulae) changed due to clot formation or mechanical failure*
	Heat Exchanger Malfunction	*Malfunction of heat exchanger leading to unintentional hypothermia <35C or hyperthermia >39*
	Thombosis/Clots: Circuit Component	*Circuit component (e.g. pigtails, connectors, bridge, arterial or venous tubing) requiring change due to clot formation or mechanical failure*
	Clots Hemofilter	*Clots in hemofilter causing hemofilter to need to be changed or to fail*
	Air in Circuit	*Requiring circuit intervention or circuit clamping for bubble detector alarm, visualized air, air entry into patient*

Date/Time	Hemorrhage	Definition
	GI Hemorrhage	*Upper or lower GI hemorrhage requiring PRBC transfusion (>20ml/kg/24 hrs of PRBCS or >3U PRBCs/24 hrs in neonates and pediatrics or >3U PRBCS/24 hrs in adults), and/or,* *endoscopic intervention, and/or hemostatic agent deployment*
	Peripheral Cannulation Site Bleeding	*Select this complication if there is bleeding from a peripheral cannulation site such as the neck, groin, or axilla.* *Peripheral cannulation site bleeding requiring PRBC transfusion (>20ml/kg/24 hrs of PRBCS or >3U PRBCs/24 hrs in neonates and pediatrics or >3U PRBCS/24 hrs in adults) and/or, surgical intervention (includes intravascular hemostatic agent deployment).* *A reperfusion cannula is a type of peripheral cannulation site.*
	Mediastinal Cannulation Site Bleeding	*Select this complication if there is bleeding from cannulae that are placed across the mediastinum.* *Mediastinal cannulations are also referred to as central cannulations and are placed via their mediastinum. Mediastinal cannulation site bleeding requiring PRBC transfusion (>20ml/kg/24 hrs of PRBCS or >3U PRBCs/24 hrs in neonates and pediatrics or >3U PRBCS/24 hrs in adults, and/or surgical intervention.*
	Surgical Site Bleeding	*Select this complication if there is bleeding from a surgical site other than mediastinal or peripheral cannulation site.* *Requiring PRBC transfusion (>20ml/kg/24 hrs of PRBCS or >3U PRBCs/24 hrs in neonates and pediatrics or >3U PRBCS/24 hrs in adults), and/or surgical intervention*

Date/Time	Neurological	Definition
	Brain Death	*Select this complication if a patient suffered brain death or neurological determination of death.* Please refer to Data Definitions for specific criteria.

Date/Time	Neurological	Definition
	Seizures Clinically Determined	*Clinically determined by assessment*
	Seizures Confirmed by EEG	*Confirmed by Electroencephalograph*

Date/Time	Neurological	Definition
	CNS Diffuse Ischemia (CT/MRI)	*CT or MRI demonstrating diffuse ischemic changes*
	CNS Infarction (US or CT or MRI)	*CT or US or MRI demonstrating localized ischemic change*
	Intra/extra Parenchymal CNS Hemorrhage (US or CT or MRI)	*May be intraparenchymal, subdural or subarachnoid*
	Intraventricular CNS Hemorrhage (US or CT or MRI)	*>= Grade 2 IVH on US, CT or MRI*
	Neurosurgical intervention performed	*Neurosurgical procedure performed during ECLS run (e.g. intracranial pressure monitor, external ventricular drain, craniotomy)*

Date/Time	Renal	***Definition***
	Creatinine 1.5 – 3.0	*After ECMO start time, patient newly acquires a creatinine serum measurement of 1.5- 3.0*
	Creatinine > 3.0	*After ECMO start time, patient newly acquires a creatinine serum measurement of >3.0*
	Renal Replacement Therapy Required	*Peritoneal Dialysis (PD), Continuous Venovenous Hemodiafiltration (CVVHD), Continuous Venovenous Hemofiltration (CVVHF) or Continuous Venovenous Hemodiafiltration (CVVHDF) or Hemodialysis (HD) based on the patient's ultimate mode of therapy*

Date/Time	Cardiovascular	***Definition***
	CPR Required	*Chest compressions and cardiopulmonary resuscitation required during ECLS run*
	Cardiac Arrhythmia	*Requiring antiarrhythmic medication infusion, overdrive pacing, cardioversion or defibrillation*
	Tamponade (not blood)	*Tamponade during ECLS run requiring pericardial drain or mediastinal washout*
	Tamponade (blood)	*Tamponade during ECLS run requiring pericardial drain or mediastinal washout*

Date/Time	Pulmonary	Definiton
	Pneumothorax	*Requiring insertion of chest drain*
	Pulmonary Hemorrhage	*Requiring pRBC transfusion(>20ml/kg/24 hrs of PRBCS or >3U PRBCs/24 hrs in neonates and pediatrics and >3U PRBCS/24 hrs in adults)*

Date/Time	Metabolic	***Definition***
	Hyperbilirubinemia	*For neonatal patients (< 28 days) = conjugated bilirubin >20umol/L (>1.2mg/dL).* *For pediatric (>30days) or adult patients = total bilirubin >170umol/L (> 10mg/dL) or conjugated bilirubin >51umol/L (>3mg/dL),* *Or need for extracorporeal purification for elevated bilirubin*
	Moderate Hemolysis	*Peak plasma hemoglobin 50-100 mg/dL or 500-1000 mg/L occurring at least once during ECLS run. Sustained for at least 2 consecutive days*
	Severe Hemolysis	*Peak plasma hemoglobin > 100mg/dL or >1000 mg/L occurring at least once during ECLS run. Sustained for at least 2 consecutive days*

Date/Time	Patient Limb	***Definition***
	Fasciotomy	*Fasciotomy performed secondary to compartment syndrome from ECLS cannulation (fasciotomy performed during ECLS hospitalization)*
	Limb Amputation	*Limb amputation secondary to complications from ECLS run (amputation performed during ECLS hospitalization)*
	Limb Ischemia Requiring Limb Reperfusion Cannula	*Post peripheral cannulation, requiring addition of limb reperfusion cannula >=6 hrs post cannulation*

Infections (pre and those occurring on ECMO)

Date/Time/Estimated?	Culture Site	Organism Type	Organism

Sites: Blood, Bone, Cerebrospinal fluid, Peritoneal fluid, Pleural fluid, Respiratory tract, Skin/soft tissue, Stool, Urine, Wound – surgical, Wound – traumatic, Other, Unknown

Type: All, Unknown, Gram + Bacteria, Gram – Bacteria, Mycobacterium, Fungus (yeast and mold), Viruses and Prions, Protozoa

Organisms are listed in the Data Definiitons. If an organism is not listed, please contact prycus@elso.org

Outcomes

Discontinuation Reason (Why the patient was separated from ECLS)

- ☐ Unknown
- ☐ Expected recovery
- ☐ Poor prognosis
- ☐ Resource limitation
- ☐ ECLS complication
- ☐ Transition to VAD Support
- ☐ Pumpless Lung Assist (Pa to LA)
- ☐ Heart transplant
- ☐ Lung transplant
- ☐ Heart and lung transplant

Cannulation Repair

- ☐ None
- ☐ Internal Jugular Vein
- ☐ Other
- ☐ Common Carotid Artery
- ☐ Both Carotid and Jugular

Extubated

- ☐ Endotracheally extubated ≥ 48 hrs
- ☐ N/A - Transferred intubated
- ☐ N/A - Other
- ☐ N/A - Tracheostomy
- ☐ N/A - Intubated at time of death

Oral Endotracheal Tube Removed Date/Time: _____

Discharged Alive

☐ Yes ☐ No ☐ On ECMO

ICU Discharge Date/Time: _____

Hospital Discharge Date/Time: _____

Death Date/Time: _____

Discharge Location

- ☐ Home
- ☐ Transferred to Other Hospital
- ☐ Other
- ☐ Transferred to Long Term Care or Rehab
- ☐ Transfer to Hospice
- ☐ Unknown

Form completed by: _____ *Completed date is automatically added when you submit the run.*
Select Validate Data – to assure mandatory fields complete, dates are correct.
Select Submit and Lock – to finalize the record and submit to ELSO.

Supplemental Table 1: Complications

Mechanical: Oxygenator failure
Mechanical: Raceway rupture
Mechanical: Other tubing rupture
Mechanical: Pump Failure
Mechanical: Heat exchanger malfunction
Mechanical: Clots: hemofilter
Mechanical: Air in circuit
Mechanical: Cannula problems
Mechanical: Circuit change
Mechanical: Clots and Air Emboli
Mechanical: Thrombosis/Clots: circuit component
Hemorrhagic: GI hemorrhage
Hemorrhagic: Surgical site bleeding
Hemorrhagic: Peripheral cannulation site bleeding
Hemorrhagic: Mediastinal cannulation site bleeding
Neurologic: Brain death
Neurologic: Seizures: clinically determined
Neurologic: Seizures Confirmed by EEG
Neurologic: CNS Infarction (US or CT or MRI)
Neurologic: Intraventricular CNS hemorrhage (US or CT or MRI)
Neurologic: Intra/extra parenchymal CNS Hemorrhage (US or CT or MRI)
Neurologic: CNS diffuse ischemia (CT/MRI)
Neurologic: Neurosurgical intervention performed
Renal: Creatinine 1.5 - 3.0
Renal: Creatinine > 3.0
Renal: Renal Replacement Therapy Required
Cardiovascular: CPR required
Cardiovascular: Cardiac arrhythmia
Cardiovascular: Tamponade (blood)
Cardiovascular: Tamponade (not blood)
Pulmonary: Pneumothorax requiring treatment
Pulmonary: Pulmonary hemorrhage
Infectious: WBC < 1,500
Metabolic: Hyperbilirubinemia
Metabolic: Moderate hemolysis
Metabolic: Severe hemolysis
Limb: Ischemia
Limb: Compartment Syndrome
Limb: Fasciotomy
Limb: Amputation

Supplemental Table 2: Missing data

Patient Characteristics	On-hours (n = 4331)	Off-hours (n=5069)
Sex	1%	2.8%
Age	0%	0%
Race	0%	0%
Time from admission to intubation	7.1%	8.9%
Time from intubation to ECLS	6.7%	8.7%
Pre ECLS characteristics		
Systolic blood pressure	25.6%	21.6%
pH	16.5%	15.4%
pCO2	17.0%	16.1%
pO2	17.5%	16.4%
CPB	0%	0%
ECLS run characteristics		
Mode	0.9%	1.2%
Support type	0%	0%

CPB = cardiopulmonary by-pass

Supplemental Table 3: Results of multivariable model for different outcomes for off hours versus on hour cannulation not including predictors that were missing in >10% (n=8497)

Outcomes	Model	Point estimate	95% CI	p-value
Hospital mortality	logistic	0.99	0.91-1.09	0.99
Any complication	logistic	10.7	0.94-1.22	0.29
Number of complications	linear	0.03	-0.06-0.13	0.49
Specific complications*				
Mechanical	logistic	1.09	0.91-1.30	0.19
Hemorrhagic	logistic	0.99	0.84-1.17	0.90
Neurologic	logistic	1.22	0.99-1.48	0.006
Renal	logistic	1.0	0.82-1.23	0.96
Cardiovascular	logistic	1.02	0.85-1.22	0.85
Pulmonary	logistic	0.96	0.76-1.23	0.68
Metabolic	logistic	0.93	0.76-1.33	0.31
Limb	logistic	0.83	0.30-2.31	0.62
Hours on ECLS	competing risk	1.0	0.95-1.06	0.93
LOS	competing risk	1.02	0.97-1.08	0.46

*Bonferroni correction for specific complications, p-value < 0.006, 99.4% CI

LOS = length of stay
Adjusted for age, sex, race, ECLS type (pulmonary, cardiac, ECPR), time to intubation, time from intubation to ECLS, number of CCC, number of inotropes/vasopressors
All models took clustering on center level (random effect) into account
Point estimate for logistic model is odds ratio, for linear model is the linear coefficient and for LOS sub-hazard ratio for discharge, for hours on ECLS it is the sub-hazard ratio for coming off ECLS

Supplemental Table 4: P-values for interaction between on/off hour cannulation, mortality and complications (complete case analysis, n=6144)

Outcome	**Mortality**	**Any complications**	**Number of complications**	**Hours on ELCS**	**LOS**
Mode					
VV	reference	reference	reference	reference	reference
VA	0.80	***0.019****	0.20	0.47	0.59
Type					
Pulmonary	reference	reference	reference	reference	reference
Cardiac	0.41	0.56	0.82	0.79	0.80
ECPR	0.83	0.11	0.71	0.79	0.67

Adjusted for age, sex, race, time to intubation, time from intubation to ECLS, number of CCC, pre-ecls blood pressure, pH and pO2

All models took clustering on center level into account