



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

General Principles for using ELSO Registry data for Publication

1. ELSO supports the use of ELSO Registry data for research to improve the care of ECMO patients.
2. Released data must only be used to test the hypotheses included in the study proposal.
3. Investigators are allowed 12 months of exclusive access to the data for the questions articulated in the proposal, with the following caveats.
4. I agree to only publish one (1) manuscript from this data request. This does not include abstracts for scientific meetings.

All requests for ELSO Registry data constitute my own work and that of the co-investigators included in this request. By submitting this data request form, I acknowledge and agree to the [ELSO Policy on Data](#). Please email the completed data request form to ELSODataRequest@elso.org.

Internal ELSO Registry Number (<i>ELSO will complete this part</i>)	
	Number

ADMINISTRATIVE INFORMATION (<i>Investigator has to complete all fields</i>)	
PROJECT and corresponding contact	
Principal Investigator(s)	Joseph G. Kohne, MD MSc
Organization	University of Michigan
Telephone number (cell)	513-484-8334
Email address of Principal Investigator(s)	jkohne@med.umich.edu
Co-Investigator(s) (please include role and ELSO Site)	Ryan Barbaro, MD (senior author), UM Phil Boonstra, PhD (statistician), UM Graeme MacLaren, MBBS, National University Hospital, Singapore Matthew Friedman, MD MS, Riley Children's Hospital Lakshmi Raman, MD, University of Texas Southwestern Natalie Rintoul, MD, Children's Hospital of Philadelphia Adam Vogel, MD, Texas Children's Hospital Peta Alexander, MBBS, Boston Children's Hospital
Any additional person who will have access to the data?	Additional persons
ELSO CENTER	
Name of Center Director / Coordinator requesting data	Ryan Barbaro, MD
Email address of Director / Coordinator	barbaror@med.umich.edu
Electronic Signature of Center Director / Coordinator	Ryan P. Barbaro
Date	9/20/2022
ELSO Center Name	University of Michigan
ELSO Center Number	1
DATA USE	
Publication in a peer-reviewed journal (yes/no)	Yes
Anticipated journal of submission? (specify)	Critical Care Medicine



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

I have existing data requests from ELSO? (yes/no) <i>If yes, provide updates for any released dataset</i>	No
--	----



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

Study Title	
	Impact of Changing Cannulation Strategies on Neurologic Injury in Infants with Respiratory Failure

Overall Study Objective	
	There has been increasing use of venoarterial (VA) ECMO for infants with respiratory failure, up to 92% of neonatal respiratory support in 2021. We seek to leverage the increased use of VA ECMO in this cohort to enrich an evaluation of the differences in rate of intracranial hemorrhage and ischemic stroke between venovenous (VV) and VA ECMO among infants with respiratory failure where clinicians may choose either strategy.

Study aims (we encourage study aims to include a hypothesis)	
	<p>We will use the overlap created when cannulation strategies for infants with respiratory failure shifted towards primarily VA cannulation (Figure 1). This “natural experiment” allows for a comparison of patient outcomes (risk of ischemic/embolic stroke and intracranial hemorrhage).</p> <p>Aim 1: Test the hypothesis that there were patients who received VA ECMO in 2020-2022 who were likely to receive VV-ECMO from 2013-2018. We will create a propensity score model using pre-cannulation patient and center features to determine the likelihood of receiving VV ECMO when clinicians could choose either approach (2013-2018).</p> <p>Aim 2: Estimate the effect that a change in cannulation strategy towards more VA cannulation had on the rate of neurologic injury in infants. We will compare the rate of stroke and neurologic complications between children who had a similar propensity to receive VV ECMO in 2013-2018 to those who received VA ECMO in 2020-2022</p>

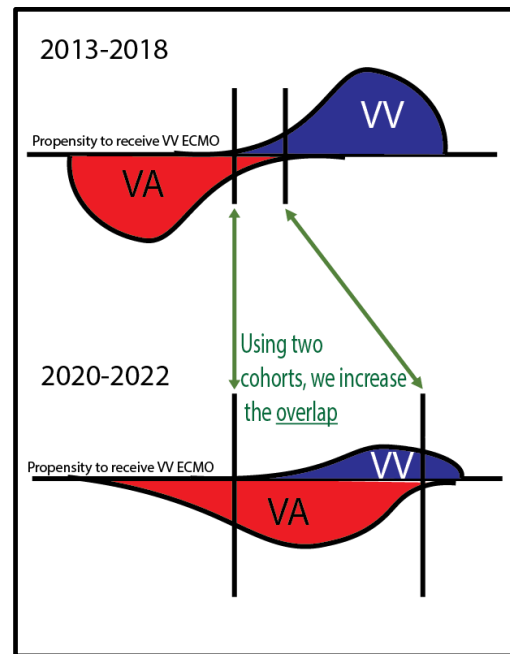


Figure 1: Conceptual model showing the benefit of using the two described cohorts to increase the overlap for comparisons between patients who received VA and VV ECMO

Background and Significance	
	In 2019, the producers of a commonly-used infant-sized dual-lumen veno-venous (VV) ECMO cannula announced that their products would not return to the market (1). While centers had other dual-lumen cannula options or even rarely multi-site VV support (2, 3), centers increasingly supported infants with respiratory failure with veno-arterial (VA) ECMO via the right carotid artery



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

and internal jugular vein — from 68% of neonatal respiratory failure patients in 2015 to 92% in 2021 (4, 5).

Neurologic injury, specifically intracranial hemorrhage and ischemic stroke, remains a feared and devastating complication of ECMO support. Carotid arterial access for ECMO support is thought to carry an increased risk of stroke; however, previous reviews of the ELSO registry have not demonstrated a difference in stroke rate compared to VV ECMO (4.35% vs 4.28%, respectively) (6). Importantly, this data reflects outcomes when clinicians had more available options to place a child on VV support. Consequently, the clinician choice necessarily imparts selection bias in the two cohorts. With the limited availability of VV ECMO, it is likely that patients that otherwise would have been placed on VV ECMO in fact received VA ECMO support.

Counter to what would be expected with carotid artery cannulation, current evidence does not support an increased risk of stroke with VA support for infant respiratory failure. If there is a true difference in stroke rate which was masked by clinician selection in prior studies, this would have important implications for future cannulation approaches and product development.

Study inclusion criteria (defined by ICD-9 / ICD-10 codes, procedure codes, age, ECMO support type, e.g. 28 days to 18 years, pulmonary, 2018-2021 who had any mention of P27.1 ICD-10 diagnoses 2018-2021 who had any mention of P27.1 ICD-10 diagnoses)

Children and Neonates
Weight ≤ 10 kilograms
Support Type: Respiratory

Study exclusion criteria

ECPR
Post-cardiotomy receiving ECMO for respiratory support- we will exclude patients who received central cannulation and where hospitalizations included cardiac surgery, identified by the Risk Adjustment for Congenital Heart Surgery (RACHS-1 for ICD-9 and RACHS-2 for ICD-10) (7, 8)

Study years

2013-2022
We plan to use two cohorts in the study. First, a cohort of children from 2013-2018 will be used to derive a propensity score for the likelihood of receiving VV ECMO during a period of dual-lumen cannula availability.

The propensity score model will then be applied to a cohort of children from 2020-2022 and children from this cohort will be matched to children from 2013-2018 with a similar likelihood of receiving VV ECMO support.

Planned statistical analysis

Our overall approach will be to use a propensity score model derived from the 2013-2018 cohort to match children who received VV ECMO from 2013-2018 with those who had a similar likelihood to receive VV ECMO in 2020-2022 but actually received VA ECMO. We considered approaches using time-series data (difference-in-differences, interrupted time-series). However, the extended and



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

variable “washout” periods where centers transitioned from VV to VA strategies made these approaches less feasible than our proposed approach. We have tested this approach in simulations.

We will determine for each patient the cannulation approach (including rate of conversion):

- 1) dual lumen VV ECMO
- 2) carotid VA ECMO
- 3) Two-site VV ECMO
- 4) other cannulation strategies

To determine the difference in stroke rate among patients who received VV and VA ECMO, we will perform the following steps:

Step 1: Estimate the likelihood to receive VV ECMO cannulation during a period when clinicians could choose either VV or VA ECMO: 2013-2018

To estimate the likelihood of receiving VV ECMO, we will use a propensity scoring approach. Among the cohort of children who received ECMO for respiratory support from 2013 to 2018, we will derive a propensity score model using pre-cannulation center and patient factors.

Step 2: Apply the propensity score model developed in Step 1 to a cohort during a period of increased VA ECMO use (2020-2022).

Because the availability of VV ECMO cannulas appropriate for infants changed in 2019, we expect clinicians that would have previously chosen VV ECMO will use VA ECMO support. Using the propensity score model developed in Step 1, we will calculate propensity scores for patients cannulated during 2020-2022. This will estimate for a given patient, the likelihood that they would have received VV ECMO in 2013-2018.

Step 3: Match patients with a similar propensity to receive VV ECMO who received VV (2013-2018) and VA (2020-2022) (Figure 2)

We will use nearest neighbor

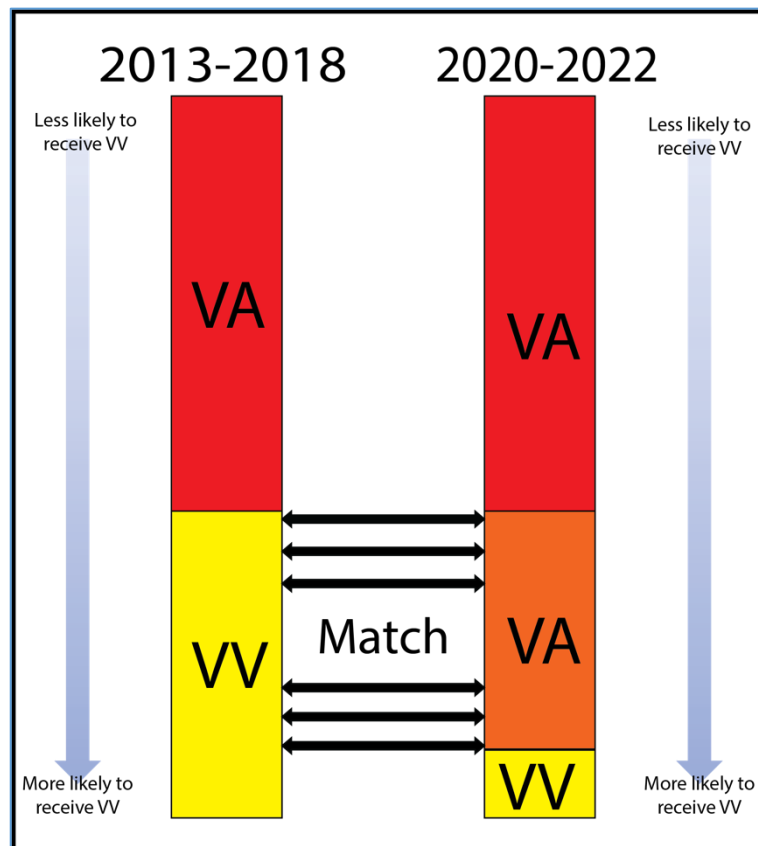


Figure 2: Using the overlap created by increasing use of VA ECMO, patients from cohort with similar propensity to receive VV ECMO will be matched and compared to patients from cohort 2 who received VA ECMO



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

matching to match patients in 2020-2022 who received VA ECMO to those who received VV in 2013-2018, based on their likelihood to receive VV ECMO. By using this approach, the introduction of a new dual-lumen VV ECMO cannula will not affect the analysis. This approach will also not be affected by the continued use of two-site VV cannulation or other dual-lumen cannulas, since only those who received VA in 2020-2022 will be matched with similar propensity patients in 2013-2018.

Step 4: Compare the rate of neurologic complications between matched pairs.

Our primary outcome will be the rate of neurologic injury (ischemic stroke, intracranial hemorrhage, and brain death) during the ECMO hospitalization. Our approach will estimate the average treatment effect among the treated (ATT). We will secondarily assess the occurrence of individual neurologic complications separately, seizures, and other relevant outcomes (duration of ECMO support, mortality, length of hospital stay).

Individual Contributions

JGK, RPB, and PB conceived the study and analytic plan. All contributors have reviewed and revised the analytic plan. JGK and PB will perform the statistical analyses. JGK will draft the initial manuscript. All contributors will analyze and interpret the results and critically edit the manuscript.

Relevant ELSO variables (do not state – 'All Available', do not list dates)

* for variables not listed in ELSO including addenda, the data request will be rejected:

Patient Information
- including center number (deidentified)
First Run Information
- including ECMO year
Run Information (Support Type, pre-existing tracheostomy, invasive ventilation)
Pre-ECLS Ventilator Settings
Pre-ECLS Support (transported on ECMO)
Neonatal Information (Birthweight, gestational age, CDH, CDH Side, Repair of CDH)
Renal, Pulmonary, and Other Support Codes
SARS-CoV-2
24-Hour ECLS Ventilator Settings
Vasoactive Infusions
Unit where ECLS Received
Initial Mode Information
Mode and Cannulations
Blood Pump (Centrifugal or Roller)
Diagnoses
Patient Neurologic Complications
Patient Hemorrhage Complications
Outcomes (Discontinuation reason, Discharged Alive, Discharge Location, Hospital Length of Stay)

References (please include references for cited works in background, significance, and analysis plan)

1. OriGen Reinforced Dual Lumen Catheter Status Update. Available at: <https://www.origen.com/news-and-insights/origen-reinforced-dual-lumen-catheter-status-update>. Accessed 07-11, 2022
2. Moscatelli A, Febbo F, Buratti S, et al: Intensivists Performed Percutaneous Bicaval Double-Lumen Echo-Guided Extracorporeal Membrane Oxygenation Cannulation at Bedside in Newborns



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

<p>and Children: A Retrospective Analysis. <i>Pediatr Crit Care Med</i> 2019; 20(6):551-559</p> <p>3. Lillie J, Pienaar A, Budd J, et al: Multisite Veno-Venous Cannulation for Neonates and Nonambulatory Children. <i>Pediatr Crit Care Med</i> 2021; 22(8):692-700</p> <p>4. Barbaro RP, Brodie D, MacLaren G: Bridging the Gap Between Intensivists and Primary Care Clinicians in Extracorporeal Membrane Oxygenation for Respiratory Failure in Children: A Review. <i>JAMA pediatrics</i> 2021; 175(5):510-517</p> <p>5. ECLS Registry Report: International Summary. Available at: https://elso.org/Registry/InternationalSummaryandReports/InternationalSummary.aspx. Accessed August 31, 2022</p> <p>6. Johnson K, Jarboe MD, Mychaliska GB, et al: Is there a best approach for extracorporeal life support cannulation: a review of the extracorporeal life support organization. <i>J Pediatr Surg</i> 2018; 53(7):1301-1304</p> <p>7. Allen P, Zafar F, Mi J, et al: Risk Stratification for Congenital Heart Surgery for ICD-10 Administrative Data (RACHS-2). <i>J Am Coll Cardiol</i> 2022; 79(5):465-478</p> <p>8. Jenkins KJ, Koch Kupiec J, Owens PL, et al: Development and Validation of an Agency for Healthcare Research and Quality Indicator for Mortality After Congenital Heart Surgery Harmonized With Risk Adjustment for Congenital Heart Surgery (RACHS-1) Methodology. <i>Journal of the American Heart Association</i> 2016; 5(5):e003028</p>
--

Previous ELSO publication(s) by the study team that support the team's ability to complete the work (if no previous experience, please write N/A)	
1.	Kohne JG, MacLaren G, Cagino L, Boonstra PS, Brodie D, Barbaro RP. Tracheostomy Practices and Outcomes in Patients With COVID-19 Supported by Extracorporeal Membrane Oxygenation: An Analysis of the Extracorporeal Life Support Organization Registry. <i>Crit Care Med</i> . 2022.
2.	Kohne JG, MacLaren G, Rider E, Carr BD, Mallory P, Gebremariam A, et al. Tracheostomy Practices and Outcomes in Children During Respiratory Extracorporeal Membrane Oxygenation. <i>Pediatr Crit Care Med</i> . 2022.
3.	Barbaro RP, MacLaren G, Boonstra PS, Combes A, Agerstrand C, Annich G, et al. Extracorporeal membrane oxygenation for COVID-19: evolving outcomes from the international Extracorporeal Life Support Organization Registry. <i>Lancet</i> . 2021;398(10307):1230-8.
4.	Barbaro RP, MacLaren G, Boonstra PS, Iwashyna TJ, Slutsky AS, Fan E, et al. Extracorporeal membrane oxygenation support in COVID-19: an international cohort study of the Extracorporeal Life Support Organization registry. <i>Lancet</i> . 2020;396(10257):1071-8.
5.	Barbaro RP, Paden ML, Guner YS, Raman L, Ryerson LM, Alexander P, et al. Pediatric Extracorporeal Life Support Organization Registry International Report 2016. <i>ASAIO J</i> . 2017;63(4):456-63.

Have any previous ELSO reviews for this hypothesis been published ? (if yes, explain how your analysis will contribute to science, if no previous publications, please write N/A)	
Johnson K, Jarboe MD, Mychaliska GB, Barbaro RP, Rycus P, Hirschl RB, et al. Is there a best approach for extracorporeal life support cannulation: a review of the extracorporeal life support organization. <i>J Pediatr Surg</i> . 2018;53(7):1301-4.	<p>In this analysis, the authors did not find an increase in stroke rate with carotid cannulation after adjustment for patient and disease factors. However, this review from 1989-2013 reflects clinician and surgeon choice for VV or VA cannulation. The proposed study would assess the</p>



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

<p>stroke rate from a more modern cohort and an approach that is enriched with increased overlap from a period of changing cannulation strategies.</p> <p>Teele SA, Salvin JW, Barrett CS, Rycus PT, Fynn-Thompson F, Laussen PC, et al. The association of carotid artery cannulation and neurologic injury in pediatric patients supported with venoarterial extracorporeal membrane oxygenation*. <i>Pediatr Crit Care Med.</i> 2014;15(4):355-61.</p> <p>In this analysis, the authors found an increase rate of neurologic injury in children cannulated through the carotid artery when supported with VA ECMO in 2007 and 2008. The proposed study will specifically evaluate respiratory ECMO and among VV and VA cannulations.</p>



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

Registry Data: Access, Requests, and Publication Policy

OVERVIEW

The purpose of the ELSO Registry (“Registry”) is to provide ELSO members with data to improve the quality of care to patients requiring ECLS support. Data submitted by Centers to the Registry includes personally identifiable information including date of birth, sex, race, main diagnoses and comorbidities, pre ECLS support, technical details of extracorporeal support, duration of ECLS, complications, and outcomes. All collected data is listed in the ELSO ECLS registry forms and addenda (<https://www.elso.org/Registry/DataDefinitions,Forms,Instructions.aspx>) completed by ELSO Centers when they submit data. All data provided to centers, regulatory bodies, industry, researchers by ELSO is de-identified.

RELEASE of ELSO REGISTRY DATA

- The ELSO Registry will release only de-identified data on approval by the **Scientific Oversight Committee (SOC)**, <https://www.elso.org/AboutUs/Committees/Registry.aspx>, and / or **Large Dataset Committee (LDS)**. Any ELSO Centre identifiers, specific dates of ECLS support or any equipment or manufacturer details will not be released.
- ELSO provides several ways for ELSO Centers to view their data relative to the ELSO Registry, including quality assurance reports, a quality dashboard, and views of a center’s data for certain metrics.
- ELSO may allow queries to the Registry of de-identified data by regulatory bodies and industry to advance the care and safety of patients requiring Extracorporeal Life Support. Approval by the SOC and / or LDS is required for all such requests.
- ELSO Centers can query the Registry, as needed, for support in clinical decision-making (**Data Request for Internal Use**), for institutional quality assurance and benchmarking. This review process is separate from data requests for research, publication or presentation (**Data Request for Publication**).

DATA

- All data submitted to the ELSO Registry enclose no patient identifiers except for what is allowed under ELSO’s Data Use and Transfer Agreement (<https://www.elso.org/ELSODataUsepolicy.aspx>)



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

- The ELSO Center ID that connects the data to the providing ELSO Center is used only for quality assurance reports submitted to the ELSO Center, and is not released. For research purposes, only anonymised de-identified ELSO Center codes are used thus protecting ELSO Centre and patients' confidentiality.
- All Registry data is stored in a secure server environment with enhanced cyber security protocols in place.

ACCESS

- Registry data is only available to active participating ELSO Centers. An active ELSO Center registers at least one patient (neonatal, pediatric, or adult) per quarter. A Center not registering a patient for 12 consecutive months will be queried. An ELSO Center registering no patient for 18 consecutive months will be considered inactive.
- Only ELSO Centers whose ELSO fees are paid in full will be considered active. Data requests from ELSO Centers that have not paid fees for more than six months will not be honored.
- A signed Data Use Agreement (DUA) must be on file before any data requests will be granted. A DUA is required when a center joins ELSO.
- Requestors other than the depositing Center will be given data either in aggregate form or without the Centers' names or identifiers.
- Special requests from Regulatory bodies or Organisations that serve the national health and the Industry will be considered and are released subject to the approval of the ELSO SOC and the EC.

PROCESS for DATA REQUESTS

- Data Request Forms for publication and internal use can be found on the ELSO website (<https://www.elso.org/Registry/DataRequest.aspx>). Please follow information and instructions on how to fill the Data Request Form for Publication or Internal Use.
- Data requests from a Center must be submitted and signed by either the ECMO Director or the ECMO Coordinator of the Center.
- Requests that involve joining external datasets to the ELSO registry data will only be possible with financial compensation for the work involved. Specific charges will be determined by the scope of work. As of January 1, 2022, there will be a minimal expected fee of \$18,500. Please contact the ELSO office for details, email to ELSODataRequest@elso.org.
- New requests for Data for publication will be limited to one outstanding and one new request per principal investigator. An outstanding request is one that has not been submitted as an abstract to a scientific conference or a manuscript to a scientific journal.
- Requests for data to be used for publication will be reviewed with previous data request submissions to ensure there is no substantial overlap. The date/ time of request establishes the priority of the request. Data is only to be released to one investigator at a time for a particular study question. In cases where an overlap is identified with existing approved studies, both investigators will be contacted to determine if substantial overlap exists. Final discretion for data release is the decision of the ELSO Registry chairs.
- The SOC does not disclose the submitting ELSO Centers' name in conjunction with data provided by ELSO Centers. Some research studies may benefit from analyses accounting for clustering of patients from the



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

same ELSO Centers. These requests will be reviewed by both the SOC and the LDS committees as required, and if approved, an anonymized ELSO Center identifier will be provided to the researcher (policy available on the ELSO website).

- ELSO Registry will release large datasets to investigators if the SOC determines that a Large Dataset is required to address the research question. The release will be based on the impact of the intended research and analytic approach. However, special rules regarding handling, use, and reporting of these data will be enforced. Please see the ELSO Large Dataset Policy found on the ELSO website (<https://www.elso.org/Registry/ELSODataRequestsInstructions.aspx>).
- A submitted Data Request for Publication form will be reviewed by the members of the SOC at the monthly meetings where each application is discussed based on a scoring system and approval is finalized by the SOC Chairs. Datasets from the ELSO Registry are released to the primary investigator named on the Data Request Form only after review and approval by the SOC.

TERMS and CONDITIONS POST SOC and / or LDS APPROVAL

- Once the data is released, the data must **only** be used to test the hypotheses included in the study proposal. Any further analysis of the dataset needs to be resubmitted to the SOC for review to ensure the data has not been released to other investigators. This process is important to avoid any duplication of efforts by investigators.
- Any additional data required for analysis must be re-requested with the Data Request Form, which will be reviewed by the Registry or SOC Chair(s) to determine whether the additional data is a significant enough change to be presented at a full Data Request SOC and / or LDS Review Meeting.
- Data cannot be shared or distributed to anyone besides those listed in the submitted Data Request for Publication form and can only be used for the sole purposes outlined in the request.
- ELSO does not release manufacturer information and does not allow investigators to identify individual manufacturers, products, or centers in their publications or reports.
- ELSO does not release dates other than the year of ECMO run, only time intervals.
- Approved data requests will be published on the ELSO website (<https://www.elso.org/Registry/ELSODataRequestsInstructions.aspx>) including date of data delivery and expected date of completion. The purpose of publishing this list is to allow researchers the ability to view current ongoing projects in order to avoid overlapping requests.

PUBLICATION

- Only **one** published manuscript per data request is allowed.
- Investigators are allowed **12 months of exclusive access to the data** for the questions articulated in the proposal, with the following caveats. Some proposals have broad questions that cover entire populations, groups, or concepts. In these cases, we may release specific subpopulations or data for specific narrow questions in situations where this does not explicitly overlap with the stated aims of the investigators. Example: Investigator 1 receives data on “outcomes from VA ECMO in adults” and has not specifically specified analysis of patients with pre-existing renal failure. Investigator 2 may be released data <12 months later, focusing on “the outcomes of adult VA ECMO patients who were supported on RRT before ECMO.” At 12 months, we will notify the investigators that data may be released to other waiting investigators. Both old and new investigators will be notified that data is out to two groups. ELSO may in cases of failed progress in a reasonable period, notify the investigators that they have a 3-6 month window to finish their analysis and manuscript preparation, at which point ELSO reserves the right to inform the investigators that they can no longer publish on the data. This is to ensure that delayed



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

publications do not come out that encroach on newer investigators approved for data before they completed analysis.

- **Special circumstances:** for COVID-19 related data, investigators have only 3 months of exclusive access to the data.
- Data requests for projects intended for publication are reviewed **once a month** by the SOC. Once approval is granted the data request will be honored.
- **Investigators are invited to submit a copy of the abstract or manuscript to the SOC to ensure the accuracy of data analysis and conclusions when using registry data.** After publication, investigators are required to provide a copy of the manuscript to ELSO for purposes of monitoring the use and publication of ELSO Registry data. The SOC may request a manuscript review prior to submission. **The purpose of the manuscript review** is to: **1.** Ensure that the report does not identify/expose centers, **2.** Check that the proposed hypothesis was tested, and **3.** Check that the research team stayed within the bounds which were documented with acceptance of the proposal (if any).
- **Manuscripts from approved large dataset requests** require ELSO Registry SOC approval of the manuscript prior to submission for publication. Investigators should factor this requirement into their proposed timeline. **The purpose of the manuscript review** is to: **1.** Ensure that the report does not identify/expose centers, **2.** Check that the proposed hypothesis was tested, and **3.** Check that the research team stayed within the bounds which were documented with acceptance of the proposal (if any).

DATA VIOLATIONS

- Definition: Data use violations are defined as the use of ELSO Registry datasets to explore analyses that were not proposed as part of original approved Data Request.
- The ELSO SOC views data violations seriously and will result in consequences for the investigator(s) and the center director(s). The ensuing actions following any data use violations will be governed under the auspices of the following committees and the Chairs – SOC Chair(s), ELSO Registry Chair and ELSO Executive Committee (EC) by a joint meeting.
- Potential actions at the discretion of ELSO:
 1. Initial correspondence and discussion with the Lead Investigator (named in the ELSO Data Request Form and given approval to use the data) to understand and provide an explanation for the circumstances of the Data use violation. Depending on the circumstances of data use violation, the EC and SOC, at its discretion, may issue an initial warning and a period of review for 12 months to the Lead Investigator and the ELSO Center Director. The review period is defined as a probationary period wherein the investigators will be monitored for any further violations.
 2. If repeated infringements are noted during this probationary period despite the warning, the investigators and ELSO Center director will be refused access to the ELSO Registry data for 12-24 months (from the time of decision taken at the joint meeting between SOC and EC). If data use violation has been committed as part of multisite investigator team, lead investigators at each site will be given this notice. This will be communicated as part of the data use violations notification. Depending on the circumstances of data use violation, the EC and SOC in the joint meeting may decide to revoke Center membership in the ELSO.
 3. The EC and SOC may, at their discretion, submit a Letter of Correspondence to the journal editor from the Extracorporeal Life Support Organization. This letter will be in the public domain.



Extracorporeal Life Support Organization

ELSO Data Request Form for Publication

ELSODataRequest@elso.org

Acknowledgment of ELSO Registry in Publications
--

All academic products resulting from an investigation of ELSO Registry data must include reference to 'the ELSO Registry'. Publications in the scientific literature should reference the ELSO Registry as 'the ELSO Registry' or the Extracorporeal Life Support Organization Registry' in the published abstract or title.

The yearly ELSO Registry International Summary of Statistics report can be published with acknowledgment only and does not require prior approval. Publication of more detailed Registry data requires approval by the ELSO Registry SOC. Local IRB approval is not required to be provided to ELSO when only de-identified data is requested; however, the requester should be familiar with his or her institutional IRB policies.

The ELSO COVID-19 Registry dashboard is provided as a public service to facilitate real-time sharing of information during the COVID-19 crisis for educational purposes only by health practitioners. ELSO owns the compilation of all data, and its use or publication by any third party is strictly forbidden.

The ELSO Registry should be cited as:

ECMO Registry of the Extracorporeal Life Support Organization (ELSO), Ann Arbor, Michigan, (Month), (Year).