



Extracorporeal Life Support Organization

Registry Data: Access, Requests, and Publication Policy

updated 06-23-2023

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.else.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.else.org/AboutUs/Committees/Registry.aspx>, and if required Large Dataset Committee (LDS). ELSO Centre names and specific dates of ECLS support are not released. Specific equipment or manufacturer details are not be released for publication.
- 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-, for institutional quality assurance and benchmarking making (**Data Request for Internal Use**). ELSO Centers can also query the Registry for epidemiological data, which may be used for publication (**Data Request for Epidemiology** – excluding patient specific data). 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.else.org/ELSODataUsepolicy.aspx>)
- 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 anonymized 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 Organizations 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 FOR PUBLICATION

- Data Request Forms for publication and internal use can be found on the ELSO website (<https://www.else.org/Registry/DataRequest.aspx>). Please follow the 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@else.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 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 on the ELSO website (<https://www.else.org/Registry/ELSODataRequestsInstructions.aspx>).
- The members of the SOC will review a submitted Data Request for Publication form at the monthly meetings, where each research application is discussed based on a scoring system, and the SOC Chairs finalize approval. 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 for DATA REQUESTS FOR PUBLICATION

- **Once the data is released, the data must **only** be used to test the hypotheses included in the study proposal. Any further dataset analysis needs to be resubmitted to the SOC for review to ensure the data has not been released to other investigators.** This process is essential 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.else.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 to avoid overlapping requests.

DATA REQUEST FOR INTERNAL USE

Data requested for internal use **MUST** not be used for publication - it is provided to assist in patient care, internal quality improvement or clinical decision guidance. Manufacturer data may be released at the discretion by the SOC Chairs.

DATA REQUEST FOR EPIDEMIOLOGY

Data requested for epidemiological data may be used for publication as a citation - it is aimed to provide an epidemiological overview for the patient cohort queried. A maximum of five outcome variables are released to the investigator(s). No patient-specific data is released.

PUBLICATION – DATA REQUESTS FOR PUBLICATION

- **Only **one** published manuscript per data request for publication 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 explicitly 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 this point, ELSO reserves the right to inform the investigators that they can no longer publish the data. This is to ensure that

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

- Data requests for projects intended for publication are reviewed **monthly** by the ELSO 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 to monitor the use and publication of ELSO Registry data. The SOC may request a manuscript review before 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 documented with acceptance of the proposal (if any).
- **Manuscripts from approved large dataset requests require ELSO Registry SOC approval of the manuscript before 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 documented bounds with acceptance of the proposal (if any).

Framework for Researchers for Data Requests including the “Race” Variable

Researchers are urged to consider these principles at all stages of the research process, including design, ethical conduct, analysis, and interpretation, fulfilling professional responsibilities as scholars:

1. Race is a complex, socially constructed phenomenon that requires a considered approach to research. Researchers should reject notions of race as a fixed trait based on genetics, acknowledge limitations of socially derived categories, and have an understanding of the limitations of the “Race” variable in the ELSO Registry, including the terminology/definitions without locoregional context, as well as the complex interplay between social determinants of health and outcomes. Using the “Race” variable in research using ELSO data should be deliberate, specific, and hypothesis-driven aiming to improve understanding of health disparities and advance health equity. For example, see : <https://www.nature.com/articles/d41586-023-00973-7>
2. Researchers should use bias-free and “fair, equitable, consistent and clear” language when reporting race and racial groups. For reference see <https://www.ama-assn.org/about/ama-center-health-equity/advancing-health-equity-guide-language-narrative-and-concepts-0>
3. Research including the “race” variable from the ELSO Registry should have a sound rationale. Reasoning may include a description of race categories (without statistical comparison) to present how representative the sample is to other populations for generalizability and external validity. Examining race with severity measures or outcomes should incorporate considered statistical methods.

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 Board of Directors (BOD) 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 the approval to use the data) to understand and provide an explanation for the circumstances of the Data use violation. Depending on the circumstances of the data use violation, the EC and SOC, at their 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 the decision taken at the joint meeting between SOC and EC). If a data use violation has been committed as part of a 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 the 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.

Acknowledgment of ELSO Registry in Publications

All academic products resulting from an investigation of ELSO Registry data must include a 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 a public service to facilitate real-time information sharing 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 follows:

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