Extracorporeal Life Support Organization

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 processs 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)
- 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.

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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 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.

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