

EXTRACORPOREAL LIFE SUPPORT ORGANIZATION



Phone: 1-734-293-2101

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ELSO Scientific Oversight Committee Policy

Overview

Duties of SOC

1. Promote the Scientific Product from the ELSO Registry by
 - Ensure reference to 'ELSO Registry' in title or abstracts of publications resulting from data analysis of the registry
 - Liaising with the Communications Committee to ensure important studies from the ELSO Registry are highlighted
 - Collating selected publications in a 'Highlights from ELSO Registry' review
2. Data Request Review - make recommendations for the release of ELSO Registry data sets on the basis of study question, analysis plan and availability of dataset (ie not currently in use by other investigators).
3. Collate Scientific Product from ELSO Registry and identify avenues for as yet under-represented areas of research.
 - Transparency about Data Requests which have been allocated and where Projects are currently outstanding represented on the ELSO website
<https://www.else.org/Registry/ApprovedDataRequests.aspx>
4. Assist the Registry Chair in coordinating Registry Reports which will be led by experts in the field.
5. Consider strategies to improve membership survey delivery and completion.
6. Establish Policies and Procedures around the specified duties to ensure all are carried out with integrity and the highest professional standards.

Membership of SOC

The committee is comprised of voluntary members who represent the breadth of specialty groups who manage ECMO patients and care. The committee will include members representing adult, pediatric and neonatal intensive, surgical, and anesthesia specialties and incorporating representation from across the globe including Europe, Asia Pacific and North America. Previous Chairs of the ELSO Registry and ELSO Registry Scientific Committee will remain honorary members of the SOC.

More input from ECMO nurses and ECMO specialists should be sought, as well as physicians from related fields (eg neurology, hematology).

The committee includes:

- The ELSO Registry Chair
- Chair of the Scientific Oversight Committee

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- Members at large

Committee members will be invited to join for a term of 2 years, renewable for further 2 year terms by committee agreement. Meetings will occur quarterly, but will be rotated through 3 different timezones to encourage international collaboration and engagement. One timezone will be targeted for Asia-Pacific, another for European centers and the third for North American centers, so each timezone will have one meeting/quarter. Members of the committee will be expected to make contributions to 75% of the meetings in their respective timezones.

Committee Appointment Process

Once a year a call for committee volunteers will be sent to ELSO members after the ELSO Scientific meeting, but interested professionals can approach the ELSO Registry Chair or Scientific Oversight Committee Chair at any time.

Eligibility:

Must be an ELSO center member, and would be encouraged to be an individual ELSO member
Familiar with ELSO Registry data, ideally previously published ELSO registry study/ies.

Previous applicants will be considered for future vacancies

Nursing, ECMO specialists, Perfusionists, physicians, surgeons all welcome. Trainee members may be considered at the discretion of the committee.

Not eligible:

If you are not an ELSO member and your center does not contribute to the ELSO Registry
If you are currently serving on an ELSO committee and plan on remaining in that role

Data Review Policy

Data Request Review Committee

All multi-center data requests will be reviewed by the ELSO Scientific Committee Data Review Panel. A valid review will constitute an assessment by at least 2 members, including

- at least one present or past Chair of the ELSO Registry or Scientific Review Committee;
- ELSO Executive Director

Following acceptance of a research protocol and data delivery to the investigators, the title of project, principle investigator and date of data delivery will be added to the ELSO Registry website.

Data review process will take place at least every 2 months. Committee Members will review requests and identify potential overlap with past or ongoing studies. All data requests will be available on the share-point site. Each will be assigned to a member of the committee by the committee chair prior to the review session. Committee will then

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either agree to release data or ask the requesting organization to make modifications to their request. In those instances where there is significant overlap, data may not be released.

In principle and in practice, committee members will be respectful of other people's research proposals and have agreed to the specific points below:

1. Committee Members will keep all proposed study information confidential, including but not limited to center and investigator details, study population and design, planned analysis, target meeting and journal for publication.
2. Committee Members will not use the proposed research to inform their own research.
3. Committee Members will recuse themselves from reviewing a research project which specifically overlaps with their own research.
4. Financial interests may be held by an investigator, a Committee Member or their Employing Institutions. Committee members will recuse themselves from reviewing research projects which may positively or negatively affect any financial interest they (or their immediate family) may have. They will be aware of the potential for conflicting financial interests of their 'Employing Institutions' and the ELSO Registry as an institution, and recuse themselves from reviewing research projects in which this may be an issue.
5. Any Committee Member with a conflict of interest in a study must declare their conflict of interest, and abstain from voting on the research proposal before the committee. They may, however, contribute to the discussion of the study but must not seek to influence the other Committee Members.

Large Datasets Review Committee

Some study designs require release of large segments of the ELSO Registry (as defined above). These will be initially reviewed at ELSO Scientific Committee Data Review Committee and then submitted for Large Dataset Review Committee. A quorum for Large Dataset Review Committee is at least 4 members, including any of the following:

- members of the Data Review Panel
- Current or past ELSO Registry Chair
- Current or past Scientific Oversight Committee Chair
- ELSO Executive Director

At least 2 must be the current or past ELSO Registry Chairs or Scientific Oversight Committee Chair. Large Dataset Request Committee will be held at least twice each year.

Definition of "Large Datasets"

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Research requests that include large amount of ELSO data (for either study or comparator group) based on examples below as stated below:

- Population: e.g. All pediatric Cases of Respiratory failure
- Indication: e.g. All neonates with Cardiac Indications
- Mode: e.g. All adults with VV ECMO
- Research: e.g. Control population from ELSO data
- Requests deemed by the registry as including large proportion of the registry data
- Any study requiring center specific data for analysis

Note: Large Datasets should RARELY be requested for comparator populations

Additional requirements of Large Datasets Requests

- Research proposal must include investigators from at least 3 centers contributing data to ELSO [Rationale: for such large data release, it shouldn't involve only a single center research team.]
- Each proposal must include the statistician (MS or PhD) who is involved in the project proposal and analysis [Rationale: the project proposals worthy of release of large sets of data from ELSO would benefit from the level of sophisticated statistical analysis that a specialist in this field should bring.]
- Each proposal must include a plan of the contributions of the names investigators in the same way as this is included with some manuscripts for publication [Rationale: for release of large portions of the ELSO Registry to researchers, the level of responsibility for the data should be on all co-investigators, this will also facilitate decision making around team contribution.]

Manuscript Review prior to abstract or manuscript submission

This will be a requirement of all Large Datasets in order to:

1. Ensure that the report does not identify/expose centers
2. Check that the proposed hypothesis was tested
3. Check that the research team stayed within the bounds which were documented with acceptance of the proposal (if any)

Committee members will review submitted manuscripts as allocated by the ELSO Registry Chair within 14 days of submission and allocation.

Resolution Process for Data Use Breaches or Disagreement

Definitions:

1. *ELSO data use breach* refers to the use or publication or release of ELSO Registry data which was not approved by the ELSO Data Request Review Committee. This may include, but is not limited to:
 - a. Analysis not previously defined in a data request form
 - b. Analysis beyond the scope of that documented on a data request form

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- c. Sharing of ELSO data outside the investigator team documented on a data request form
2. *Disagreement* for the purposes of this policy, refers to a disagreement between the ELSO Registry Chair and/or proxy and investigators working with ELSO Registry Data. This may include, but is not limited to:
 - a. Occurrence of an ELSO data use breach
 - b. Non-approval of a manuscript intended for publication

The established process for managing ELSO data use breaches or disagreements around the publication of analyses of ELSO data includes:

1. The ELSO Registry Chair informs the members of the ELSO Registry Steering Committee of the issue
2. The Steering Committee nominate a past ELSO Registry Chair and/or Member of the ELSO Steering Committee to oversee a review of the issues and establish the most appropriate resolution
3. Any additional ELSO Registry Scientific Oversight Committee policies affected will be review and updated as required
4. The resolution will be reported back to the Steering Committee for review

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