Duties of the Scientific Oversight Committee (SOC)

1. Data Request Review: To
   a. Review research proposal submitted by investigators
   b. Provide guidance on the study proposal’s focus and priorities
   c. Provide scientific advice to the investigators
   d. Check for overlap with existing studies
2. Promote the Scientific output from the ELSO Registry by ensure reference to ‘ELSO Registry’ in title or abstracts of publications resulting from data analysis of the registry
3. Liaise with the Communications Committee to ensure important studies from the ELSO Registry are highlighted
4. Collate on a regular basis selected publications in a ‘Highlights from ELSO Registry’ review
5. Maintain transparency about ELSO Registry Data Requests which have been allocated and where Projects are currently outstanding represented on the ELSO website [https://www.elso.org/Registry/ApprovedDataRequests.aspx](https://www.elso.org/Registry/ApprovedDataRequests.aspx)
6. Assist the Registry Chair and SOC Chairs in coordinating Registry Reports which will be led by experts in the field.
7. Consider strategies to improve membership survey delivery and completion.
8. Establish Policies and Procedures around the specified duties to ensure all are carried out with integrity and the highest professional standards.

Structure of the SOC

The SOC believes and encourages the representation of the values of diversity, equity and inclusion, expertise and active participation.

SOC members

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 care, surgical, and anesthesia specialties, but also ECMO related specialities. We aim for for international representation including at least two participants from every ELSO chapter (ELSO, EuroELSO, Asia-Pacific ELSO, Latin-America ELSO, South West Asia and Africa). ELSO SOC members are encouraged to promote ELSO Registry related research within their chapter geographical region. Previous Chairs of the ELSO Registry and ELSO SOC will remain honorary members of the SOC for additional two terms, if desired, and continue to participate as outlined below. The general aim is to have a minimum of 25 SOC members with at least 5 members familiar with pediatric ECMO care and 15 members familiar with adult ECMO care.

SOC members will be invited to join for a term of 3 years, renewable for a further 3 year terms by SOC and SOC chairs’ agreement. All SOC meetings will occur monthly. Members of the committee will be expected to make contributions to 66% of the SOC meetings, with a minimum of 5 (out of 12) live online meetings attendance and additionally 3 (out of 12) online evaluations of proposals on a yearly basis.
SOC chairs

The ELSO SOC is chaired by three chairpersons. The SOC chairs are suggested for election from the current ELSO SOC member group from different ELSO chapters, who have been members for at least three years. Nominations are selected by majority vote of the members of the Large Dataset SOC committee. Preference is given to nominations from various ELSO chapters. SOC Chairs will be nominated at the yearly ELSO meetings in September.

*SOC chairs are elected for 2 years. SOC chairs are expected to make contributions to 80% of the SOC and Large Dataset SOC meetings.*

Eligibility for SOC membership / SOC chair

The candidate must be affiliated with an ELSO center, and should be familiar with ELSO Registry data, and ideally have worked with or have publications based on ELSO registry data. Previous applicants will be considered for future vacancies. All nursing, ECMO specialists, perfusionists, physicians, surgeons are welcome. Trainee members may be considered at the discretion of the committee. Candidates from ELSO chapters underrepresented among ELSO SOC will be preferentially evaluated.

Appointment to the SOC

Once a year, a call for SOC volunteers will be sent to ELSO members after the ELSO Scientific meeting, but interested professionals can approach the ELSO Registry Chair or SOC Chairs at any time. The ELSO Chapter chairs are encouraged to recommend ELSO research interested researchers from ELSO centers to join the SOC.

Eligible candidates will be discussed among the SOC chairs, and selected candidates will be presented to the SOC members. If multiple candidates with similar ELSO chapter affiliation, background, experience and expertise are eligible for candidacy, a majority vote among all SOC members and SOC chairs will decide the election. Elected and rejected applicants will be informed via email.

The ELSO SOC chairs can select ad hoc candidates (either from previous SOC members, current applicants or personal knowledge of external candidates) for evaluation of investigators’ proposals requiring specific expertise and / or input.

Re-appointment for SOC members

SOC members may express interest in serving another term by submitting an email request to the SOC chairs at a minimum of ninety days before the end of their term. Re-appointment of interested SOC members will then be determined by the SOC using a majority vote.

Resignation from the SOC

SOC members or chairs may resign at any time as their personal circumstances change to prevent effective contributions.

Grounds for removal from the SOC membership / chairperson

1. If at any time during a member’s or chair’s term, s/he is found to have a conflict of interest (COI) which was not fully and immediately disclosed to the SOC Chairs, the member / chair must resign.
2. Any SOC member / chair who acts in a manner or makes statement that jeopardizes the integrity of ELSO and / or ELSO SOC are grounds for removal from the SOC (see also General rules for SOC members).
3. SOC members who fail within a six months cycle to substantially contribute to the ELSO SOC as described above (SOC members), will be notified by email. If the SOC members continue not to contribute substantially with a minimum of 66% attendance as described above (SOC member), the SOC member would be removed from SOC membership to allow new applicants to join the SOC.

General rules for SOC members and SOC chairs

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

1. SOC members and chairs 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. SOC Members including SOC chairs will not use the proposed research to inform their own research.

3. SOC Members including SOC chairs will recuse themselves from reviewing a research project which specifically overlaps with their own research and / or in studies they are (co-) investigators.

4. Financial interests may be held by an investigator, a SOC member (SOC chair) or their Employing Institutions. SOC member(s) (or SOC Chair(s)) 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 SOC member or SOC chair 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 SOC members.

SOC meetings

Each ELSO data request will be independently reviewed by three SOC members by an online available evaluation form. One pre-identified SOC member will oversee the live presentation during the SOC meeting date, with further online or live input from the other assigned SOC members for the assigned proposal including other live-present SOC members for their input.

We use a grading system from 1 - 10 stars, with one (1) as the lowest, ten (10) as the highest score. A summarized score among significance, background, statistics, and methods, feasibility will be generated with 4 = lowest scoring, 40 = highest scoring.

The proposal will be evaluated in regards to:

1. Significance. Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? Whether the proposal is unique/ coherently written or vague in addition to whether it is topical and feasible from a registry point of view?

2. Background. Is the published/presented data in the background section sufficient to highlight the need for this research question? Have any previous ELSO reviews been published?

3. Statistics and Methods. The research plan describes the proposed research, stating its significance and how it will be conducted. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Have the investigators outlined a comprehensive statistical analysis plan, which would assure an appropriate data analysis?

4. Feasibility and Do-ability. Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? Have the investigators analyzed ELSO data or performed large dataset analysis prior? Are the data points available in ELSO?

The investigator(s) will be informed via email of the outcome of the evaluation of their proposal.
Large Datasets Review Committee

Some study designs require release of large segments of the ELSO Registry (as defined below). LDS data requests must fulfill certain requirements (ELSO SOC Policy and Agreement – Requesting large ELSO datasets for publications). These will be initially reviewed at ELSO Scientific Oversight Committee (SOC) Committee and then submitted for Large Dataset (LDS) Review Committee. SOC and LDS meetings are scheduled monthly. Members of the LDS committee are current and previous chairs of the ELSO SOC, the current and past registry chair. The evaluation and review process is similar as described for the SOC meetings (see above), however stricter standards in regards to statistical methods are described.

**Definition of “Large Datasets”**

Please see therefore our Policy and Agreement on Requesting large ELSO datasets for publications: [https://www.elso.org/Portals/0/Files/PDF/ELSO%20Large%20Dataset%20Agreement.docx](https://www.elso.org/Portals/0/Files/PDF/ELSO%20Large%20Dataset%20Agreement.docx)

Updated 14th August 2022