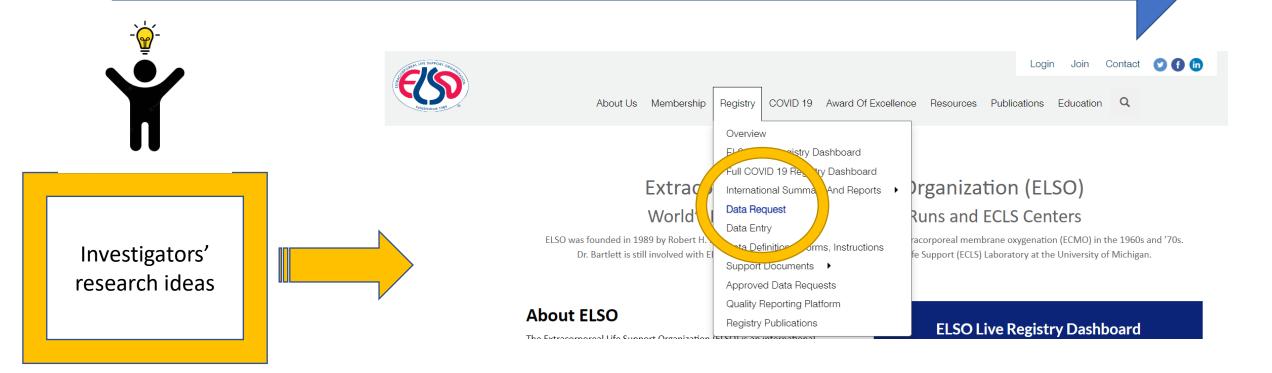
ELSO – Scientific Oversight Committee



Marc Anders, MD – Co-Chair ELSO SOC Aparna Hoskote, MD – Co-Chair ELSO SOC KR Ramanathan, MD – Co-Chair ELSO SOC



ELSO Scientific Oversight Committee – Review Process



Investigators want to file an ELSO registry related research idea $\rightarrow https://www.elso.org/Registry/DataRequest.aspx$

ELSO – Data Policy



ELSO Scientific Oversight Committee – Review Process



ECMO | Extracorporeal Membrane Oxygenation

ELSO Registry Data Policy and Data Requests

The purpose of the ELSO Registry is to provide member institutions ("Centers") with data to improve the quality of care to patients. Data submitted by Centers to the Registry includes personally identifiable information: gender, race, nature, and severity of illness, technical details of extracorporeal support used, dates of service, complications, and outcomes. For data to the basis or questions, email to ELSODataRequest@elso.org.

Data Policy Download Data Policy
Data Request for Publication
Download data request for publication form

Data Request for Internal Use	
Download not for publication data request form	

Familiarize with our data policy \rightarrow <u>https://www.elso.org/Portals/0/Files/ELSODataPolicy20221006.pdf</u>

ELSO – Data Policy



ELSO Scientific Oversight Committee – Review Process



Investigators' research idea



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), <u>https://www.elso.org/AboutUs/Committees/Registry.aspx</u>, 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 Scientific Oversight Committee – Review Process

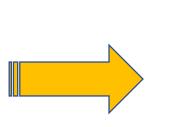


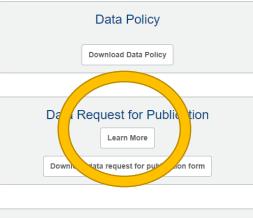
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Investigators' research idea





Data Request for Internal Use
Download not for publication data request form

Go to Data Request for publication → <u>https://www.elso.org/Registry/ELSODataRequestsInstructions.aspx</u> Only for internal data request → <u>https://www.elso.org/Portals/0/ECLS%20Data%20Request%20Form%20Internal%20Use%20Only%20-%20Not%20for%20Publiciation%202022-02-28_protected.docx</u>



ELSO Scientific Oversight Committee – Review Process



Investigators' research idea



Submitting an ELSO Data Request for Publication

For data requests aimed for publication, ELSO requires an approved ELSO data request by the Scientific Oversight Committee (SOC). The SOC meets monthly for evaluation of submitted data requests. The release will be based on the impact of the intended research. ELSO Registry will release large datasets to investigators for purposes of important research. Release will be based on the impact of the intended research.

What SOC Reviewers Look For

Careful preparation and an understanding of how your application will be reviewed can help you build a solid application. During the SOC review process, we convene a panel of selected SOC members to review your application. Although several factors contribute to whether your application will be approved, we place great emphasis on the review of scientific merit. The following sections describe the criteria reviewers employ to evaluate applications. Read them carefully for helpful hints on the information and content you should include in the application to garner a favorable evaluation.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria, and additional review criteria (as applicable for the project proposed)

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific and technical merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have a major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

How to submit a request and what reviewers are looking for.

ELSO – Evaluation criteria



ELSO Scientific Oversight Committee – Review Process

		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 is the proposal is unique/ coherently written or vague in addition to whether it is topical and feasible from a registry point of view.	
		Investigator(s)	Are the PD/PIs, collaborators, and other researchers well suited to the project? Have the investigators analyzed ELSO data or performed large dataset analysis prior?	
Investigators'		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?	
research idea		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? Note that an application does not need to be strong in all categories to be judged likely to have a major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.	

ELSO – Large Dataset Policy



ELSO Scientific Oversight Committee – Review Process



Investigators'

research idea

Submitting an ELSO Data Request for Publication



- Population and indication: all pediatric cases of respiratory failure; all neonates with cardiac indication
- Mode: all adults with VV ECMO
- Research: control population from ELSO data
- Requests deemed by the registry as including large proportion of the registry data
- Any study requiring an anonymized center identifier

Download Large Dataset agreement

Data Request for Publication

Download data request for publication form

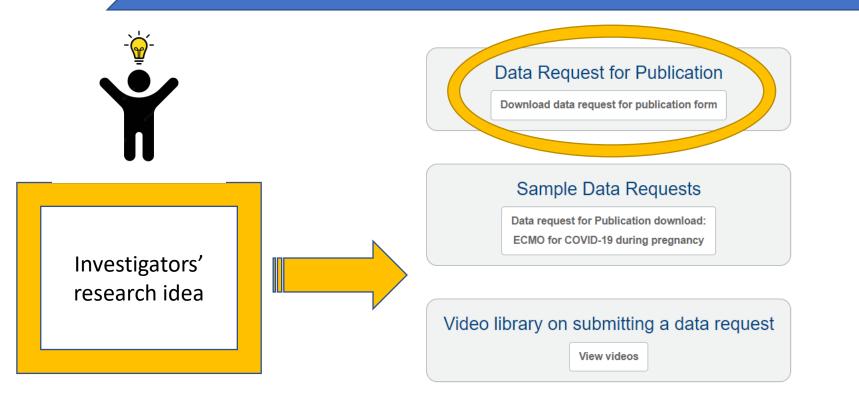
If your data request does meet pre-defined criteria, we will review in the SOC and LDS meetings.

For data request submissions or questions, email to ELSODataRequest@elso.org.

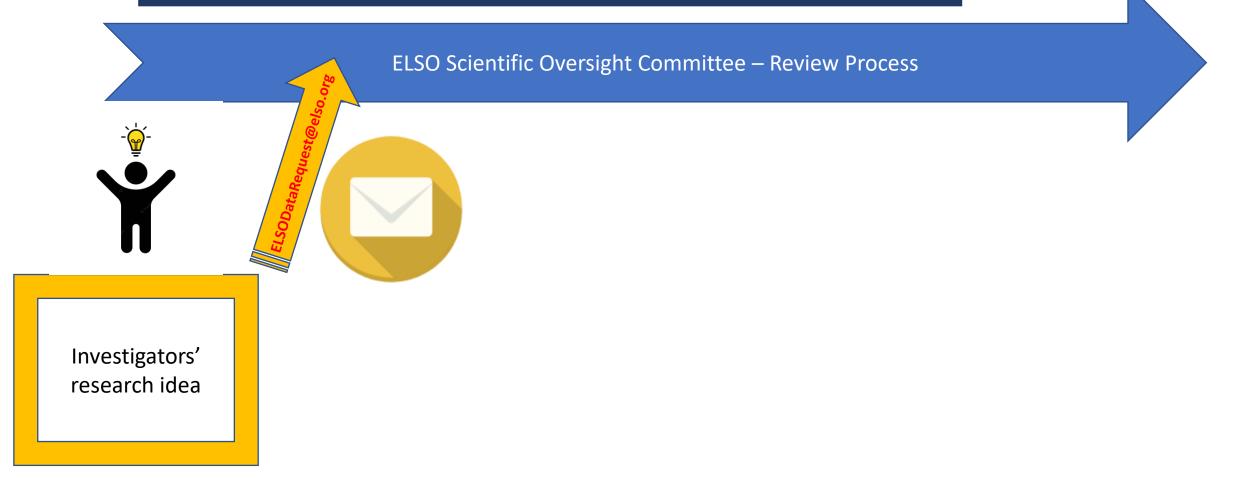
ELSO – Data Request Form



ELSO Scientific Oversight Committee – Review Process

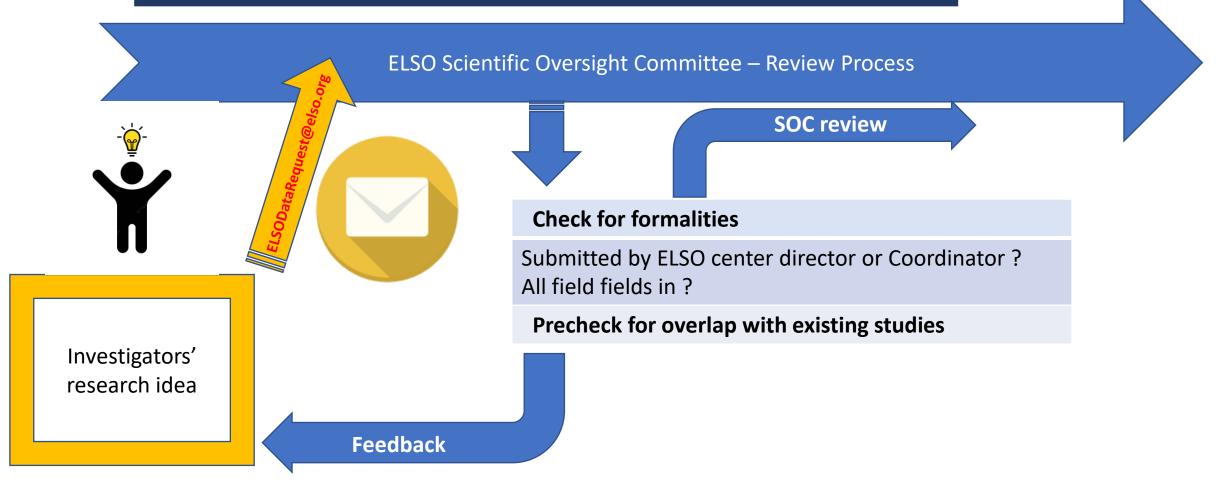






Submit your ELSO data requests to <u>ELSODATAREQUEST@ELSO.ORG</u>

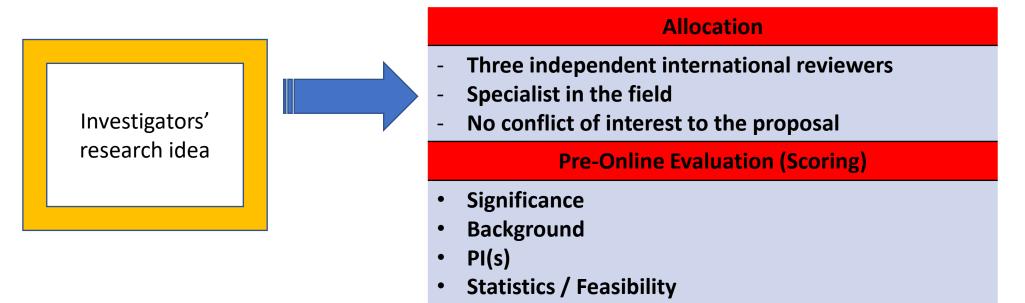




Make sure it is signed and submitted by the registered ELSO center director or coordinator. On initial pre-SOC review, we also check for completion of the form



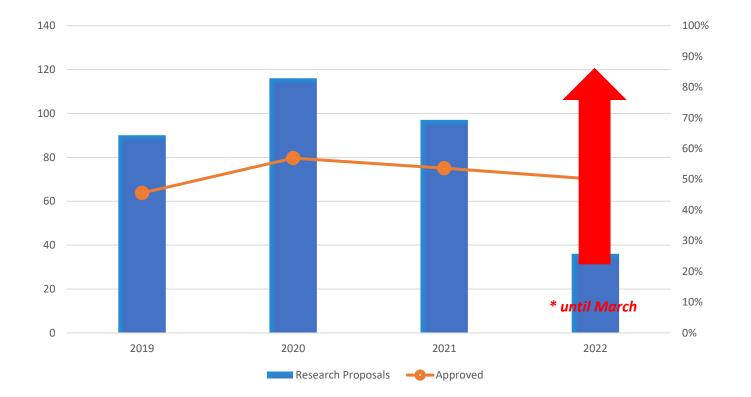




Your data request is evaluated prior the SOC meeting by 3 independent reviewers, specialist in the field of ECMO and ELSO

ELSO – Data Requests filed

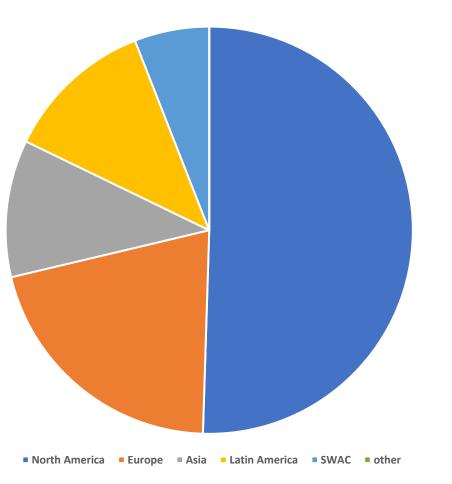




ELSO registry receives about 90 – 120 data requests each year. Investigator proposals are approved in 50 – 60%.

ELSO – Submissions by Chapter

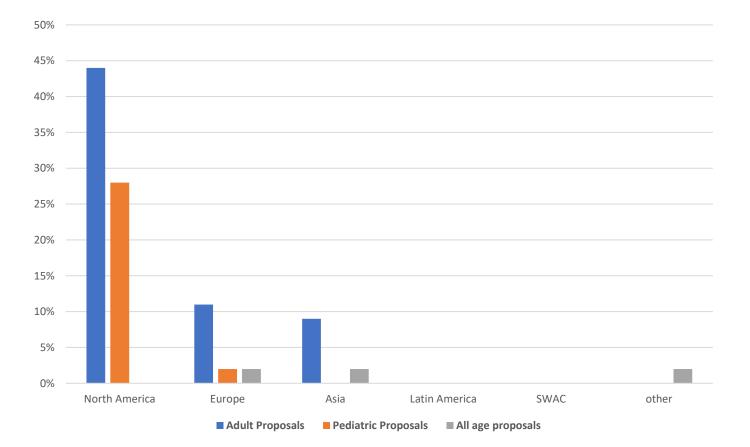




The majority of proposals are submitted by US ELSO centers, but international collaboration and submissions are encouraged and always welcomed.



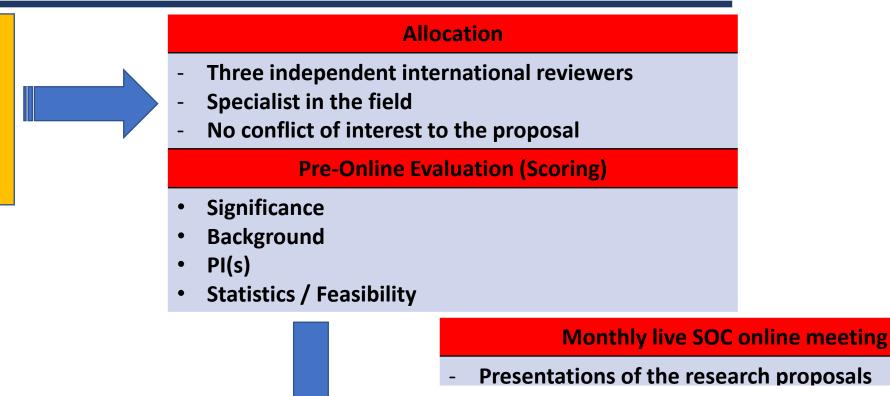
ELSO – Submissions by Age



The majority of ELSO registry data requests are targeting are adult ECMO population.



Investigators' research idea



Every individual proposal is discussed at our ELSO SOC meetings with consideration of the scores and comments of the pre SOC online evaluations.

ELSO – ELSO SOC Chairs





Dr. Aparna Hoskote



Dr. Ramanathan K. R

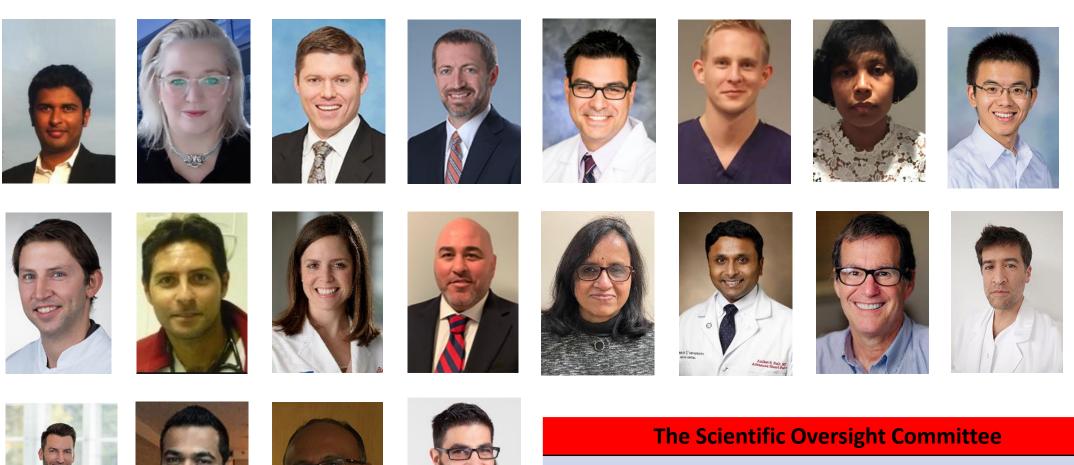


Dr. Marc Anders

Our ELSO registry SOC chairs 2021 – 2023.

ELSO – ELSO SOC Members





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- International SOC members
- Specialists in ECMO care
 - Statistician / AI



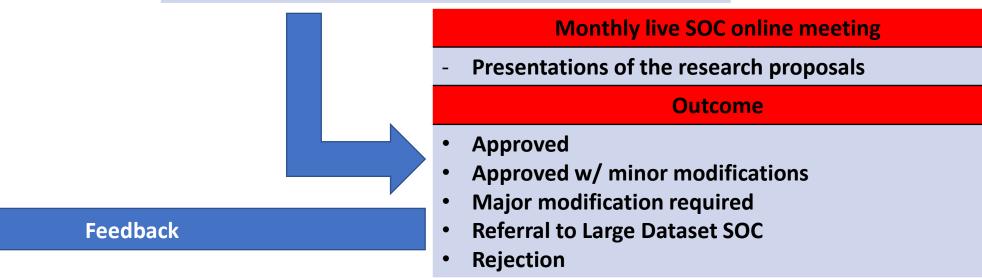
Investigators' research idea



- Three independent international reviewers
- Specialist in the field
- No conflict of interest to the proposal

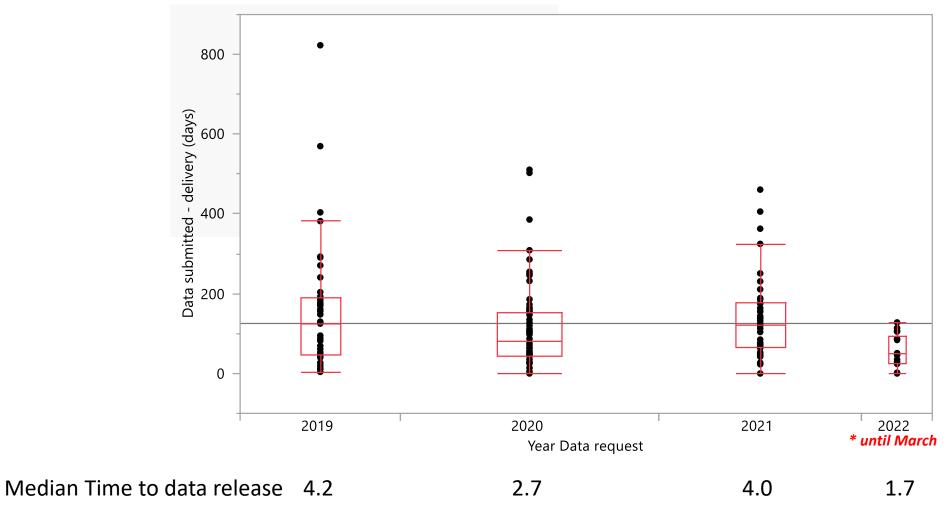
Pre-Online Evaluation (Scoring)

- Significance
- Background
- PI(s)
- Statistics / Feasibility





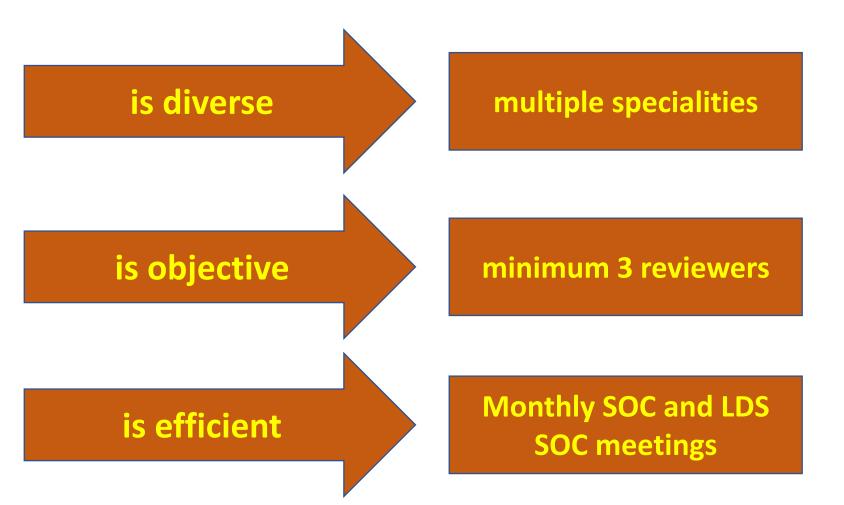
ELSO – Median Time to Data Release



Our aim (months) Our aim is to assess and respond to your research proposal with data release, if approved within 60 days.

ELSO – The SOC process Summary





Our SOC review process is diverse, objective and efficient. For any questions, please email ELSODATAREQUESTS@ELSO.ORG