

# EXTRACORPOREAL LIFE SUPPORT ORGANIZATION

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## ELSO Scientific Oversight Committee Policy and Agreement

### *Requesting large ELSO datasets for publication*

ELSO Registry will release large datasets to investigators for purposes of important research. Release will be based on the impact of the intended research. However special rules regarding handling, use, and reporting of these data will be enforced.

#### **Definition of “Large Datasets”**

Research requests that include large amount of ELSO data based on examples below as stated below:

- Population and indication: e.g. all pediatric cases of respiratory failure; all neonates with cardiac indication
- 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.]

#### **Large Datasets Review Committee**

Some study designs require release of large segments of the ELSO Registry (as defined). These will be initially reviewed at ELSO Scientific Committee Data Review Committee and then submitted for Large Dataset Review Committee. Large Dataset Request Committee will be held at least twice each year.

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## 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.

### NOTE:

1. Only one large data request per member center will be allowed. Following completion (definition of completion below) the member center can request another large dataset
2. Data should be held in a secure password protected computer and deleted within 6 months of obtaining data
3. Data may not be shared unless requested and approved by ELSO registry
4. The research should be completed at 6 months. Completion of research is defined as submission of an abstract to a scientific meeting including the ELSO registry meeting. Manuscripts should be submitted within 1 year of the research request.
5. The data should be used for purposes of research stated in the request for data and sub-analysis of the data cannot be performed without explicit permission from the Registry.
6. The Principle Investigator (PI) should keep ELSO informed of progress with their research project in a written statement submitted within 6 months after data request. Non-compliance with this will result in the assumption that the project is incomplete and data may be released to other investigators.
7. All publications from large ELSO dataset should acknowledge ELSO as 'An Analysis of the ELSO Registry'. Ideally, 'on behalf of ELSO Member Centers' should follow the last author.
8. All PIs should sign this statement acknowledging that they have read and understood guidelines for request of large datasets.

ELSO Center Name: \_\_\_\_\_

ELSO Center Number: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name Printed: \_\_\_\_\_

Project Title: \_\_\_\_\_

Request Number (Filled in by ELSO): \_\_\_\_\_

Revised January 25, 2021