**ELSO Member Data Use and Transfer Agreement**

This data use and transfer agreement (the “Agreement”) is by and between the Extracorporeal Life Support Organization, Inc. (“ELSO”), a 501(c)(3) tax exempt nonprofit organization, with its principal place of business in Ann Arbor, Michigan, and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Member”) located at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and is effective as of the date of the last signature below(the “Effective Date”).

WHEREAS, ELSO maintains a registry of data relating to extracorporeal membrane oxygenation and other forms of organ system support (the “Registry”) to support clinical research relating to the development and evaluation of novel therapies for support of failing organ systems;

WHEREAS, Member wishes to provide ELSO Protected Health Information (“PHI”), as defined in 45 C.F.R. § 164.501, that is in the form of a Limited Data Set, as defined in 45 C.F.R. § 164.514(e)(2), for use in the Registry;

WHEREAS, ELSO wishes to provide Member with access to certain data derived from the ELSO Registry in accordance with the terms and conditions of this Agreement;

WHEREAS, the terms of this Agreement shall govern the use and disclosure of PHI disclosed to, provided by, received by, or created by each party under this Agreement.

NOW, THEREFORE, the parties in consideration of the mutual promises and obligations below agree as follows:

1. ELSO will provide Member with access to certain data derived from the ELSO Registry (the “Data Set”) in accordance with the terms and conditions of this Agreement and ELSO policy.
2. Member will provide ELSO with certain data in accordance with the terms and conditions of this Agreement and applicable law (“Member Data”) to be entered into the ELSO Registry. The Member Data shall constitute a limited data set (as defined in HIPAA)
3. ELSO and Member acknowledge that the Member Data provided to ELSO by Member is owned by Member, however, Member agrees that the return of Member Data to Member by ELSO is not feasible or required once it is integrated into the ELSO Registry or is distributed to third parties as permitted in this Agreement.
4. ELSO is permitted to retain a third-party independent contractor to conduct data monitoring and audits of Member Data and Member’s collection procedures to permit ELSO to maintain the quality and integrity of the Registry. Member will cooperate with ELSO’s contractor as provided in the ELSO Data Monitoring and Audit Policy.
5. Member agrees:
6. To obtain consents, authorizations, or waivers as required by applicable law to enable use and disclosure of the Member Data as described in this Agreement and to maintain any codes or other information necessary to comply with applicable conditions of consents, authorizations, or waivers under applicable law.
7. Not to attempt to identify the individuals (other than as permitted for patients from their own institution) or specific members whose information is contained in the Registry, nor contact individual patients under any circumstances unless such identification or contact is required by law.
8. To pay the annual membership fee.
9. The Parties agree as follows:
10. Not to use or further disclose the Data Set, Member Data, or any information contained therein other than as permitted by this Agreement or required by applicable law.
11. To comply with security provisions required under applicable law, and otherwise implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of electronic personally identifiable data provided by or obtained by the party.
12. Under no circumstances will ELSO or Member be required under this Agreement to provide the other party with any information that is not permitted under applicable law.
13. ELSO may use and disclose data from the ELSO Registry for the following purposes and in accordance with applicable law and ELSO policy:
14. For research, quality assurance, and bench marking within the requirements of applicable law and ELSO policy.
15. Disclose to and permit use of de-identified data from the Data Set by regulatory bodies and the biomedical industry for the purpose of advancing the care and safety of patients requiring Extra-Corporeal Life Support (“ECLS”); provided, however, that such persons or entities agree to the same restrictions and conditions that apply to ELSO with respect to such information.
16. ELSO agrees that it will:
17. Not use or further disclose Member Data other than as permitted or required by this Agreement, or as required by law.
18. Use appropriate physical, technical, and administrative safeguards to prevent the use or disclosure of Member Data other than as provided for in this Agreement.
19. Immediately report to the Member any use or disclosure of the Member Data or any part of the Registry containing personally identifiable data provided by Member that is not authorized by this Agreement of which ELSO or any authorized person permitted access by ELSO becomes aware.
20. Ensure that any agents, including contractor and subcontractors, to whom ELSO provides Member Data or any data from the Registry agree to the same restrictions and conditions that apply to ELSO and the Member under this Agreement.
21. Not attempt to identify or contact any individual to whom the Member Data pertains or whose information is contained in the Registry, nor contact any such individuals under any circumstances, unless such identification or contact is required by law.
22. In the event either party becomes aware of any use or disclosure of the Member Data, Data Set, or ELSO Registry or any part of them, that is not authorized under this Agreement or applicable law, or any other breach of this Agreement, the party may (i) immediately terminate this Agreement upon written notice to the other party; (ii) disqualify (in whole or in part) the other party and any authorized parties of the other party from receiving data from those sources in the future; and (iii) report the inappropriate use or disclosure to the Secretary of the Department of Health and Human Services. Further sanctions may apply under applicable law.
23. The parties acknowledge that state and federal laws relating to the security and privacy of PHI are rapidly evolving and that modification of this Agreement may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA as applicable to the respective parties. Upon request of either party (the “Requesting Party”), the other party agrees to promptly enter into negotiations concerning the terms of a modification to this Agreement embodying written assurances consistent with the standards and requirements of HIPAA. The Requesting Party may terminate this Agreement and access to PHI upon thirty (30) days written notice in the event: (1) the other party does not promptly enter into negotiations to modify this Agreement when requested by the Requesting Party under this section; or (2) the other party does not enter into a modification of this Agreement providing assurances regarding the safeguarding of PHI that the Requesting Party, in its sole discretion, deems sufficient to satisfy the standards and the requirements of HIPAA.
24. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person or entity other than the Member or ELSO and their respective successors and assigns, any rights, remedies, obligations or liabilities whatsoever.
25. No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any occasion.
26. The respective rights and obligations of each party under this Agreement shall remain in force until all PHI provided or created hereunder is destroyed or returned to the other party.

The parties, through their authorized representatives, hereby accept and agree to the terms and conditions of this Agreement.

**Extracorporeal Life Support Organization, Inc. Member**

Signature: Signature:

Name (Printed): Name (Printed):

Title: Title:

Date: Date:

12/10/2020