**DATA SHARING AGREEMENT**

**North American and International Participants**

This Data Sharing Agreement (this “**Agreement**”) is made as of the \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_, 2020 (the “**Effective Date**”) by and between Extracorporeal Life Support Organization, a Michigan nonprofit corporation formed under the laws of the United States (“**ELSO**”), and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, a \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“**Participant**”) Each of ELSO and Participant is referred to herein as a “**party**” and together, the “**parties**.”

**RECITALS**

**WHEREAS**, ELSO is a sponsor of a research collaborative regarding ExtraCorporeal Membrane Oxygenation for 2019 novel Coronavirus Acute Respiratory Disease (“**ECMOCARD**”), (now known COVID-19 Critical Care Consortium) as set forth in the **Research Protocol** attached hereto as Exhibit A (the “**Study**”).

**WHEREAS**, University of Oxford, a collegiate research university in the United Kingdom (“**Oxford**”) has been, and will continue to, collect and store COVID-19 Critical Care Consortium (formerly ECMOCARD) data, including data gathered from Participant, in Oxford’s REDCap repository, in accordance with the terms and subject to the conditions of the data sharing agreement and terms of use by and between Oxford and Participant.

**WHEREAS**, the Research Protocol was developed by University of Queensland, a body corporate constituted under the *University of Queensland Act 1998* (“**UQ**”). UQ has given ELSO the right to give access to the Research Protocol to study sites located in North America and other international regions, upon the terms and subject to the conditions of an agreement among ELSO, Oxford and UQ.

**WHEREAS**, Participant’s participation in the Study is part of a global data initiative in response to the COVID-19 outbreak and will assist in pandemic planning both locally and globally, and Participant’s execution of this Agreement is a condition precedent to participation in the Study.

**NOW THEREFORE**, for due and valid consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto hereby agree as follows:

**AGREEMENT**

1. **STRUCTURE AND DESIGN OF THE STUDY**. Study is a prospective/retrospective multi-centre short period incidence observational study of patients in participating hospitals and intensive care units (ICUs) with 2019 novel coronavirus (COVID-19). Centers from around the world are being asked to participate in the Study. Participants will upload the data requested to Oxford’s REDCap data repository system. The collection, storage and access to Study data is governed by the terms and conditions of the data sharing, terms of use and other agreements by and between Oxford and Participant. The Study is managed by a Steering Committee, as set forth in the Research Protocol.
2. **ELSO’s ROLE IN THE STUDY**. ELSO has reviewed and approved of the Research Protocol. The role of ELSO as a sponsor of the Study relates to ELSO’s coordination of Participants and fundraising to support the valuable work of the Study to ELSO’s charitable mission and the public good. ELSO will not be in receipt of Participant’s data, although it will have access to Oxford’s REDCap system. ELSO has a seat on the Steering Committee but does not control it. The principal investigator of the Study is the Chairman of the Asia-Pacific Chapter of ELSO, but he is neither an employee nor agent of ELSO. Participant and Site (as defined below) shall bear its own costs and expenses involved in participating in the Study.
3. **IRB/EC APPROVAL**. Participants are responsible for compliance with their own internal review and approval processes. However, ELSO is happy to speak with Participant staff in order to assist in providing information required for such approval. As noted in the Research Protocol, no personally identifiable health information will be collected as part of the Study.
4. **INTELLECTUAL PROPERTY**. As noted in the Research Protocol, each Participant will continue to own its data, and each will have access to the data as set forth in the data sharing agreement between Participant and Oxford.
5. **INFORMATION EXCHANGE AND GOVERNANCE**. Participant will upload data to Oxford’s REDCap system. Data will be stored, protected and managed in accordance with the terms agreed between Participant and Oxford.
6. **AUTHORSHIP.** As noted in the Study Protocol, authorship will be determined according to the internationally agreed criteria for authorship (www.icmje.org). Authorship of parallel studies conducted outside of the main trial will be according to the individuals involved in the study but must acknowledge the contribution of the involved investigators.
7. **CONFIDENTIAL INFORMATION**.ELSO shall not have access to Participant’s data or other confidential information. However, as a sponsor of the Study. ELSO will have access to Oxford’s REDCap system.
8. **LIMITED ROLE OF ELSO.** Participant acknowledges that ELSO will not be receiving any of Participant’s data or other confidential information and that ELSO owes no duty or contractual obligation to Participant or Site (as defined below). Rather, on a voluntary basis, ELSO is undertaking its role to facilitate participation in the Study for the greater good. Participant agrees that its, and Site’s, only recourse for the breach of any agreement between Participant and Oxford (or another study collaborator) is directly with the counterparty to such applicable agreement and hereby covenants and agrees, on behalf of Participant, Site and their respective regents, directors, officers, agents, successors and assigns, that none of them shall bring suit or otherwise assert any claim against ELSO (its directors, officers, successors or assigns) before any court, arbitrator, mediator or administrative agency anywhere in the world relating in any way to this Agreement or the Study.
9. **REPRESENTATIONS AND WARRANTIES OF PARTICIPANT**. By execution of this Agreement, which is required as a condition precedent to Participant’s participation in the Study, Participant, on behalf of itself and its regents, directors, officers, agents, successors and assigns, hereby represents and warrants to ELSO as follows:
   1. Participant will be entering data particular to patients at a site that is under the supervision and control of Participant (“Site”);
   2. Participant, on behalf of itself and Site, have secured all relevant ethics approvals (or appropriate waivers) to enter into this Agreement and to participate in the Study;
   3. Participant and Site hereby release UQ from all claims and actions however caused (including due to negligence by UQ), inclusive of any claim for costs, which may arise in connection with the use of the Protocol by Participant at the Site.
10. **TERM.** This Agreement is effective as of the Effective Date and remains in effect for the duration of Participant’s participation in the Study; *provided, however*, that Sections 4, 6, 7, and 8 through 11, inclusive, shall survive termination of this Agreement for any reason.
11. **MISCELLANEOUS.** 
    1. *Independent Contractors*. ELSO and Participant are independent contractors and not an agent or employee of the other. Neither ELSO nor Oxford is an agent of the other.
    2. *Governing Law; Venue; Jurisdiction*. The validity, interpretation, performance and enforcement of this Agreement, and any other disputes related to it, will be governed by the laws of the State of Michigan, without regard to conflict of law principles. The parties hereby submit to the venue and jurisdiction of the state and federal courts located in Washtenaw County, Michigan, and hereby waive all claims of inconvenient forum.
    3. *Counterparts; Electronic Signature*. This Agreement and any amendment hereto may be executed in counterparts and all such counterparts taken together shall be deemed to constitute one and the same instrument. For purposes of executing this Agreement, a facsimile, including a PDF image delivered via email, copy of this Agreement, including signed signature pages, will be deemed an original, but all counterparts, taken together, will constitute one and the same instrument.
    4. *Entire Agreement; Amendment. No Assignment; Third Party Beneficiaries*. This Agreement sets forth the entire agreement between the parties as to its subject matter. None of the terms of this Agreement shall be amended except in writing signed by both parties. This Agreement may not be assigned by a party without the prior written consent of the other party. This Agreement is intended only to benefit the undersigned parties, and no other person or entity shall have standing to bring any claim pursuant to this Agreement; *provided, however*, that UQ shall have the right to enforce the limitations of liability against it under Section 9.

**IN WITNESS WHEREOF,** duly-authorized representatives of the parties have signed this Agreement as of the date first set forth above.

**Participant:**

**[insert organization name]**

By:

Print Name:

Title:

(Duly authorized)

**ELSO:**

**Extracorporeal Life Support Organization**

By:

Print Name:

Title:

(Duly authorized)