

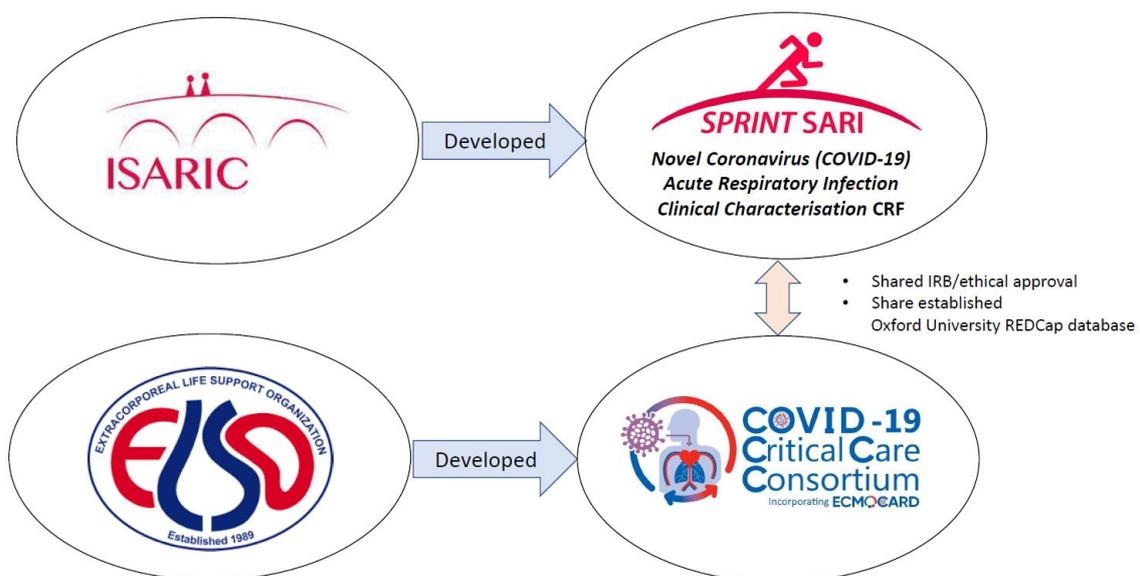


Frequently Asked Questions – Institutional Approvals

1. What is the association between ISARIC, SPRINT-SARI and the COVID-19 Critical Care Consortium Incorporating the ECMOCARD Study?

The Short PeRIod IncideNce sTudy of Severe Acute Respiratory Infection (SPRINT-SARI) study was developed to establish a research response capability for future epidemics / pandemics through a global SARI observational study. The **International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC)**, endorsed by WHO, was formed in 2011, in response to global recognition of the unmet need for timely and effective clinical research during outbreaks of emerging infectious disease with epidemic or pandemic potential. In December 2019, when a novel coronavirus (COVID-19) outbreak was described in Wuhan, China, ISARIC facilitated the coordination of SPRINT-SARI and rapidly developed the **Novel Coronavirus (COVID-19) Acute Respiratory Infection Clinical Characterisation** electronic case report form to specifically characterize this infection. **The ExtraCorporeal Membrane Oxygenation for 2019 novel Coronavirus Acute Respiratory Disease (ECMOCARD study)** was developed by the COVID-19 Critical Care Consortium in early January 2020 to characterize patients with COVID-19 infection admitted to ICU. ECMOCARD, endorsed by the Extracorporeal Life Support Organisation (ELSO), joined the SPRINT-SARI and ISARIC networks to facilitate development of an electronic case report form, linked to the established ISARIC database, and to expedite inclusion of collaborative centres of the SPRINT-SARI study.

SCHEMA OF ISARIC, SPRINT-SARI AND COVID-19 CCC inc ECMOCARD COLLABORATIVE



2. Does ECMOCARD only include patients undergoing ECMO?

No. The COVID-19 Critical Care Consortium Incorporating ECMOCARD Study does not only include ECMO patients. **It includes all COVID-19 patients in the ICU, even those which do not receive mechanical ventilation or ECMO.**

3. We do not have ethics approvals to participate in the joint ISARIC nCoV and ECMOCARD study? How do we do this?

The ECMOCARD study team will send you a starting package containing the study protocol, data collection form and an ethics approval request template letter. Study documents are also available via the ECMOCARD website: www.covid-critical.com/study. These documents can be submitted to your Institutional Review Board (IRB)/Ethics Committee (EC) for approval to participate in the combined study. It is the responsibility of the participating hospital (see Question 11 & 12 below) to obtain all ethical and regulatory approvals required by your site to participate in this study. Once all necessary approvals are obtained at your site, email them to ECMOCARD@health.qld.gov.au and the study team will forward further instructions.

4. We have ethical approval for ISARIC nCoV but not for ECMOCARD. How do we proceed to get approvals for both?

The ECMOCARD study team will send you the combined study protocol and data collection form which will supersede the ISARIC documents previously submitted to your IRB/EC. We will also send an ethics amendment request template letter, which explains the addition of ECMOCARD to the ISARIC nCoV protocol. These documents are also available on the ECMOCARD website: www.covid-critical.com/study. Once the amendment has been approved at your site and all approvals are in place, email your IRB/ethics approval letter and data sharing agreement (if applicable. See Question 6 below) to ECMOCARD@health.qld.gov.au. We will forward further instructions regarding database access.

5. Does our site need written informed consent from patients to participate?

This will be determined by the requirements of each hospital site's IRB/EC. Given that this study is gathering data which is already collected as part of standard care, and that all data leaving your hospital will be de-identified, we think that a waiver of patient consent should be considered by the IRB/EC. Participation in this study will pose negligible risk to the patient.

6. Do we need a contract/agreement between our hospital and ECMOCARD?

Only if your institution requires one.

If your site does need a contract, our preferred option is the ISARIC Data Sharing Agreement available at

https://www.else.org/Portals/0/Files/ECMOCARD/ISARIC_Data_Platform_Terms_of_Data_Submission.pdf

If the ISARIC agreement does meet your site's requirements, the study Sponsor, ELSO, can provide an alternate agreement template. This agreement is available via the ECMOCARD website: www.covid-critical.com/study

7. Is participation in sub studies mandatory?

No. Participation in sub studies is optional. If your site would like to participate in a sub-study, please ensure this is specifically mentioned in your IRB/EC approval letter. After your approval letter has been received by study coordinators at ECMOCARD@health.qld.gov.au , we will be in touch regarding access to the sub-study module/s in the REDCap database as this is a separate database to the joint ISARIC nCoV-ECMOCARD database.

8. How will we transmit our data to you?

We have developed a database which is hosted by Oxford University, United Kingdom, so that all SPRINT SARI and ECMOCARD data can be entered seamlessly into one single database, called nCov_EOT. If you already have ISARIC_nCoV database access (SPRINT SARI), the nCoV_EOT login will replace this. DO NOT ENTER DATA INTO BOTH DATABASES.

Once all ethical and regulatory approvals are received by ECMOCARD coordinators, a site-specific login/s will be provided. Only fully anonymised and de-identified data will be entered by the participating sites.

9. When can we start collecting data?

Once you have received all necessary ethical and regulatory approvals at your site, you can immediately commence data collection using the integrated ISARIC nCoV and ECMOCARD paper data form and data dictionary provided. Once you are supplied with your site-specific login/s for the REDCap database, you can enter data directly into the database.

10. We are having problems with the REDCap database. Who do we contact?

The REDCap Database Coordinator can deal with technical issues you are experiencing with the database (ECMOCARD@health.qld.gov.au) such as not being able access or login to the database. A REDCap CRF data completion guide will be provided to you at the time your REDCap logins are generated. In case of specific issues with the ECMOCARD content on the database you should contact g.libassi@uq.edu.au or ECMOCARD@health.qld.gov.au .

11. Who owns the data once it is entered into the REDCap database? Can my hospital access it for our own internal use? Can we publish it?

Clinical investigators contributing to the research efforts will be given full recognition for their efforts and will be given the opportunity to access data. Ownership of any data transferred to the REDCap eCRF will be retained by the site that contributed it. Authorship of any manuscripts arising from the data 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.

12. We are unsure of one of the questions on the CRF. Who do we contact?

For resolution of a clinical query regarding the study, firstly refer to your Principal Investigator and, if still unresolved, the Chief Investigator, Gianluigi Li Bassi (g.libassi@uq.edu.au) or Research Coordination Team, ECMOCARD@health.qld.gov.au

'Drop-in' teleconferences are held between 4:15pm – 5:15pm AEST every Tuesday and 7:30am – 8:30am AEST every Thursday, in which sites may discuss any ECMOCARD-specific data queries they have with ECMOCARD investigators. The teleconference is accessible via the link: Tuesday <https://uqz.zoom.us/j/98419097289> and Thursday <https://uqz.zoom.us/j/94398152451>. If you need any further information regarding the teleconference, please contact us at ECMOCARD@health.qld.gov.au

13. What are Regional Lead/s and what are their responsibilities?

The ECMOCARD project team will liaise with each participating region to identify an individual who will lead the project for that region.

The regional lead/s is responsible for:

- Identifying the investigator at participating sites
- Ensuring distribution of study materials (as required)
- Researching the country's ethical regulatory requirements and ensuring each site is adhering to ethical requirements
- Communicating with sites within their nation
- Communicating with the management committee.

The regional co-ordinator will be the primary contact for each site within the country and/or region.

14. What are the responsibilities of the Principal Investigator at my hospital?

The Principal Investigator at your hospital agrees to:

- Perform the study in accordance with the study protocol, ICH guidelines for GCP and the applicable regulatory requirements.
- Produce progress reports, and any other required documentation required by the local IRB/EC
- Maintain records of study correspondence and applicable documentation as required by the local IRB/EC.
- Be responsible for the maintenance of a securely held enrolment log linking the patient hospital record number and the ECMOCARD study number.
- Provide reliable data and all information requested by the study protocol in an accurate and legible manner according to the instructions provided.

15. Do I need to submit an IRB/EC amendment to get benefits from the Basic CRF?

No you do not need to submit an IRB amendment. The paper version of the Basic CRF is based on version 1.2.8 of the main CRF. However, sites that do not have IRB approval for version 1.2.8 may still use the data upload schedule outlined in the basic CRF (see below). Sites using this approach should only upload data that is covered under their existing IRB approval. Using this upload schedule, in combination with existing CRFs, leads to a reduction in overall data collection, without including additional variables that may not be approved by the respective IRB.

