Frequently asked questions

1. What is the association between SPRINT-SARI, ISARIC and ECMOCARD?

*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 an electronic case report form to specifically characterize this infection. *The ExtraCorpoereal Membrane Oxygenation for 2019 novel Coronavirus Acute Respiratory Disease (ECMOCARD study)* was developed early in January 2020 to characterize patients with COVID-19 infection admitted to ICU and requiring ECMO. ECMOCARD 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.

2. We do not have ethics approvals to participate in the joint SPRINT-SARI 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. 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 g.libassi@uq.edu.au and amanda.corley@health.qld.gov.au and the study team will forward further instructions.
3. We have ethical approval for SPRINT SARI 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 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 SPRINT-SARI protocol. Once the amendment has been approved at your site and all approvals are in place, email the approvals to g.libassi@uq.edu.au and amanda.corley@health.qld.gov.au. We will forward further instructions regarding database access.

4. 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.

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

Only if your institution requires one.

If your site does need a contract, the SPRINT SARI Data Sharing Agreement can be accessed here https://media.tghn.org/medialibrary/2020/02/ISARIC_Data_Platform_Terms_of_Data_Submission.pdf.

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

7. 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 on the integrated SPRINT SARI and ECMOCARD paper data form provided. Once you are supplied with your site-specific login/s for the REDCap database, you can enter data directly into the database.

8. 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 (ncov@isaric.org) such as not being able access or login to the database. In case of specific issues with the ECMOCARD content on the database you should contact g.libassi@uq.edu.au or amanda.corley@health.qld.gov.au.

9. 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 eCRF will be retained by the site that contributed it. 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.

10. 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, your Regional Lead. If the query is still outstanding, the Regional Lead should contact the Chief Investigator, Gianluigi Li Bassi g.libassi@uq.edu.au

11. 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.

12. 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.