ISARIC

International Severe Acute Respiratory and emerging Infection Consortium

Site Capacity: Points to Consider

- This "Points to Consider Checklist" is designed to help the user review the capacity of their facility (a hospital or research site), to take part in the ISARIC CCP Global COVID-19 Study, and consider which tier their site can recruit patients to.
- Items shown in pink are considered to be the minimum requirements for Tier 0 (data collection only)
- For more information, please refer to the study protocol on the ISARIC website https://isaric.tghn.org/covid-19-clinical-research-resources/

Equipment:

- ❑ Access to a computer.
- ❑ Access to a printer.
- ❑ Access to internet.
- ❑ Access to a health facility.
- ❑ Access to Personal Protective Equipment (PPE).
- ❑ A secure office space for storing study documents.
- ❑ A designated area for group meeting.
- ❑ Scales for assessing patient body weight.
- ❑ Measuring tape for assessing patient height.
- ❑ Consumables e.g. blood collection tubes, RNA tubes etc.
- ❑ Appropriate biological sample shipment containers.
- ❑ Freezers.

Human Resources/Staffing:

- ❑ Adequate number of doctors /nurses/clerks.
- ❑ Staff with available time to recruit patients and obtain their consent.
- ❑ Clinicians or nurses with sufficient time to collect blood, urine and stool samples as per protocol.
- ❑ Are there available resources to allow the completion of the sampling protocol? e.g. Tier 2 requires frequent sampling - at least every few days per patient during acute illness.
- ❑ Laboratory processing (spinning and aliquoting blood samples).

If you are using the ISARIC Clinical Data Platform;

- ❑ Staff with sufficient time to enter the data.

Data Management and Processing:

Consider the mode of data collection e.g. paper case report forms versus electronic.

- In collaboration with WHO, ISARIC has created two forms: the CORE form and the RAPID form.
- Each form is available in hard copy, paper, and electronically.

More information can be found here: https://isaric.tghn.org/COVID-19-CRF/

Consider how you will process the data

- The ISARIC/WHO CORE and RAPID forms each have a data dictionary (a set of information which describes the contents, format, and structure of the ISARIC database, which will help with analysing the data.)
- A data platform has been created to capture the clinical data recorded on the forms; Ownership and control of all data entered on this system are retained by those who enter the data.

- To use the ISARIC COVID-19 database - your institution must accept the Terms of Data Submission that outline the measures taken to protect your interests and to ensure patient confidentiality and data security.

More information can be found here: https://isaric.tghn.org/COVID-19-Data-Management-Hosting/

Additional facility considerations:

- ❑ Clinical laboratory close to the hospital/patient ward.
- ❑ Centrifuge equipment.
- ❑ Serological testing equipment.
- ❑ Sufficient sample kits for stool, urine and blood samples.
- ❑ A functioning freezer for storage of samples (see protocol).

Additional logistical considerations:

- ❑ Is there an established transport link between the hospital and laboratory site.
- ❑ Is there a tracking system in place for samples.

Staff training:

- ❑ Are the clinical staff aware of this study.
- ❑ Are there regular planned meetings to discuss study progress.
- ❑ Have team members responsible for data collection been briefed on the study protocol.
- ❑ Have the team members been briefed on how to fill out the case report form.
- ❑ Practical training in 'Sampling' for team members responsible for conducting sample collection (see protocol)
- ❑ The sampling protocol must also be shared with healthcare workers supporting patient management in order to minimize disruption to patient care.
- ❑ Consent training for staff obtaining consent from participants.

If you are using the ISARIC Clinical Data Platform;

- ❑ Have appropriate team member(s) been issued a username and password for data entry? (For assistance, please email ncov@isaric.org)
- ❑ Have appropriate team member(s) been briefed on using the software?
- ❑ Has the site received a site number? To obtain this, please email ncov@isaric.org).

Research ethics requirements:

- ❑ Has the study protocol been reviewed and approved by the ethical and regulatory review boards required by the participating site?

PLEASE NOTE: Check appropriate local/national guidelines. As a guide, patients should only be enrolled once appropriate approvals have been obtained for the applicable site.