# 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 ALERRT COVID-19 CCP 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

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 Electronic 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 ALERRT/ISARIC has created a modified CRF form
- The form is available electronically.

Consider how you will process the data

- The ALERRT/ISARIC  forms each have a data dictionary (a set of information which describes the contents, format, and structure of the ALERRT 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 ALERRT 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.

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 ALERRT Clinical Data Platform;

- ☐ Have appropriate team member(s) been issued a username and password for data entry? (For assistance, please contact your local site manager)
- ☐ Have appropriate team member(s) been briefed on using the software?
- ☐ Has the site received a site number? To obtain this, please please contact your local site manager).

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.