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.
- 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 Subm ission 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.