How do I operationalise COVID-19 CCP Global?

OVERVIEW OF THE MAIN STEPS: Tiers 1, 2 & 3

For successful study implementation, it is important for the study not to be seen as a separate activity in the facility's response strategy to COVID-19.

A Principal Investigator must be appointed; They will be responsible for all aspects of the study, following the main steps outlined below.

1. DETERMINE SITE CAPACITY

- Adapt and amend the Clinical Characterisation Protocol (CCP) to local context/capacity.
- Conduct a review to assess the resources required to carry out the CCP locally.

CCP Global; Where to start?

Clinical Characterisation Protocol

2. PREPARE DOCUMENTATION/OBTAIN ETHICS APPROVAL

- Review 'Site Capacity: Points to consider', to assist with determining the tier level for your site.
- Organise a Study Master File (electronic/paper); A File, which contains key documents and procedures.
- Develop standard operational procedures (SOPs) to be used by the study team e.g. Adapt ISARIC templates as required i.e. ISARIC Data Platform, Data Entry Guides.
- Decide on electronic versus paper-based data collection; Register to use the free ISARIC data collection portal: ncov@isaric.org.
- Obtain relevant approvals e.g. local ethics approval; Review the Ethics Example Text Guide.

Site Capacity: Points to consider

Study Master File Template

Data Entry Guides

Ethics Example Text Guide

3. PLANNING RESOURCES

- Ensure staff are trained in research e.g. collecting patient data, processing and labelling samples.
- Ensure staff have access to PPE for delivering research.
- Assess consumables/technology and other resources.

Competency/Training Needs: Points to consider

4. THE PATIENTS JOURNEY

- Consider the different groups of patients e.g. Children, and/or, Illiterate adults, and/or, adults who are unable to give informed consent due to mental or physical status.
- Consider conducting a study walk-through.
- Ensure documents i.e. Informed Consent/Sensitive Data are stored safely and securely.

The Global Health Network's Study Walk-through

5. COMMUNITY AND PUBLIC ENGAGEMENT

- Ensure all facility staff are familiar with the concept of the study; gather input from community/patient led groups.
- Public engagement; Creation of patient and family education materials (NB other facilities/groups may be interested in participating e.g. public health/epidemiologists etc.)

Community Engagement Toolkit - coming soon!

6. SCREENING AND STUDY ENROLMENT

- Ensure all correct staff have read the required documents and received appropriate training.

Patient Information Sheets & Informed Consent Forms

Guidance for Consultee (Consent taker)

Case studies

6 Easy Steps, Version 1, 4th May 2020 [Based on the WHO/ISARIC Clinical Characterisation Protocol (CCP), Version 3.1/3.2; Citation: Dunning, J. W., et al. (2014). "Open source clinical science for emerging infections." Lancet Infect Dis 14(1): 8-9].