

# 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.

### 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](mailto:ncov@isaric.org).
- Obtain relevant approvals e.g. local ethics approval; Review the 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.

### 4. THE PATIENTS JOURNEY

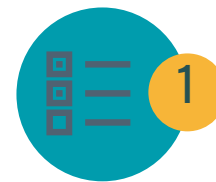
- Consider the different groups of patients e.g. Children, and/or, Illiterate adults, and/or, adults who are unable to give informed consent due to mental or physical status.
- Consider conducting a study walk-through.
- Ensure documents i.e. Informed Consent/Sensitive Data are stored safely and securely.

### 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.)

### 6. SCREENING AND STUDY ENROLMENT

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



CCP Global; Where to start?  
Clinical Characterisation Protocol

Site Capacity: Points to consider  
Study Master File Template  
Data Entry Guides  
Ethics Example Text Guide



Competency/Training Needs: Points to consider

The Global Health Network's Study Walk-through



Community Engagement Toolkit  
- coming soon!

Patient Information Sheets & Informed Consent Forms

Guidance for Conslee (Consent taker)

Case studies

