Research guidelines for COVID-19 related proposals

External Principal Investigators’

Submission to
Institutional Review Board (Ethics Committee)

Email to: research@cmcvellore.ac.in for expedited clearance

Approved

CMC Principal Investigators’

Submission to
Institutional Review Board (Ethics Committee)

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IBSC/IAEC approval if required

After Approval

Proposals involving human participants

Proposals involving human participants requesting data/sample sharing access

Consent, CRF, Sample Integration Committee

- Dr. George M Varghese, Infectious Diseases (In-charge)

Committee Members:
- Dr. Sujith Chandy, Clinical Pharmacology
- Dr. Karthik Gunasekaran, Medicine
- Dr. KPP Abhilash, Emergency Medicine
- Dr. Deepthi Boddu, Pediatric
- Dr. Lovely Thomas, Critical Care Medicine
- Dr. Sushil Selvarajam, Haematology
- Dr. Mahesh Moorthy, Clinical Virology

Filled consent/CRF

Access Control Committee (ACC)

Dr. J. V. Peter, Director, CMC (Member)
Dr. Anna. B. Pulimood, Principal, CMC (Chairman)
Dr. Prasad Mathews, Medical Superindent, CMC
Dr. Suceena Alexander, Addl. Vice Principal (Research), (Secretary)
Dr. Joy Mammen, Associate Director (Medical), CMC (Member)
Dr. George Thomas, External Member

Any Manuscript being submitted needs to be approved by the Covid-19 Core Research Team to avoid Conflict of Interest and for proper acknowledgement of stakeholders
Important Guidelines for Researchers


2. To ensure optimum collaborations, research proposals need to have co-investigators from all relevant departments in CMC.

3. The proposals will be reviewed by the Institutional Review Board and Ethics Committee and given expedited clearance within 72 hours and need to be submitted for a full IRB review following the expedited clearance.

4. No bio-banking of COVID 19 positive patients should happen in individual departments. All biological samples to be tested should be routed to Clinical Virology.

5. **Clinical Trial Registry of India (CTRI)** registration of all clinical trials is **MANDATORY** before recruitment of the first participant.

Foreign Funding

1. **Health Ministry Screening Committee (HMSC)** clearance is **MANDATORY** before receiving any funds into either an already existing or a new FCRA account and for any intellectual, technical or material support from foreign investigators.

Funding for Studies

1. The PI’s are requested to budget for all applicable designations when applying for external funds (Eg. Research Coordinator, JRF, Data entry operator & ARO) for optimization and sharing of resources

2. All clinical trials should have a mechanism for financial compensation of SAE (death/ disability/ hospitalizations) if related to the intervention and DSMB reporting.

Govt. Approvals And Guidelines

1. Appropriate government approvals should be taken as per DBT notification dated 20.03.2020 (N-BT/03/27/2020-PID) which was already circulated.

2. Please be aware of the NITI Aayog guidelines for sharing of biospecimens and data related to COVID-19 research dated 21.04.2020 (No.15(8)/2020-H&FW) which was already circulated.