

**OBSERVATIONAL STUDIES IN COVID SUSPECT/CONFIRMED CASES USING
INTEGRATED DATABASE IN A TERTIARY CARE CENTRE
PATIENT INFORMATION SHEET FOR PEDIATRICS**

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus SARS CoV2. You may be aware that this virus has spread to many countries and has caused a global health crisis. The clinical manifestations in children have been reported to be mild but is evolving. We still do not know the full impact of this infection in children. Therefore, it is very important that we collect as much information as possible from children seen in our hospital in a systematic manner.

Research about this new infection is being conducted at the Christian Medical College, Vellore to understand various aspects of the disease such as symptoms, laboratory tests, course of the disease, complications, response to treatment, spread of infection in the community and development of immunity.

Your child is invited to participate in this research as he/she is suspected to have this infection or is at risk of developing it

The research will involve close monitoring of progression of the disease in your child, interpreting investigations which maybe routine or specific to diagnose, assess severity, response to treatment and immunity of COVID-19 infection.

Your child will receive treatment as recommended and this will not change depending on your decision whether to participate in this research. Please, take your time to read the following information carefully before you decide whether you wish to take part in this research study or not. You are encouraged to ask the study investigator if you need any additional information or clarification about what is stated in this form and/or in the research study. Please note that, should you decide to participate, you are free to withdraw at any time without any consequence.

If you agree for your child to take part in this study, you will be asked to sign the Consent Form on the last page of this document. This document includes the information sheet and the consent form. Please make sure you have read and understood all the pages.

What is the purpose of this research?

We plan to study the clinical features, laboratory parameters and outcome in children with suspected and confirmed cases of COVID-19 infection.

What happens when your child takes part in this study?

On giving consent to the study, you agree to share the following information with us and allow us to take the required samples during your child's stay in the hospital

1. Demographic details (including your child's age, sex, socio economic status, place of stay etc.)
2. Clinical history leading to the visit to the hospital

3. Relevant history such as
 - i. Travel and exposure history to known Coronavirus infected patient
 - ii. History of medications
 - iii. Comorbidities history
 - iv. And such other details which maybe relevant for the research

4. Laboratory samples
 1. Blood: Apart from the routine blood samples, blood may be collected for special tests pertaining to the viral infection – this may include viral antibody level, viral load, immune response, and blood test to assess the organ functions
 2. Swab: The virus is detected in RT-PCR test run on respiratory samples. The specimen may be collected through nose/mouth and /or Endotracheal tube (ET only if patient is intubated for worsening lung condition)
 3. And if any such other samples which may be required will be explained to you before you consent for the study

We would like to assure you, that the amount of blood taken will be minimal and will not cause any major discomfort to your child. All the laboratory sample collection will be performed by experienced health care workers only.

5. Other investigations:

Some other investigations maybe performed during your childs stay in the hospital to carefully monitor your lung and cardiac function. These tests are non-invasive and will not hurt your child.
6. Your child’s clinical course in the hospital will be closely followed and documented in the database
7. On discharge, there may be telephonic follow up of your child’s health condition.

Are there any risks to participate in this study?

Your child will not be exposed to any risk other than routine risk involved in blood collection, which may cause a small amount of pain, bleeding, and/or bruising at the place in the arm

where blood is drawn. We will also do throat swabs which are a part of routine testing and might cause mild discomfort and gagging during the test. The other tests done also will have a minimal risk. As there is no intervention involved no compensation will be offered.

What are the possible benefits of taking part?

We cannot promise the study will help your child (you or your family member), but the information we get from the study may help other patients and contribute to better understanding of the new infection and the healthcare associated with that.

Can you withdraw from this study after it starts?

Participation is entirely voluntary, and you are free to decide to withdraw permission to participate in this study. If you do so, this will not affect your child's usual treatment at the hospital in any way.

Will I have to pay for the check up?

There is no need to pay extra apart from your routine payment as per institutional rules and regulations. Additional tests done as a part of research will be done free of cost.

What happens when the study is over?

The information collected from all participants will be analyzed to see if we can identify any patterns specific to COVID-19 infection.

Will my child's personal details be kept confidential?

The participation in the study will be strictly confidential and shall be known only to the investigators. The results of the study will be published in a medical journal, but you will not be identified by name in any publication or presentation of results.

If you have any questions, please contact

Dr. Deepthi Boddu
Associate Professor
Pediatrics Department
Christian Medical College, Vellore
child1@cmcvellore.ac.in

Dr. Leni G Mathew
Professor and Head
Pediatrics Department
Christian Medical College, Vellore
child1@cmcvellore.ac.in

Mobile number: 8300205529