OSERVATIONAL STUDIES IN COVID SUSPECT/CONFIRMED CASES USING INTEGRATED DATABASE IN A TERTIARY CARE CENTRE

PATIENT INFORMATION SHEET FOR ADULTS

CORONA VIRUS infection, also known as COVID 19 is spreading very rapidly in our country. What we know so far is that it is a virus mainly affecting the respiratory system. Symptomatic patients present with fever, cough and breathlessness. However a large number of infected patients are asymptomatic or have mild illness. Very rarely, patients are critically ill and require ICU admission.

Corona virus infection is a relatively new disease. The medical fraternities 'knowledge about the patho-physiology, natural course and treatment options for this disease is very limited. If you have been asked to participate in this study, it is likely that you or a family member is a patient who has presented with respiratory illness and is suspected or confirmed to have COVID infection. We would like to invite you to take part in research studies which are planned in our institution under different medical specialities to aid us in better understanding of this disease. Your participation will help us offer better care for similar patients in future.

Please take time to read the following information carefully. Ask questions if anything you read is not clear or you would like more information. Take time to decide whether or not to take part.

What is the research about?

You have been asked to enrol in this research because we suspect / or have been diagnosed to have Corona virus infection. This research may include different studies which are being done under different departments looking at various aspects of the COVID virus effect on thehuman body.

Do I have to take part?

It is up to you to decide. We will describe the study to you. Additional information is

available in this information sheet. We will then ask you to sign a consent form to show you agreed to take part. You are free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive.

What will be done 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 stay in the hospital

1. Demographic details (including your age, sex, marital status, socio economic status, place of stay etc)
2. Clinical history leading to the visit to the hospital
3. Relevant history
    i. Travel and exposure history to known Corona virus infected patient
    ii. History of medications
    iii. Comorbidities history
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. Dialysis effluent: In very rare situations, if dialysis is initiated for kidney failure, the fluid which is removed during dialysis may be stored and processed for viral testing.

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

5. Other investigations:
   Radiological imaging modalities such as Chest X rays / CT scans and Echocardiograms (imaging the heart function) may be performed during your stay in the hospital to

carefully monitor your lung and cardiac function. All these tests are non-invasive and won't hurt you.

6. Your 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 health condition.

Are there any additional expenses that I will need to pay for?

There are no additional expenses that you/your patient will undergo in this study. The institution will cover the extra cost of the tests which are done extra for the study purpose. As this is an observational research project, no additional payments/reimbursement for participation will be done.

What are the possible disadvantages and risks of taking part?

Other than the possibility of minimal discomfort during sampling, there are no other disadvantages or risks involved in taking part. The swabs /blood sample collection/Chest X Ray / Echocardiogram are known medical procedures and have been in practice for several decades.

What are the possible benefits of taking part?

We cannot promise the study will help the patient (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.

Will my taking part in the study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that the patient cannot be recognized.

Data from this study will be stored electronically and will be password protected. A Master list identifying participants to the research codes data will be held on a password protected computer accessed only by the researcher.

What will happen if I withdraw from the study?

If you withdraw from the study all the information and data collected from you, to date, will be destroyed and your name removed from all the study files. This will not affect your treatment in any way. There are no penalties for withdrawing from the study.

What will happen to the results of the research study?

The results of this research study will be collated and analyzed. This data if published / presented will not be identifiable to the patient in any form.

Who is organising or sponsoring the research?

This research project is funded by the Christian Medical College, Vellore. Very few of the studies within this project may be funded by an external funding source.

In case you have any further doubts or questions, a health professional will be free to answer your queries in the following contact number.

Phone No: 9385285975.

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