Information Sheet & Consent Form (English Version)

COVID-19 - quality of life after infection

This Informed Consent Form has two parts:

- Participant Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Participant Information Sheet

The Accident & Emergency Medicine Academic Unit and the Department of Medicine and Therapeutics of The Chinese University of Hong Kong are collaborating to conduct this study.

You are invited to participate in this study. Before you decide to participate or not it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with friends, relatives and your family doctor if you wish. Ask us if there is anything that is not clear and/or if you would like more information. Take time to decide whether or not you wish to take part in this research. This study plans to recruit 200 participants from the Prince of Wales Hospital (PWH) outpatient clinics.

Aim of the research

This study aims to investigate the quality of life of COVID-19 patients after recovery and discharge from the hospital. This study aims to determine the quality of life of COVID-19 survivors up to six-months after discharge from hospital.

Your participation is important to help to understand the quality of life (QoL) after COVID-19. Doing so can help enhance recovery from COVID-19 disease. If you are willing to participate in our research study, it would be greatly appreciated.

What will happen if you join the study

With your permission, we would like to have a face-to-face interview to assess your quality of life before and after the diagnosis of COVID-19 during your hospital stay. We would like to follow up your quality of life at 1, 3, and 6 months after your discharge via a telephone follow-up interview or by electronic means, e.g. an online form or email.

The treatment of your medical condition will not be affected by whether or not you agree to participate in this research.

We would like to use data from measurements already taken from patients as part of their treatment. We will collect other relevant clinical data from the hospital electronic medical records, and we would like to follow your condition to monitor your progress and the final outcome. All data will be kept for 7 years and will be used only for the purposes of research. All

PWH ICF (English) Version 2; 29 April 2020 data will be kept confidential. If you agree to participate in this study, we may contact you again in the future to ask you if you would consent to participating in other relevant research studies.

Possible benefits

Your participation in this study may or may not make your health better. While investigator hope to find out long-term incremental impact of COVID-19. The study will provide insight in forecasting the time required for patients with COVID-19 to return to their baseline health status and in the factors associated with recovery. Healthcare providers will be able to help patients and their families know better about the specific needs for COVID-19 patients' recovery from illness.

Possible risks

There are no physical risks and discomfort to you in this study. The risk of identity disclosure will be kept to a minimum as all collected information will be de-personalized and kept confidential. The information will only be accessed by the research team. No additional blood tests or medical interventions will be performed as part of this research.

Alternative Procedures or Treatments

If you decide not to join this study, your treatment will be decided by your treating physician. The treatment you receive will not be affected in anyway.

Cost and Payment

There is no additional cost or payment for your participation in this study.

New Information

You will be told in a timely manner about significant new information that might affect your decision to stay in the study. You will be notified of the published results of this research project if you so choose (see check-box below).

Voluntary Participation / Withdrawal

Participation in this study is entirely voluntary. You may withdraw consent at any time and request us not to use your data. If the patient is unable to give consent, the study will be explained to the patient's relative (next-of-kin). The patient's relative will also receive a detailed information leaflet explaining the study. Relative consent will be obtained, patient consent will be sought once patient is capable. If the subject does not agree to participate in the study after enrolling, then all their data cannot be used for the study. The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (The Joint CUHK-NTEC CREC) may access your records in this study for ethics review purpose.

Confidentiality and Privacy

Your confidentiality will be the highest priority. If the information you provide is reported or published, this will be done in a way that does not identify you as its source. To ensure the highest form of confidentiality, your signed consent forms will be stored separately from your interview notes and personal data to further protect your confidentiality. Access to the data will be restricted to the researchers of this study. Along with this, interview notes as well as personal data will be stored in the computers which are only accessible by the researchers. Data can be withdrawn and destroyed if requested by participants. Except for data to be kept for future comparative studies, all data will be destroyed three years after the completion of the study. Your privacy is important. All information gathered in this study will be kept private. Under the laws

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of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his officer (Tel no.: 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By signing a written informed consent form, you are authorizing the Research Ethics Committee (REC) and the regulatory authority(ies) will be granted direct access to the subject's study data for data verification.

Contacts

If you have any further questions, please contact: Research Associate, Dr. Leung Ling Yan (Tel: 3505 1698)

Principal Investigator, Prof. Joseph Walline, Assistant Professor, Accident and Emergency Medicine Academic Unit, Prince of Wales Hospital, The Chinese University of Hong Kong (Tel: 3505 1698)

To assure you that your rights are well protected you may contact an independent body at any time. The contact is: The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (The Joint CUHK-NTEC CREC) (Tel: 3505 3935).

By signing a written informed consent form, you will be given a signed copy of the consent form and participant information sheet for record.

Thank you for your involvement.

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I hereby consent to participate in this research study.

I have read the PARTICIPANT INFORMATION SHEET. The study has been explained to me. I understood all the benefits and the risks associated with this study. I have had opportunities to ask questions and all my questions have been satisfactorily answered. I have received enough information about the study.

If the result of my participation in this study causes any physical injury or feel uncomfortable emotionally, the investigator will treat me or refer for treatment. I am not giving up any of my legal rights by signing this form.

By signing this informed consent form, I certify that all information provided is true and correct. I understand that I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and the withdrawal will not affect my present and future medical care.

I understand that my identity will be kept confidential. I agree to authorize the Research Ethics Committee (REC) and the regulatory authority(ies) a direct access to my research data for verification of clinical trial data, without violating my confidentiality, to the extent permitted by the applicable laws and regulations.

I would like to receive notification about the published results of this research project.

Name of patient/ next of kin	Signature	Date
Contact number of patient/next o	f kin:	
Name of witness	Signature	Date
Name of person obtaining conser	nt Signature	Date