Written Patient Informed Consent Form

Study Title: Respiratory virus infections in acutely hospitalized adult patients with pulmonary and extrapulmonary complications

You are invited to participate in a research study conducted by Dr Kelvin To and Prof Ivan Hung at the University of Hong Kong, Queen Mary Hospital. This study has been reviewed and approved by Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster.

PURPOSE OF THE STUDY

The purpose of this study is to assess the incidence of respiratory virus infection in adult acutely hospitalized patients with exacerbation of underlying lung disease, heart attack or stroke.

PROCEDURES

In this study, we will collect saliva (~1 ml) for testing of respiratory viruses. You will also be asked to fill in a questionnaire about your symptoms. We will also collect demographic, clinical and laboratory data for analysis. The specimens will be stored in case re-testing is required. Furthermore, the specimens may be screened for novel respiratory pathogens in the future, and may be sent overseas for further testing.

EXPECTED BENEFITS

A better understanding of the incidence of respiratory virus infection is important for patient management and infection control practices.

POTENTIAL RISKS / DISCOMFORTS AND THEIR MINIMIZATION

There is no risks or discomforts.

COMPENSATION FOR PARTICIPATION

None

PARTICIPANT’S RIGHT

The subject’s participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

CONFIDENTIALITY

You have the rights of access to personal data and publicly available study results, if and when needed. All records identifying the subject will be kept confidential. The subject or the subject’s legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject’s willingness to continue participation in the trial.
Under the laws 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 Privacy Data or his office (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 consenting to participate in this study, you expressly authorize:

- The principal investigator and his research team and the ethics committee (Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster) responsible for overseeing this study to get access to, to use, and to retain your personal data for the purposes and in the manner described in this informed consent process; and
- The relevant government agencies (e.g. the Hong Kong Department of Health) to get access to your personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

QUESTIONS AND CONCERNS
If you have any questions or concerns about the research, please feel free to Ms. Deborah Ho at 91210105.

SIGNATURE

I understand the purpose of this study and authorize the use of my medical records as described in this document. Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster is one of the authorized parties to access the subjects’ records related to the study for ethics review purpose. I do freely give my consent to join in this Study and understand that I will receive a copy of this document as signed below.

PATIENT'S SIGNATURE........................................... Date:……………

PATIENT'S NAME: ..............................................................

INVESTIGATOR’S SIGNATURE.......................... Date:.............................

INVESTIGATOR’S NAME: .......................................................

Department of Microbiology and Department of Medicine, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Queen Mary Hospital, Hong Kong.