National Healthcare Group
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NHG DSRB Ref: **2018/00354**

11 June 2018

Dr Andrew Li Yunkai
Department of Respiratory & Critical Care Medicine
National University Hospital

Dear Dr Li

NHG DOMAIN SPECIFIC REVIEW BOARD (DSRB) APPROVAL

STUDY TITLE: Prevalence, causes, management, and outcomes of sepsis in Asia's intensive care units

We are pleased to inform you that the NHG Domain Specific Review Board has approved the application as titled above to be conducted in **National University Hospital**, **Changi General Hospital**, **Tan Tock Seng Hospital**, **Khoo Teck Puat Hospital**, **Ng Teng Fong General Hospital** and **Singapore General Hospital**.

This approval is mutually recognised by SingHealth Centralised Institutional Review Board (CIRB).

The approval period is from **11 June 2018** to **10 June 2019**. The NHG DSRB reference number for this study is **2018/00354**. Please use this reference number for all future correspondence.

Please note that this is a human biomedical research that is regulated by the Human Biomedical Research Act (HBRA) and researchers are required by law to comply with all the relevant regulatory requirements of the HBRA.

The documents reviewed are:

a) NHG DSRB Application Form: **Version No. 1**
b) Informed Consent Form (CGH): Version 1 dated 14 May 2018
c) Informed Consent Form (KTPH): Version 1 dated 14 May 2018
d) Informed Consent Form (NTFGH): Version 1 dated 14 May 2018

e) Informed Consent Form (NUH): Version 1 dated 14 May 2018
f) Informed Consent Form (SGH/SKH): Version 1 dated 14 May 2018
g) Informed Consent Form (TTSH): Version 1 dated 14 May 2018
h) Study Protocol: Version 1.0 dated 15 December 2017

Continued approval is conditional upon your compliance with the following requirements:
1. Only the approved Informed Consent Form should be used. It must be signed by each subject prior to initiation of any protocol procedures. In addition, each subject should be given a copy of the signed consent form.

2. No deviation from or changes to the study should be implemented without documented approval from the NHG DSRB, except where necessary to eliminate apparent immediate hazard(s) to the study subjects.

3. Any deviation from or changes to the study to eliminate an immediate hazard should be promptly reported to the NHG DSRB within seven calendar days.

4. Please note that for studies requiring CTA/CTN/CTC, apart from the approval from NHG DSRB, no deviation from, or changes of the Research Protocol and Informed Consent Form should be implemented without documented approval from the Health Sciences Authority unless otherwise advised by the Health Sciences Authority.

5. Please submit the following to the NHG DSRB:

a. All Unanticipated Problems Involving Risk To Subjects Or Others (UPIRTSOs) must be reported to the NHG DSRB. For more than minimal risk studies, all problems involving local deaths must be reported as soon as possible, but not later than **7 calendar days** after first knowledge by the Investigator, regardless of the causality and expectedness of the death event, and any additional relevant information about the death should be reported within **8 calendar days** of making the initial report. For no more than minimal risk studies, only problems involving local deaths that are related or possibly related to the study must be reported as soon as possible, but not later than **7 calendar days** after first knowledge by the Investigator, and any additional relevant information about the death should be reported within **8 calendar days** of making the initial report. For problems which are life threatening, it should be reported as soon as possible, but not later than **7 calendar days** after first knowledge by the investigator, and any additional relevant information about the problems should be reported within **8 calendar days** of making the initial report. All other problems that fulfil the UPIRTSOs reporting criteria must be reported as soon as possible but not later than **15 calendar days** after first knowledge by the Investigator.

b. Report(s) on any new information that may adversely affect the safety of the subject or the conduct of the study.

c. NHG DSRB Study Status Report Form – this is to be submitted 4 to 6 weeks prior to expiry of the approval period. The study cannot continue beyond **10 June 2019** until approval is renewed by the NHG DSRB.

d. Study completion – this is to be submitted using the NHG DSRB Study Status Report Form within 4 to 6 weeks of study completion.

With the enactment of the Human Biomedical Research Act, Health Products Act, Medicines Act and their subsidiary legislations, Principal Investigators are reminded to ensure that their research complies

with the regulatory requirements stipulated in the applicable Acts. Contraventions under any of these Acts are criminal offences and would result in fines or imprisonment or both, subject to the nature of the offence.

Established since May 2006, the NHG Research Quality Management (RQM) Program seeks to promote the responsible conduct of research in a research culture with high ethical standards, identify potential systemic weaknesses and make recommendations for continual improvement. Hence, this research study may be randomly selected for a review by the Research Quality Management (RQM) team. For more information, please visit www.research.nhg.com.sg.

The NHG DSRB operates in accordance to the ICH GCP and all applicable laws and regulations.

Yours Sincerely

Dr Ross Soo
Chairman
NHG Domain Specific Review Board B2

Cc: Institutional Representative, NUH
c/o Research Office, NUH
Departmental Representative of Respiratory & Critical Care Medicine, NUH

Cc: Institutional Representative, KTPH
c/o Clinical Research Unit, KTPH
Departmental Representative of Anesthesia, KTPH

Cc: Institutional Representative, TTSH
c/o Clinical Research & Innovation Office, TTSH
Departmental Representative of Anaesthesiology, Intensive Care and Pain Medicine, TTSH

Cc: Institutional Representative, NTFGH
Departmental Representative of Intensive Care Medicine, NTFGH

Cc: Institutional Representative, CGH
Departmental Representative of Anaesthesia, CGH

Cc: Institutional Representative, SGH
Departmental Representative of Respiratory & Critical Care Medicine, SGH

(This is an electronic-generated letter. No signature is required.)