

NHG DSRB Ref: **2014/01194**

09 April 2015

Dr Lee Guan Huei
Department of Gastroenterology & Hepatology
National University Hospital

Dear Dr Lee

NHG DOMAIN SPECIFIC REVIEW BOARD (DSRB) APPROVAL

STUDY TITLE: The clinical profile and outcome of acute-on-chronic liver failure in Singapore

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**.

The approval period is from **09 April 2015** to **08 April 2016**. The NHG DSRB reference number for this study is **2014/01194**. Please use this reference number for all future correspondence.

The documents reviewed are:

- a) NHG DSRB Application Form: **Version No. 1**
- b) ACLF Data Collection Form: **Version 1 dated 15 October 2014**

The NHG DSRB has approved your request for waiver of informed consent.

Continued approval is conditional upon your compliance with the following requirements:

1. 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.
2. 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.
3. Please note that for studies requiring Clinical Trial Certificate, 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.

4. Please note that all research studies submitted from National University Hospital (NUH), involving the use of radioactive materials and/or radiation-emitting equipment are subjected to the NUH Radiation Safety Committee (RSC) review. Approval from the NUH RSC is mandatory prior to commencement of the study.

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. All problems involving local deaths must be reported immediately within 24 hours after first knowledge by the Investigator, regardless of the causality and expectedness of the death. All other problems must be reported as soon as possible but not later than seven 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 **08 April 2016** 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.

6. 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.

Yours Sincerely

Dr Teng Gim Gee
Deputy Chairperson
NHG Domain Specific Review Board E

Cc: Institutional Representative, NUH
c/o Research Office, NUH
Departmental Representative of Gastroenterology & Hepatology, NUH

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