

NHG DSRB Ref: **2014/00531**

20 October 2014

Dr Lee Guan Huei
Department of Medicine
National University Hospital

Dear Dr Lee

NHG DOMAIN SPECIFIC REVIEW BOARD (DSRB) APPROVAL

STUDY TITLE: A study of the genetic variants associated with non-alcoholic fatty liver disease in ethnic-Chinese population 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** and **NUS - Yong Loo Lin School of Medicine**.

The approval period is from **20 October 2014** to **19 October 2015**. The NHG DSRB reference number for this study is **2014/00531**. Please use this reference number for all future correspondence.

The documents reviewed are:

- a) NHG DSRB Application Form: **Version No. 1**
- b) Genetic Variants Associated with NAFLD in Singapore, Study Protocol: Version 1 dated 28 September 2014
- c) Genetic Variants Associated with NAFLD in Singapore, PIS-ICF Version 6 dated 13 October 2014
- d) Genetic Variants Associated with NAFLD in Singapore, Questionnaire version 1 dated 30 Sep 2014
- e) NAFLD SNP – Data Collection Form: Version 2 dated 11 July 2014

The NHG DSRB acknowledges the receipt of the following document:

- a) Genetic Variants Associated with NAFLD in Singapore, PIS-ICF Version 6 with short consent form (Chinese) dated 13 October 2014

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 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.
5. 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.
6. 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 **19 October 2015** 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.
7. 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

Prof A Vathsala
Deputy Chairperson
NHG Domain Specific Review Board E

Cc: Institutional Representative, NUH
c/o Research Office, NUH
Departmental Representative of Medicine, NUH

Cc. Institutional Representative, NUS-YLL SoM
Departmental Representative of Medicine, NUS-YLL SoM

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