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RCB No. 200002150H

NHG DSRB Ref: **2012/00394**

30 July 2014

A/Prof Theresa Tan May Chin
Department of Biochemistry
NUS - Yong Loo Lin School of Medicine

Dear A/Prof Tan

RENEWAL OF NHG DOMAIN SPECIFIC REVIEW BOARD (DSRB) APPROVAL

STUDY TITLE: Role of microRNAs in metastasis of hepatocellular carcinoma

We are pleased to inform you that the NHG DSRB has renewed the approval for the application as titled above, being conducted in **National University Hospital**. The approval period is from **30 July 2014 to 29 July 2015**.

The documents reviewed are:

- a) NHG DSRB Study Status Report Form ID: **2012/00394-SRF0002**
- b) NHG DSRB Application Form: **Version No. 1**
- c) Study Protocol: Version dated 09 May 2012

The document acknowledged is:

- a) micro RNA Tier 1 RGF (Application) : dated 01 May 2010

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

1. No deviation from, or changes of the protocol 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 a change of, the protocol 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 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 **29 July 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 or termination.

5. 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 Nicholas Paton
Chairperson
NHG Domain Specific Review Board E

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

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