National Healthcare Group
Adding years of healthy life

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NHG DSRB Ref: **2016/00825**

21 December 2016

Dr Shelat
Department of Surgery
Tan Tock Seng Hospital

Dear Dr Shelat

**NHG DOMAIN SPECIFIC REVIEW BOARD (DSRB) APPROVAL**

**STUDY TITLE: Early Achievable SeveritY (EASY) index for simple and accurate early risk stratification in acute pancreatitis**

We are pleased to inform you that the NHG Domain Specific Review Board has approved the application as titled above to be conducted in **Tan Tock Seng Hospital**.

The approval period is from **21 December 2016** to **20 December 2017**. The NHG DSRB reference number for this study is **2016/00825**. Please use this reference number for all future correspondence.

The documents reviewed are:

a) NHG DSRB Application Form: **Version No. 1**
b) Informed Consent Form: **Version 02 dated 15 December 2016**
c) EASY Form: **Version 02 dated 07 December 2016**
d) EASY Questionnaire: **Version 02 dated 07 December 2016**
e) Trial Protocol: **Version dated 20 September 2014**

The NHG DSRB acknowledges the receipt of the following documents:

f) Informed Consent Form Version 02 with Short Consent Form (Chinese): Version dated 15 December 2016
g) Informed Consent Form Version 02 with Short Consent Form (Malay): Version dated 15 December 2016
h) Informed Consent Form Version 02 with Short Consent Form (Tamil): Version dated 15 December 2016

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 **20 December 2017** 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.

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 Faith Chia
Deputy Chairperson
NHG Domain Specific Review Board E

Cc: Institutional Representative, TTSH
c/o Clinical Research Unit, TTSH
Departmental Representative of Surgery, TTSH

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