

CIRB Ref: **2018/2400**

29 Jun 2018

Dr Elaine Lim Hsuen
Division of Medical Oncology
National Cancer Centre

Dear Dr Lim

SINGHEALTH CENTRALISED INSTITUTIONAL REVIEW BOARD (CIRB) APPROVAL

Protocol Title: Prescribing Practices of Medical Oncologists in the Treatment of Metastatic Breast Cancer

We are pleased to inform you that the SingHealth CIRB B has approved the above research project to be conducted in National Cancer Centre.

The documents reviewed are:

- 1) CIRB Application Form dated 19 Jun 2018
- 2) Data Collection Form: Version 1 dated 27 May 2018

The SingHealth CIRB has approved your request for waiver of informed consent based on ethical consideration. Please ensure that this study complies with your Institution policies.

The SingHealth CIRB operates in accordance with the ICH Guideline for Good Clinical Practice, and with the applicable regulatory requirement(s).

The approval period is from **29 Jun 2018 to 28 Jun 2019**. The reference number for this study is CIRB Ref: 2018/2400. Please use this reference number for all future correspondence.

The following are to be observed upon SingHealth CIRB Approval:

1. No participant should be admitted to the trial before the Health Sciences Authority notification/ authorisation/ approval has been obtained (for studies involving therapeutic or medicinal products).
2. The Principal Investigator should ensure that this study is conducted in compliance with the ICH Guideline for Good Clinical Practice, the ethical guidelines of which are applicable to all studies to be carried out, and to ensure that the study is carried out in accordance to the guidelines and the submitted protocol. The Principal Investigator should meet with his collaborator(s) regularly to assess the progress of the study, and be familiar and comply with all applicable research policies in the Institution.

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National Cancer Centre Singapore • National Dental Centre Singapore • National Heart Centre Singapore
National Neuroscience Institute • Singapore National Eye Centre • SingHealth Community Hospitals • SingHealth Polyclinics

3. No deviation from, or changes of, the protocol should be initiated without prior written SingHealth CIRB approval of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involve(s) only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone number(s)).
4. Only the approved Participant Information Sheet and Consent Form should be used. It must be signed by each participant prior to enrolling in the study and initiation of any protocol procedures. Two copies of the Informed Consent Form should be signed and dated. Each participant or the participant's legal representative should be given a copy of the signed consent form. The remaining copy should be kept by the PI / medical record.
5. The Principal Investigator should report promptly to the SingHealth CIRB of:
 - i. Deviations from, or changes to the protocol including those made to eliminate immediate hazards to the trial subjects.
 - ii. Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial.
 - iii. All serious adverse events (SAEs) and adverse drug reaction (ADRs) that are both serious and unexpected.
 - iv. New information that may affect adversely the safety of the subjects or the conduct of the trial.
 - v. Completion of the study.
6. Study Status Report should be submitted to the SingHealth CIRB for the following:
 - i. Study renewal: the Study Renewal Report is to be submitted at least two months prior to the expiry of the approval period. A valid SingHealth CIRB renewal is essential, as any research performed outside of an approved time frame is not legal, and thus not covered by the hospital's research insurance in case of unexpected adverse reactions.
 - ii. Study completion, withdrawal or termination: the Study Closure Report is to be submitted within 30 days after completion of the study. When the study is withdrawn or terminated by the Institution, PI or the sponsor, the PI should submit the Study Closure Report within 7 days.

Yours sincerely,

Dr Toh Chee Keong
Deputy Chairman
SingHealth Centralised Institutional Review Board B

cc: Institution Representative, NCC
Head, Division of Medical Oncology, NCC

This application is approved online. No signature is required.