National Healthcare Group
Adding years of healthy life

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RCB No. 200002150H

DSRB Ref: D/11/017

5 May 2011

Dr Tan Ern Yu
Department of Surgery
Tan Tock Seng Hospital

Dear Dr Tan

NHG DOMAIN-SPECIFIC REVIEW BOARD (DSRB) APPROVAL

Project Title: Optimising Hormonal Therapy in Hormone Responsive Breast Cancer

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

Please note that this study can only be initiated after a Clinical Trial Certificate has been issued, or the Health Sciences Authority has given a written notification that a Clinical Trial Certificate is not required.

The documents reviewed are:

a) Complete Application Form: Optimising Hormonal Therapy in Hormone Responsive Breast Cancer, **Version 1 dated 5/05/2011**
b) Study Protocol: **Version 1 dated 23/12/2010**
c) Participant Information Sheet and Consent Form: **Version 3 dated 5/05/2011**
d) Data Collection Form: **Version 1 dated 27/12/2010**

The approval period is from **5 May 2011** to **4 May 2012**. The reference number for this study is **DSRB-D/11/017**. Please use this reference number for all future correspondence.

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

1. Only the approved Participant Information Sheet and 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 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, or when the change(s) involves only logistical or administrative aspects of the trial (e.g. change of monitor or telephone number).

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3. 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.

4. Please note that for studies requiring Clinical Trial Certificate, apart from the approval from DSRB, no deviation from, or changes of the Research Protocol and Participant Information Sheet and 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 should be reported. In order to assist the DSRB, all reports should be accompanied by the NHG DSRB Unanticipated Problems Involving Risk to Subjects or Others Reporting Form. Please find all forms and guidelines on reporting on the internet at www.b2bresearch.nhg.com.sg.

   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 Project Status Report Form – this is to be submitted 4 to 6 weeks prior to expiry of the approval period. The study cannot continue beyond **4 May 2012** until approval is renewed by the NHG DSRB.

   d. Study completion – this is to be submitted using the NHG DSRB Project Status Report Form within 4 to 6 weeks of study completion or termination.

5. The NHG Research QA Program was launched in May 2006. The program aims to promote responsible conduct of research in a research culture with high ethical standards, and to identify potential systemic weaknesses and make recommendations for continual improvement. This research project may be randomly selected for completion of self assessment worksheet or for a study review by the QA team. For more information please visit www.b2bresearch.nhg.com.sg.

Yours sincerely,

A/Prof Low Yin Peng
Chairman
Domain Specific Review Board D
National Healthcare Group

Cc: Institution Representative, TTSH
Department Representative, TTSH