

NHG DSRB Ref: **2018/01054**

31 January 2019

Dr Wong Kar Yong
Department of Surgery
Tan Tock Seng Hospital

Dear Dr Wong

NHG DOMAIN SPECIFIC REVIEW BOARD (DSRB) APPROVAL OF EXEMPTION

STUDY TITLE: Robotic Assisted Bladder Sparing Pelvic Exenterations for Locally Advanced Rectal Cancers – A Single Centre early experience

The NHG Domain Specific Review Board has determined that the application as titled above qualifies for exemption according to its policies because of the following reason(s):

1. Your declaration that the research involves analysis of data available publicly / dataset without identifiers.

The NHG DSRB reference number for this study is **2018/01054**. Please use this reference number for all future correspondence.

The documents reviewed are:

a) NHG DSRB Application Form: Version No. 01

1. Please note that an exempted study should be conducted in compliance with all applicable institutional policies, regulations and guidelines. Where necessary, approvals from the relevant authorities within your institutions should be sought before the conduct of the study.
2. Changes to the protocol that may affect the exempt status should not be initiated without prior approval by the NHG DSRB, except where necessary to eliminate apparent immediate hazard(s) to the study subjects.
3. Study completion – this is to be submitted using the NHG DSRB Study Status Report Form within 4 to 6 weeks of study completion.

With the enactment of the Human Biomedical Research Act, Health Products Act, Medicines Act and their subsidiary legislations, Principal Investigators are reminded to ensure that their research complies with the regulatory requirements stipulated in the applicable Acts. Contraventions under any of these Acts are criminal offences and would result in fines or imprisonment or both, subject to the nature of the offence.

Thank you.

Yours Sincerely

A/Prof Patrick Chan Mun Yew
Deputy Chairperson
NHG Domain Specific Review Board D

Cc: Institutional Representative, TTSH
c/o Clinical Research & Innovation Office, TTSH
Departmental Representative of Surgery, TTSH

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