

CIRB Ref: **2022/2114**

7 March 2022

Dr Seow En Isaac
Department of Colorectal Surgery
Singapore General Hospital

Dear Dr Seow

SINGHEALTH CENTRALISED INSTITUTIONAL REVIEW BOARD (CIRB) APPROVAL

Protocol Title: Natural orifice specimen extraction (NOSE) in Colorectal Surgery

We are pleased to inform you that the SingHealth CIRB D has approved the above research project to be conducted in Singapore General Hospital.

The documents reviewed are:

- 1) CIRB Application Form dated 24 Feb 2022
- 2) Participant Information Sheet and Consent Form: Version 1 dated 1 Jan 2022
- 3) Data Collection Form

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 **7 March 2022 to 6 March 2023**. The reference number for this study is CIRB Ref: 2022/2114. Please use this reference number for all future correspondence.

The following are to be observed upon SingHealth CIRB Approval:

1. No participant should be enrolled in the trial before the Health Sciences Authority notification/ authorisation/ approval has been obtained (for studies involving therapeutic or medicinal products).
2. The Principal Investigator must not start any restricted human biomedical research before approval has been obtained from the Ministry of Health.
3. The National Electronic Health Record (NEHR) is intended primarily for patient care purposes. NEHR is not to be used for research without prior approval from MOH (MOH Directive 05/2020).

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4. 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 the study team regularly to assess the progress of the study, and be familiar and comply with all applicable research policies in the Institution.
5. 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)).
6. 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. Each participant or the participant's legal representative should be given a copy of the signed consent form.
7. 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. Serious adverse events based on the reporting requirements as stipulated by the SingHealth CIRB Reporting Requirement and Timeline for SAE.
 - iv. New information that may affect adversely the safety of the subjects or the conduct of the trial.
 - v. Completion of the study.
8. 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 Steve Yang
Chairman
SingHealth Centralised Institutional Review Board D

cc: Institution Representative, SGH
Head, Department of Colorectal Surgery, SGH

This submission is reviewed online. No signature is required.