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RCB No. 200002150H

NHG DSRB Ref: **2020/00055**

23 July 2020

Dr Toon Dong Hao
Department of Orthopedic Surgery
Khoo Teck Puat Hospital

Dear Dr Toon

NHG DOMAIN SPECIFIC REVIEW BOARD (DSRB) APPROVAL OF EXEMPTION

STUDY TITLE: The Utility of Magnesium-Based bioabsorbable screws in fixation of upper limb radial head and coronoid fractures – A Case Series

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 **2020/00055**. Please use this reference number for all future correspondence.

The documents reviewed are:

- a) NHG DSRB Application Form: **Version No. 1**
- b) Data Collection Dataset: **Version 4 dated 24 May 2020**

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.

4. It is the responsibility of the Principal Investigator to ensure that the translations for any document are an accurate reflection of the original approved content and to maintain the certification/documentation of the translations.

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 Low Yin Peng
Chairman
NHG Domain Specific Review Board D

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

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