National Healthcare Group
Adding years of healthy life

3 Fusionopolis Link
#03-08 Nexus@one-north
Singapore 138543
Tel: 6496 6600 Fax:6486 6870
www.nhg.com.sg
RCB No. 200002150H

NHG DSRB Ref: **2020/00176**

25 August 2020

Ms Debbie Boey
Department of Occupational Therapy
Tan Tock Seng Hospita

Dear Ms Boey

NHG DOMAIN SPECIFIC REVIEW BOARD (DSRB) APPROVAL

STUDY TITLE: Characterising Activities, Participation and Goals of Older adults with Different Patterns of Visual Loss in Singapore

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

The approval period is from **25 August 2020** to **24 August 2021**. The NHG DSRB reference number for this study is **2020/00176**. Please use this reference number for all future correspondence.

Please note that this is a human biomedical research that is regulated by the Human Biomedical Research Act (HBRA) and researchers are required by law to comply with all the relevant regulatory requirements of the HBRA.

The documents reviewed are:

a) NHG DSRB Application Form: **Version No. 1**
b) Appendix 4 Visual Screening: **Version 03 dated 04 August 2020**
c) Appendix 1 Abbreviated Mental Test: **Version 03 dated 04 August 2020**
d) Appendix 3 Short Physical Performance Battery: **Version 03 dated 04 August 2020**
e) Appendix 5 Chinese Impact of Vision Impairment Profile (English & Chinese): **Version 02 dated 03 July 2020**
f) Appendix 6 Activity Card Sort – Singapore: **Version 02 dated 03 July 2020**
g) Appendix 7 Canadian Occupational Performance Measure: **Version 07 dated 03 July 2020**
h) Appendix 8 COPM and PQRS: **Version 02 dated 03 July 2020**
i) Study Schedule: **Version 04 dated 18 August 2020**
j) Appendix 1 Bells Test: **Version 1 dated 03 July 2020**
k) Appendix 9 Recruitment Poster: **Version 02 dated 03 July 2020**

l) Appendix 10 Recruitment Brochure: **Version 02 dated 03 July 2020**
m) Phase 1 Data Collection Form: **Version 01 dated 01 April 2020**
n) Phase 2 Data Collection Form: **Version 02 dated 03 July 2020**
o) List of Variables to be Extracted: **Version 01 dated 26 March 2020**
p) Appendix 11 Informed Consent Form: **Version 04 dated 18 August 2020**

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

1. Only the approved Informed 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. 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.

3. No deviation from or changes to the study should be implemented without documented approval from the NHG DSRB, except where necessary to eliminate apparent immediate hazard(s) to the study subjects.

4. Any deviation from or changes to the study to eliminate an immediate hazard should be promptly reported to the NHG DSRB within seven calendar days.

5. Please note that for studies requiring CTA/CTN/CTC, apart from the approval from NHG DSRB, no deviation from, or changes of the Research Protocol and Informed Consent Form should be implemented without documented approval from the Health Sciences Authority unless otherwise advised by the Health Sciences Authority.

6. Please submit the following to the NHG DSRB:

a. All Unanticipated Problems Involving Risk To Subjects Or Others (UPIRTSOs) must be reported to the NHG DSRB. For more than minimal risk studies, all problems involving local deaths **must be reported as soon as possible**, but not later than 7 calendar days after first knowledge by the Investigator, regardless of the causality and expectedness of the death event, and any additional relevant information about the death should be reported within 8 calendar days of making the initial report. For no more than minimal risk studies, only problems involving local deaths that are related or possibly related to the study **must be reported as soon as possible**, but not later than 7 calendar days after first knowledge by the Investigator, and any additional relevant information about the death should be reported within 8 calendar days of making the initial report. For problems which are life threatening, it **must be reported as soon as possible**, but not later than 7 calendar days after first knowledge by the investigator, and any additional relevant information about the problems should be reported within 8 calendar days of making the initial report. All other problems that fulfil the UPIRTSOs reporting criteria **must be reported as soon as possible** but not later than 15 calendar days after first knowledge by the Investigator.

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 Study Status Report Form – this is to be submitted 4 to 6 weeks prior to expiry of the approval period. The study cannot continue beyond **24 August 2021** until approval is renewed by the NHG DSRB.

d. 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.

NHG sites of studies regulated under the Human Biomedical Research Act will be subjected to the NHG Monitoring Programme. For Full Board studies, this will include on-site monitoring activities.

Established since May 2006, the NHG Research Quality Management (RQM) Programme seeks to promote the responsible conduct of research in a research culture with high ethical standards, identify potential systemic weaknesses and make recommendations for continual improvement. Hence, this research study may be randomly selected for a review by the Research Quality Management (RQM) team. For more information, please visit www.research.nhg.com.sg.

The NHG DSRB operates in accordance to the ICH GCP and all applicable laws and regulations.

Yours Sincerely

A/Prof Sim Kang
Chairman
NHG Domain Specific Review Board A

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

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