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CIRB Ref: **2017/2061**

20 March 2017

Dr Ang Seng Bin
Department of Family Medicine Service
KK Women's and Children's Hospital

Dear Dr Ang

SINGHEALTH CENTRALISED INSTITUTIONAL REVIEW BOARD (CIRB) APPROVAL

Protocol Title: A pilot study of a customised nanotextile wet garment treatment on moderate and severe atopic dermatitis

We are pleased to inform you that the SingHealth CIRB E has approved the above research project to be conducted in KK Women's and Children's Hospital and Singapore General Hospital.

The documents reviewed are:

a) CIRB Application Form dated 13 Mar 2017
b) Participant Information Sheet and Consent Form - Adult (SGH): Version 2.2 dated 08 Mar 2017
c) Participant Information Sheet and Consent Form - Parent (KKH): Version 2.2 dated 08 Mar 2017
d) Consent to Photography of Skin Lesions/ Eczema Areas (SGH): Version 1 dated 08 Mar 2017
e) Consent to Photography of Skin Lesions/ Eczema Areas (KKH): Version 1 dated 08 Mar 2017
f) Child/ Participant Assent Form (KKH): Version 2.1 dated 01 Mar 2017
g) Infants' Dermatitis Quality Of Life Index (IDQOL): Version 1 dated 08 Dec 2016
h) Children's Dermatology Life Quality Index (CDLQI): Version a dated 08 Dec 2016
i) Children's Dermatology Life Quality Index (CDLQI) - Carton Version: Version 1 dated 08 Dec 2016
j) Dermatology Life Quality Index (DLQI): Version 1 dated 08 Dec 2016
k) Data Collection Form (excel format): Version 1 dated 09 Dec 2016
l) Patient Feedback Form: Version 1 dated 08 Dec 2016

The SingHealth CIRB operates in accordance with the ICH/ Singapore Guideline for Good Clinical Practices, and with the applicable regulatory requirement(s).

The approval period is from **20 March 2017 to 23 February 2018**. The reference number for this study is CIRB Ref: **2017/2061**. Please use this reference number for all future correspondence.

The SingHealth CIRB acknowledges receipt of the following translated document:

i. Chinese Dermatology Life Quality Index (DLQI): Version 1 dated 08 Dec 2016

Please ensure that the translations are an accurate reflection of the original content approved by SingHealth CIRB.

Kindly note that the SingHealth CIRB accepts the authenticity of the translations based on the translation certificates, if any, provided by the Principal Investigator. Consequently, it is the responsibility of the Principal Investigator to ensure that the translations are an accurate reflection of the original approved content.

The following are to be observed upon SingHealth CIRB Approval:

1. No subject should be admitted to the trial before the Health Sciences Authority issues the Clinical Trial Certificate. (only applicable for drug-related studies).

2. The Principal Investigator should ensure that this study is conducted in compliance with the Singapore 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 his collaborator(s) regularly to assess the progress of the study, and be familiar and comply with all applicable research policies in the Institution.

3. 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).

4. Only the approved Participant Information Sheet and Consent Form should be used. It must be signed by each subject prior to enrolling in the study and initiation of any protocol procedures. Two copies of the Informed Consent Form should be signed and dated. Each subject or the subject's legally accepted representative should be given a copy of the signed consent form. The remaining copy should be kept by the PI / medical record.

5. 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. All serious adverse events (SAEs) and adverse drug reaction (ADRs) that are both serious and unexpected.
    iv. New information that may affect adversely the safety of the subjects or the conduct of the trial.
    v. Completion of the study.

6. Study Status Report should be submitted to the SingHealth CIRB for the following:
    i. Annual review: Status of the study should be reported to the SingHealth CIRB at least annually using the Study Status Report.
    ii. Study renewal: the Study Status 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.

iii. Study completion or termination: the Final Report is to be submitted within three months of study completion or termination.

Yours sincerely,

A/Prof Agnes Ng
Chairman
SingHealth Centralised Institutional Review Board E

Enc.

cc: Institution Representative, KKH
Head, Department of Family Medicine Service, KKH

cc: Institution Representative, SGH
Head, Department of Dermatology, SGH

cc: Dr Lee Haur Yueh, Site PI, Department of Dermatology, SGH

This application is approved online. No signature is required.

Annex 1

LIST OF CIRB E MEMBERS INVOLVED IN THE REVIEW ON 24 FEBRUARY 2017			
Name	**CIRB Membership**	**Designation, Institution**	**Gender**
A/Prof Agnes Ng	Chairman	Senior Consultant, Paediatric Anaesthesia, KKH	Female
Ms Ang Su-Lin	Member	Partner, K.L. Tan & Associates	Female
Dr Daniel Koh Kah Soon	Member	Lecturer, Theology - Social Ethics, Trinity Theological College	Male
Ms Kwek Koon Roan	Member	Deputy Director, Nursing Administration, NHCS	Female
Dr Swah Teck Sin	Member	Senior Consultant, Bedok Polyclinic, SHP	Male
Dr Tan York Kiat	Member	Consultant, Rheumatology & Immunology, SGH	Male
Dr Xu Shaorong Kelvin	Member	Principal Clinical Pharmacist, Pharmacy, KKH	Male
Ms Khoo Lay See	Member	Layperson	Female