Bangkok Metropolitan Administration Human Research Ethics Committee

Certificate of Approval

Bangkok Metropolitan Administration Human Research Ethics Committee has approved the following protocol which is to be carried out in full compliance with the international guidelines for human research protection such as the Declaration of Helsinki, the Belmont Report, CIOMS Guidelines and ICH-GCP Guidelines.

Protocol Title : Prevalence of Vitamin D Deficiency in Exclusively Breastfed Infants Aged 4 Months at Charoenkrung Pracharak Hospital

Protocol Code : S008h/63

Principal Investigator: Supawut Suksantilerd, MD / Charoenkrung Pracharak Hospital

Co-investigator(s) : 1. Nattapol Rungrojjananon, MD / Charoenkrung Pracharak Hospital
2. Rotchanart Thawatchai / Charoenkrung Pracharak Hospital

Research Site : Charoenkrung Pracharak Hospital

Document Reviewed:

1.	Protocol	Version 2 Date 10 April 2020
2.	Participant Information Sheet	Version 2 Date 10 April 2020
3.	Written Informed Consent Form	Version 2 Date 10 April 2020
4.	Investigator's CV	Version 2 Date 10 April 2020
5.	Case Record Form	Version 2 Date 10 April 2020

[redacted]

(Prof. Manit Sripramote, MD.)
Chairperson

Certificate of Approval No. ..... 37 .....
Approval Date: 27 April 2021
Expiry Date: 26 April 2022
Approval Type: ☐ Original ☑ Renewal..... 1.....
Progress Report to be submitted in every ☑ 1 yr ☐ 6 m ☐ 3 m
Approval granted is subjected to the following conditions (see back of this Certificate)

Comply with the following conditions:

(1) Strictly conduct the research as required by the protocol.

(2) Use only the information sheet, consent form (and recruitment materials, if any), record form, questionnaire bearing the BMAHREC's seal of approval.

(3) Provide reports to the BMAHREC concerning the progress of the research upon the specified period or when requested, not more than 15 days after submit date. Attach herewith three copies of the most recently approved version of informed consent document and case record form of the current subject recruited. (Date stamps to indicate an approved version).
- *In case of non-reapplication for approval, attach these documents to the final report.*

(4) If the study cannot be finished within expiry date of the approval, the investigator is obliged to reapply for approval 30 days before the date of expiration.

(5) Any correction of the previously approved protocol, the investigator should reapply the amended protocol for approval prior to the execution of the amended section (except for the subject safety).

(6) Report to the BMAHREC any serious adverse event or any changes in the research activity within seven calendar days (within 24 hours in case of death due to SAE).

(7) Report to the BMAHREC within 15 calendar days after the detection of the non-compliance of the previously approved protocol / deviation/ violation.

(8) Report to the BMAHREC within 30 days after the premature termination or suspension of a trial.

(9) Provide the final report including the abstract to the BMAHREC as a close-out within 30 days upon completion of the study.

***Note**: Download the report forms at http://www.msdbangkok.go.th/research/download.html*