OFFICE: CENTRAL RESEARCH ETHICS COMMITTEE (CREC)

3rd Fl Building3, The National Research Council of Thailand, 196 Moo 5, Phaholyothin Rd., Ladyao, Chatuchak, Bangkok 10900 Tel: 082 258 9529, 098 325 2765

Certificate of Approval

CREC NUMBER	CREC025/68BT-BIO01
CERTIFICATE NUMBER	COA-CREC074/2025
BOARD ACTION DATE	4th / 2025
CREC MEETING DATE	13 July 2025
PANEL	Biomedicine (Surgery and other specialties)
PROTOCOL TITLE	Experience, Knowledge and Attitudes of Healthcare Providers and Parents Towards Non- Invasive Prenatal Testing (NIPT) for Prenatal Aneuploidy Screening in Thailand: A Mixed-Method Study ประสบการณ์ ความรู้ และเจตคติของ บุคลากรสาธารณสุข และคู่สมรส เกี่ยวกับการตรวจคัดกรองก่อนคลอดของภาวะจำนวนแท่งโครโมโซมผิดปกติ ด้วยวิธี non-invasive prenatal testing (NIPT) ในประเทศไทย: การวิจัยแบบผสมผสาน
PROTOCOL NUMBER	ETH24-9772
PRINCIPAL INVESTIGATOR	Rapphon Sawaddisan
SPONSOR	Faculty of Health, University of Technology Sydney, Sydney, Australia

DATE OF APPROVAL	13 July 2025
DATE OF EXPIRATION	12 July 2026
CONTINUING REVIEW	12 Months

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Approval documents	Reference (e.g. version and date)
Research protocol	1. Full Protocol_V4_19June2025 (Version 4, 19June2025) 2. โครงร่างการวิจัยภาษาไทย (ฉบับย่อ)_V4_19June25 (Version 4, 19June2025)
Informed consent Documents	1. Supplementary data III - Informed consent form_V3_19June25 (Version 3, 19June2025) 2. Supplementary data IX_ verbal-consent_V4_19June2025 (Version 4, 19June2025)
Case Report Form	1. Supplementary data IV_Survey HPs_V4_19June2025 (Version 4, 19June2025) 2. Supplementary data V_Surveys for parents_V4_19June25 (Version 4, 19June2025) 3. Supplementary data VII - Interviews protocol_HPs_V3_22April2025 (Version 3, 22April2025) 4. Supplementary data VIII_Interview protocol_parents_V3_22April2025 (Version 3, 22April2025) 5. Supplementary data I - Information sheet for HPs_V4_19June2025 (Version 4, 19June2025) 6. Supplementary data II - Information sheet_V4_19June25 for parents (Version 4, 19June2025) 7. Supplementary data X_ online advertisement for HPs_V2_22April25 (Version 2, 22April2025) 8. Supplementary data XI_advertisement for parents_v2_22April25 (Version 2, 22April2025) 9. Supplementary data VI - Distress form_V3_19June25 (Version 3, 19June2025)
Research Tools	1. Supplementary data IV_Survey HPs_V4_19June2025 (Version 4, 19June2025)

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Approval documents	Reference (e.g. version and date)
	2. Supplementary data V_Surveys for parents_V4_19June25 (Version 4, 19June2025) 3. Supplementary data VII - Interviews protocol_HPs_V3_22April2025 (Version 3, 22April2025) 4. 4. Supplementary data VIII_Interview protocol_parents_V3_22April2025 (Version 3, 22April2025)

CREC approval includes:

Principal investigators	**Investigator's CV and ICH-GCP Training Certificate and Declaration of conflict of interest** 1. Rapphon Sawaddisan 2. Noppasin Khwankaew
Study sites	1. Songklanagarind Hospital

The Central Research Ethics Committees (CREC) is in full compliance with international guidelines for human research protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines.

Waipoj Chanvimalueng

(Assoc. Prof. Waipoj Chanvimalueng)
Chair, Central Research Ethics Committee
Biomedicine (Surgery and other specialties)

Date: 14 July 2024

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All CREC approved investigators must comply with the followings:

1. Conduct the research in accordance with the approved protocol and the principles of research ethics as set forth in the Belmont Report.
2. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate.
   - Use only the most current consent form bearing the CREC **"APPROVED"** stamp
   - Use only recruitment documents / materials approved by CREC
3. CREC approval is required before implementing any changes in the research protocol, information sheet and research-related documents unless those changes are required urgently for the safety of the research subjects.
4. Promptly report to CREC all unanticipated problems (adverse events, protocol deviations and violations and other problems) that meet all of the following criteria:
   - Unexpected (in terms of nature, severity or frequency);
   - Related or possibly related to participation in the research; and
   - Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.
5. Any new information that may affect the risk and benefit of the research subjects must be promptly reported to CREC.
6. Summit to CREC a progress report (with currently used informed consent documents) for continuing review and for renewing the approval at least 30 days before expiration date.
   - For failure to provide a progress report for continuing review to CREC, all research activities involving research subjects must stop. Enrollment of new subjects cannot occur after the expiration of CREC approval.

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