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දිනය } 11.09.2025
Date }

ද සොයිසා කාන්තා රෝහල (ශික්ෂණ) - කොළඹ -08
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DE SOYSA HOSPITAL FOR WOMEN (TEACHING) - COLOMBO 08

Yasiru Alahakoon

Induwara Morawakgoda

Lasitha Amarasinghe,

Sahan Abeyrathna

Ethical Clearance – Application No.037/2025

Title: Neo Care –Contactless Neonatal Health Monitoring System

I am pleased to inform you that the Ethical Review Committee Meeting (ERC) held on 11.09.2025 at De Soysa Hospital for Women has granted ethical approval for your proposal.

The approval is valid until one year from the meeting date stated above. You may make a written request for renewal/extension of the validity, along with the submission of an annual progress report. As the principal investigator, you are expected to ensure that procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving human participants. You are requested to submit a copy of the final report to the office of De Soysa Hospital for Women.

The Certificate of Ethical clearance is attached.

Regards,


Director
De Soysa Hospital for Women
Colombo 08.

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De Soysa Hospital for Women
Colombo 8.

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DE SOYSA HOSPITAL FOR WOMEN (TEACHING) - COLOMBO 08

CERTIFICATE OF ETHICAL CLEARANCE

Principal Investigator/s : Yasiru Alahakoon
Induwara Morawakagoda
Lasitha Amarasinghe
Sahan Abeyrathna

Application Number:037/2025

Approval Date:11.09.2025

Approval Expiry date: 10.09.2026

Project Title: Neo Care –Contactless Neonatal Health Monitoring System.

Condition of Approval: **Approved**

This certificate of approval is valid for the above term provided there is no change in the protocol.

ADVERSE EFFECTS OR UNFORESEEN EVENTS - You should notify to Institutional Ethical Review Committee of De Soysa Maternity Hospital for Women (IERC, DSHW) immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.

Suspend or modify the project if the risks to participants are found to be disproportionate to the benefits.

Stop any involvement of any participant if continuation of the research may be harmful to that person.

COMPLAINTS - The researchers are required to inform IERC, DSHW promptly of any complaints made or expressions of concern are raised, in relation to the project.

AMENDMENTS TO THE APPROVED PROJECT

Including changes in personnel: Requires the submission of a request for Amendment from to IERC, DSHW and must not be without written approval from IERC, DSHW. Substantial variations may require a new application.

ANNUAL REPORTS: Continued approval of this project is dependent on the submission of an Annual Report.

EXTENSION OF APPROVAL: The researchers are required to submit a request to extend the period of validity of approval one month prior to approval expiry date along with the Annual Report.

FINAL REPORT: A final report should be provided at the conclusion of the project. IERC, DSHW should be notified if the project is discontinued before the expected date of completion.

MONITORING - Projects may be subjected to an audit or any other form of monitoring by IERC, DSHW at any time.


Senior Professor Athula Kaluarachchi
Chair Professor
Department of Obstetrics & Gynaecology
Faculty of Medicine
University of Colombo

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