

Mr Arthur Hui
Manager
Research and Ethics Secretariat
Tel: +61 3 8345 3720
Fax: +61 3 8345 3702
Email: arthur.hui@thewomens.org.au



the women's
the royal women's hospital

ABN 62 787 822 077

Locked Bag 300
Cnr Grattan St & Flemington Rd
Parkville VIC 3052 Australia

Tel +61 3 8345 2000
www.thewomens.org.au

23.5.23

Associate Professor C Theda
Newborn Services
RWH

Dear Professor Theda,

Re: Project 22/23 – NeoNav ECHO Study: Electrocardiogram (ECG) waveforms associated with central venous catheter tip position as verified by Echocardiography (ECHO)

EPIC/EMR Study Code: RWH 88237
HREC Project ID: HREC/88237/RWH-22-23

Thank you for submitting the clarification and amendments as requested by the RWH Human Research Ethics Committee.

I confirm the project is now approved.

Enclosed please find Project Approval and Notification of Project Commencement Forms for your record.

Please return the completed Notification of Project Commencement Form to me when the project begins.

Please note:

1. Good Clinical Practice (GCP) Training

The RWH Human Research Ethics Committee has now agreed that GCP training should be mandatory for all principal investigators. The Committee also strongly encourages GCP training for other associate investigators and student researchers.

2. Use of the Electronic Medical Record (EMR) for research

Accessing identified patient information from health services other than your own for research purposes is NOT permitted. Precinct policies regarding appropriate access MUST be followed. Identified patient information must ONLY EVER be accessed after governance authorisation or audit/quality assurance (QA) approval from the appropriate health service.

REMINDER

If you have not already done so, you are reminded that researchers should complete an EMR Pre-Submission Survey (for REDCap) for their project to be activated in EMR.

The link researchers should use to complete the EMR Pre-Submission Survey is:
<https://biredcap.mh.org.au/surveys/?s=LN7MT4PYF4>

This is important. For EMR (Electronic Medical Record - EPIC) processes to work, it needs timely notification of research projects and for staff to follow the agreed processes.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'A. C. B. Hui', with a small mark below it.

A. C. B. Hui
Manager
Research and Ethics Secretariat

Cc epic.research@mh.org.au

Encl:

THE ROYAL WOMEN'S HOSPITAL
RESEARCH AND HUMAN RESEARCH ETHICS COMMITTEES
PROJECT APPROVAL

PROJECT NO: 22/23

PROJECT TITLE: NeoNav ECHO Study: Electrocardiogram (ECG) waveforms associated with central venous catheter tip position as verified by Echocardiography (ECHO)

INVESTIGATOR (S): C Theda, S Rogerson, M Yousuf, SY Sheung, K Barons, P Davis, A Martin, B Philips

DATE OF APPROVAL: 23 May 2023

ANTICIPATED DURATION: Twelve (12) months

SIGNED



23.5.2023

Secretary, Research & Human Research Ethics Committees

CONDITIONS OF APPROVAL

The Principal Investigator is reminded of the following:-

1. *GCP training is mandatory for all principal investigators. The Human Research Ethics Committee also strongly encourages GCP training for other associate investigators and student researchers.*
2. *Prior to commencement of the project, you must contact the relevant RWH Divisional Directors / Department Heads to confirm your actual commencement date. Failure to inform these RWH personnel may jeopardise their approval and support for your project.*
3. *A Project may commence once the Principal Investigator has received written confirmation that the Human Research Ethics Committee has approved the Project.*
4. *Substantial changes in protocols must be submitted to the Research/Human Research Ethics Committees for approval.*
5. *Progress reports must be submitted annually. A request will be forwarded to the Principal Investigator. If no report is supplied, permission to continue the project may lapse.*
6. *The Research/Human Research Ethics Committees must be notified **IMMEDIATELY** of any untoward or unexpected complications or side affects arising during the project or of any ethical or medico-legal problems that may arise.*
7. *Consent forms must be available for audit and retained on file for at least five (5) years.*
8. *Raw data and details of analysis must be retained by the Principal Investigator for at least five (5) years.*
9. *Principal Investigator **MUST** upon leaving the Institution, inform the Human Research Ethics Committee as to the nominated person to replace him/her.*

PLEASE QUOTE PROJECT NO. AND TITLE FOR ALL CORRESPONDENCE

RWH PROJECT NUMBER 22/23

THE ROYAL WOMEN'S HOSPITAL
RESEARCH AND HUMAN RESEARCH ETHICS COMMITTEES
NOTIFICATION OF PROJECT COMMENCEMENT

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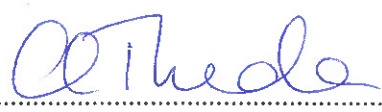
DATE OF APPROVAL: 23 May 2023

ANTICIPATED DURATION: Twelve (12) months

DATE OF COMMENCEMENT 24 / 05 / 2023

PRINCIPAL INVESTIGATOR:

NAME A / PROF CHRISTIANE THEDA
(PLEASE PRINT)

SIGNATURE  **DATE** 23 / 05 / 2023