Mr Arthur Hui
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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 polices 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. 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 <u>IMMEDIATELY</u> 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 <u>MUST</u> 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

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

DATE OF COMMENCEMENT 24 / 05 / 2023

PRINCIPAL INVESTIGATOR:

NAME A/PROF CHRISTIANE THEDA

(PLEASE PRINT)

SIGNATURE C Theda **DATE** 23 / 05 / 2023