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school of health research

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23 May 2022

Ethics Administration Office
File Reference Number: HREC-2022-4291
Phone: (08) 8946 8687 or (08) 8946 8692
Email: ethics@menzies.edu.au

Prof Yvette Roe
Molly Wardaguga Research Centre
Charles Darwin University
yvette.roe@cdu.edu.au

CC: sarah.ireland@cdu.edu.au
Via Email

Dear Prof Roe,

HREC Reference Number: 2022-4291
Project Title: ***To Be Born Upon a Pandanus Mat- Yothuw gayatha dhäwal' guyanja' nharaw: Redesigning maternity services for Yolnju mothers and babies living on Elcho Island Northern Territory (NT), using Birthing on Country principles and the RISE translational Framework, to reduce preterm birth and improve health outcomes: A prospective, non-randomised, intervention trial.***
Protocol Number:

Thank you for letter dated 02/05/2022 and taking the time to respond to the issues of concern identified by the Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research (HREC) at its meeting held on the 20/04/2022.

This project was considered by the HREC and the Aboriginal Ethics Sub-Committee (AESC) and assessed against guidelines for human research including the NHMRC *National Statement on Ethical Conduct in Human Research 2007.*

I am pleased to advise that **full ethical approval** of this research project has been granted following assessment by representatives of both the AESC and the HREC. Please note that approval applies only to research conducted after the date of this letter and continued approval is dependent on annual reporting.

Approval Date: ***23/05/2022***

Approval is granted for the above research project until the next report due date.

Annual progress report due: ***23/05/2023***

Approved timeframe (subject to compliance and annual reporting): ***23/05/2023 – 30/11/2026***

The nominated sites/s participating in this project that have been approved by this HREC is/are:

- **Galiwin' ku township (and homelands) on Elcho Island, NT**
- **Nhulunbuy, NT**
- **Darwin, NT**

Please note:

* Researchers must comply with site specific governance regulations, data custodian and other stakeholder requirements.

The documents listed below are approved:

Document	Version	Date
Research Protocol	1	29/03/2022
Participant Information Sheet	1	02/05/2022
Consent Form	1	02/05/2022

Draft General Interview Topic Guide	**1**	**02/05/2022**
Risk Management Plan	**1**	**29/03/2022**

The documents listed below are noted:

Document	Version	Date
Data Access Support letter: Department of Health NT		16/03/2022
Data Access Support letter: Miwatj Health Aboriginal Corporation		04/08/2021
Data Access Support letter: Menzies School of Health Research		18/03/2022
Data Access Support letter: Careflight		08/03/2022
Partner and Community Support Letter: Department of Health NT,		07/06/2021
Partner and Community Support Letter: Miwatj Health Aboriginal Corporation		06/04/2021
Partner and Community Support Letter: Australian Red Cross		06/04/2021
Partner and Community Support Letter: Yalu Aboriginal Corporation		06/04/2020
Partner and Community Support Letter: Australian Doula College		31/03/2020
Partner and Community Support Letter: CareFlight		06/04/2021
CV – Prof Yvette Roe		29/03/2022
Research Team OCHRE Card Records		

APPROVAL IS SUBJECT TO the following conditions being met:

1. The Coordinating Principal Investigator will **immediately report anything that might warrant review** of ethical approval of the project.

2. The Coordinating Principal Investigator will notify the Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research (HREC) of any event that requires a **modification or amendment to the protocol or other project documents** and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found on the Menzies' website.

3. The Coordinating Principal Investigator will submit any necessary reports related to the **safety of research participants (e.g. protocol deviations, protocol violations)** in accordance with the HREC's policy and procedures. These guidelines can be found on the Menzies' website.

4. The Coordinating Principal Investigator will **report** to the HREC **annually** and notify the HREC when the project is completed at all sites using the specified forms. Forms and instructions may be found on the Menzies' website.

5. The Coordinating Principal Investigator will notify the HREC if the project is **discontinued at a participating site before the expected completion date** and provide the reason/s for discontinuance.

6. The Coordinating Principal Investigator will notify the HREC of any plan to **extend the duration of the project past the approval period listed above** and will submit any associated required documentation. The preferred time and method of requesting an extension of ethical approval is during the **annual progress report**. However, an extension may be requested at any time.

7. The Coordinating Principal Investigator will notify the HREC of his or her **inability to continue as Coordinating Principal Investigator**, including the name of and contact information for a replacement.

8. The safe and ethical conduct of this project is entirely the responsibility of the investigators and their institution(s).

9. Researchers should immediately report anything which might affect continuing ethical acceptance of the project, including:

- Adverse effects of the project on participants and the steps taken to deal with these;
- Other unforeseen events;
- New information that may invalidate the ethical integrity of the study; and
- Proposed changes in the project.

10. Approval for a further twelve months, within the original proposed timeframe, will be granted upon receipt of an annual progress report if the HREC is satisfied that the conduct of the project has been consistent with the approved protocol. Report templates are available on the Menzies ethics webpage.

11. Confidentiality of research participants should be maintained at all times as required by law.

12. The Patient Information Sheet and the Consent Form shall be printed on the relevant site letterhead with full contact details.

13. The Patient Information Sheet must provide a brief outline of the research activity including: risks and benefits, withdrawal options, contact details of the researchers and must also state that the Human Research Ethics Administrators can be contacted (telephone and email) for information concerning policies, rights of participants, concerns or complaints regarding the ethical conduct of the study.

14. You must forward a copy of this letter to all Investigators and to your institution (if applicable).

This letter constitutes ethical approval only.
This project, including amendments to the research protocol or conduct of the research which may affect the site acceptability of the project, cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site, if not already obtained.
Any transfer of data is subject to institutional research governance arrangements for data ownership, data custodianship, and data transfer agreements.
Please forward this approval letter to the relevant research governance office.

Should you wish to discuss the above research project further, please contact the Ethics Administrators via email: ethics@menzies.edu.au or telephone: (08) 8946 8687 or (08) 8946 8686.

The Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research wishes you every continued success in your research.

Yours sincerely,

Dr. Mary Morris
Chair
Human Research Ethics Committee
of the Northern Territory Department of Health
and Menzies School of Health Research
http://www.menzies.edu.au/ethics

This HREC is registered and certified for multi-site review with the Australian National Health and Medical Research Council (NHMRC) and operates in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research (2007)*. NHMRC Reg no. EC00153