Office for Research

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Government of South Australia

Health
Southern Adelaide
Local Health Network

Final Approval for Ethics Application

19 June 2024

Professor Neil Pillar
Lymphoedema Clinical Research Unit,
College of Medicine and Public Health
Flinders University

Email contact: neil.piller@flinders.edu.au, marielle.esplin@flinders.edu.au

Dear Neil

OFR Number: 90.24
Project title: The effect of Niagara® Cycloid® action on legs with chronic oedema/lymphoedema following treatment for cancer
Chief Investigator: Prof Neil Piller
Associate Investigators: Richard Allan, Marielle Esplin
Ethics approval dates: 19 June 2024 – 19 June 2027
The annual review is due: 19 June 2025

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) (EC00188) have reviewed and approved this application out of session, through the low and negligible risk pathway, and provided approval which meets the requirements of the *National Statement on Ethical Conduct in Human Research (updated 2023).*

The below documents have been reviewed and approved:

Document	Version	Date
Protocol	3.0	14 June 2024
Participant information sheet and consent form	3.0	17 June 2024
Study advert	1.0	30 April 2024
Participant diary	1.0	30 April 2024
Niagara massage pad instructions for use	1.0	17 June 2024
Questionnaires: General medical history, LYMQOL Tool, Symptom Scale Tool	1.0	20 April 2024

TERMS AND CONDITIONS OF ETHICS AND GOVERNANCE APPROVAL
The Principal Investigator must ensure this research complies with the National Statement on Ethical Conduct in Human Research (2018) & the Australian Code for the Responsible Conduct of Research (2007 updated 2018) by immediately reporting to the Office for Research (OFR) anything that may change the ethics or scientific integrity of the project. Final approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. Confidentiality of research participants MUST be maintained at all times.
2. If the research involves the recruitment of participants, a signed copy of the 'Consent Form' must be given to the participant. Any changes to the Participant Information Sheet/Consent Form must be approved by the lead HREC prior to being used.
3. No promotion of a study can commence until final ethics and SALHN executive approval has been obtained. All advertisements/flyers need to be approved by the committee and media contact should be coordinated through the FMC media unit.

4. Non-SA Health researchers viewing confidential SALHN data are required to complete and sign a SALHN Confidentiality Disclosure Deed

5. My Health Record data will not be accessed for research and public health purposes.

6. All approved requests for access to medical records at any SALHN site must be accompanied by this approval letter.

7. If your study involves a tertiary institution, contact the University to ensure compliance with University requirements prior to commencement of this study. This includes any insurance and indemnification.

8. The PI must adhere to Monitoring and Reporting requirements for both ethics and governance which are available on the SALHN Research Website.

9. The PI must immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project

10. An annual report must be submitted to the SAC HREC and SALHN governance by the ethics approval date, stated above, each year for the life of the research project. Failure to submit a progress report or final report by the due date violates the terms and conditions of SAC HREC approval and will result in immediate suspension of the SAC HREC approval until a valid progress report or final report is submitted. Submission of a valid progress report will continue the SAC HREC approval for the next 12 months, at which point a new progress report will be due.

11. Non-SA Health researchers coming onsite at SALHN must provide evidence of a recent (<3 years) screening check. It is the responsibility of the Principal Investigator to ensure any non-SA Health personnel who conducts or monitors research meets SA Health screening requirements as per the SA Health Criminal & Relevant History Screening Policy Directive before they access any SA Health site. The cost of any such screening is the responsibility of the individual accessing the site or their employer.

12. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.

13. Once the research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable). Please refer to the relevant committee link on the SALHN intranet for further information.

14. SALHN site-monitoring of authorised studies - this approval/authorisation is subject to participation in this monitoring process. You will be notified in advance if your site has been selected for an inspection.

Please visit the SALHN Research website regularly and comply with all submission requirements as they may change from time to time.

For any queries about this matter, please contact The Office for Research on (08) 8204 6453 or via email to Health.SALHNOfficeforResearch@sa.gov.au

Yours sincerely,

Professor Bill Heddle
Chair
Southern Adelaide Clinical Human Research Ethics Committee