

Office for Research

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Government of South Australia

SA Health

Southern Adelaide Local Health Network

Final Approval for Ethics Application

17 July 2019

Dr Chris Delaney
Vascular
Flinders Medical Centre

Dear Dr Delaney

OFR Number: 82.19

HREC reference number: HREC/19/SAC/92

Project title: A randomised trial of perioperative use of combination oxidized regenerated cellulose, collagen and silver (Promogran Prisma) dressing in lower limb minor amputations

Chief Investigator: Dr Chris Delaney

Ethics Approval Period: 17.07.2019 – 17.07.2021

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 (2007, updated 2018)*.

You are reminded that this letter constitutes **Ethics** approval only. **Ethics approval is one aspect of the research governance process.**

You must not commence this research project at any SA Health sites listed in the application until a Site Specific Assessment (SSA), or Access Request for data or tissue form, has been approved by the Chief Executive or delegate of each site.

Public health sites approved under this application:

- Flinders Medical Centre

The below documents have been reviewed and approved:

| Document | Version | Date |
|--|---------------|------------|
| Cover letter | 1 | 05.03.2019 |
| HREA | AU/14/8C8A311 | 26.06.2019 |
| Project description | 1.5 | 25.06.2019 |
| Participant information sheet and consent form | 1.3 | 06.06.2019 |
| Baseline wound ischemia foot infection score | 1.0 | 01.04.2019 |
| Patient data collection sheet | 1.1 | 26.06.2019 |

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. All approved requests for access to medical records at any SALHN site must be accompanied by this approval letter.
6. 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.
7. The PI must adhere to Monitoring and Reporting requirements for both ethics and governance which are available on the SALHN Research Website.
8. The PI must immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project
9. An annual report must be submitted to the SAC HREC and SALHN governance on each anniversary of the date of final approval. Please visit the Office for Research website for the current template.
10. 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.
11. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
12. 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.
13. 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