Gold Coast Health
Building a healthier community

Queensland Government

21 August 2019

Enquiries to: HREC Coordinator
Phone: 07 5687 3879
HREC Ref: HREC/2019/QGC/51088
Project ID: 51088
E-mail: GCHEthics@health.qld.gov.au

Professor Brigid Gillespie
Room 2.04, G01
Griffith University
Gold Coast Campus
QLD 4222

Dear Prof Gillespie

HREC Reference: **HREC/2019/QGC/51088**
Project ID: **51088**
Project title: Efficacy and Effectiveness of Prophylactic fOam dressings in the prevention of saCral pressure injuries in at-risk hospitalised patients: The EEPOC Trial

Thank you for submitting the above project for ethical and scientific review, which has been undertaken by the Gold Coast Hospital and Health Service Human Research Ethics Committee (HREC).

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2018)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. The GCHHS HREC has been certified by the NHMRC to review multi centre research. Attached is the HREC Composition with specialty and affiliation with the Hospital and Health Service (HHS) (Attachment I).

This research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)-Updated May 2018*

HREC approval is valid for **3 years**. Expiry 21 August 2022

The documents reviewed and approved include:

Document	Version	Date
HREA	2	29 July 2019
Protocol	2.0	29 July 2019
Master Participant Information and Consent Form	3.0	16 August 2019
Master Participant Information and Consent Form for Nursing Staff	1.0	29 July 2019
Master Participant Information and Consent Form for Person Responsible	2.0	16 August 2019
The EEPOC Trial REDCap Data Collection Tool – Screening Log	2	17 July 2019
The EEPOC Trial REDCap Data Collection Tool – Enrolment and Allocation	2	17 July 2019

The EEPOC Trial REDCap Data Collection Tool – Baseline Data	2	24 July 2019
The EEPOC Trial REDCap Data Collection Tool – Daily Outcome Assessment	2	17 July 2019
The EEPOC Trial REDCap Data Collection Tool – Daily Preventative Economic Data	2	17 July 2019
The EEPOC Trial REDCap Data Collection Tool – Day 2 (48 hours after enrolment)	2	17 July 2019
The EEPOC Trial REDCap Data Collection Tool – Daily Treatment Economic Data	2	17 July 2019
The EEPOC Trial REDCap Data Collection Tool – Data Completion Form	2	17 July 2019
The EEPOC Trial REDCap Data Collection Tool – Discharge Data	2	17 July 2019
Response to request for further information	-	29 July 2019
Australian Register of Therapeutic Goods Certificate, Molnlycke Health Care Pty Ltd - Dressing, wound-nonadherent, absorbent	-	30 May 2017
NHMRC Grant Approval Letter for application number APP1158379	-	-
Investigator CVs: • Prof Brigid Gillespie (GCHHS/Griffith University) • Ms Donna McLean (Logan Hospital) • Dr Rachel Walker (Griffith University) • Dr Ishtar Sladdin (Griffith University) • Prof Jennifer Whitty (University of East Anglea) • Dr Jill Campbell (RBWH) • Prof Lukman Thalib (Qatar University) • Prof Marie Cooke (Griffith University) • Ms Rosalind Probert (Princess Alexandra Hospital) • Dr Sharon Latimer (GCHHS/Griffith University) • Prof Wendy Chaboyer (Griffith University)	-	-

Please note the following conditions of approval:

1. **This letter constitutes ethical approval only.** You must not commence this project at a public health service site until authorisation has been granted by the Institutional Chief Executive or delegate. A copy of this approval must be submitted to the HHS Research Governance Officer/(RGO) along with a completed Site-Specific Assessment (SSA) Form and applicable documents for authorisation from the CE to conduct this research within the HHS.

    a. Once authorisation to conduct the research has been granted, please complete the Commencement Form (Attachment II) and return to the office of the Human Research Ethics Committee GCHEthics@health.qld.gov.au

2. **Reporting to the HREC:** The following reports are required to be submitted to the HREC. Failure to fulfill these reporting requirements may result in withdrawal or suspension of HREC approval:

    a. **Progress Reports:** The Coordinating/Principal Investigator will provide a progress report annually to the HREC and at completion of the project. Progress reports are due on the anniversary of the HREC approval date. Progress Reports are created as subforms of the ethics application form. The first annual report for this project is due by Month/Year.

    b. **Safety Reporting**: In Queensland Health, all reporting to the Reviewing HREC aligns with the guidance of the NHMRC – *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC 2016). In this guidance, the responsibility of

reporting to the Reviewing HREC is assigned to the sponsor of the research project. The sponsor may be an institution, investigator, collaborative group or commercial company.

c. **Other monitoring:** The HHS administration and/or the HREC may inquire into the conduct of any research or purported research, whether approved or not and regardless of the source of funding, being conducted on HHS premises or claiming any association with the HHS; or which the Committee has approved if conducted outside its HHS.

3. **Amendments to this project**:

Amendments for review by an HREC:

a. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review.

b. Amendments should be reflected in a cover letter from the Principal Investigator, providing a brief description and rationale for the changes, and their implications for the ongoing conduct of the study. All relevant updated documentation should also be provided. Amendments should be submitted on a subform created from the ethics application.

c. **Amendments for review by an HREC Coordinator**
Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted using the relevant ERM subform.. These should include a cover letter from the Principal Investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.

Amendments for review by an RGO:

d. Amendments to the research project which affect only the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r (by-passing the HREC).

4. **Early termination or routine completion of the project:**

a. The HREC must be notified if the project is discontinued at a site before the expected date of completion. Notification should be in the form of a cover letter from the Principal Investigator, providing a rationale for the early termination.

b. For projects that are completed, the HREC must be notified by submission of a progress report, along with a copy of any research summaries or intended publications.

Should you have any queries about the HREC's consideration of your project please contact the HREC Coordinator on ph. 07 5687 3879. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

The HREC wishes you every success in your research.

Yours sincerely

Carine Ruthenberg
HREC Coordinator
On behalf of
Ms Jill Mahoney
A/Chair
Gold Coast Hospital and Health Service
Human Research Ethics Committee (EC00160)

Sites Approved

Site	Principal Investigator/s
Gold Coast University Hospital	Prof. Brigid Gillespie
Logan Hospital	Prof. Wendy Chaboyer
Princess Alexandra Hospital	Dr Rachel Walker
Royal Brisbane and Women's Hospital	Dr Jill Campbell