

18 December 2019

Enquiries to: HREC Coordinator
Phone: 07 5687 3879
HREC Ref: HREC/2019/QGC/50128
Project ID: 50128 (VD)
E-mail: GCHEthics@health.qld.gov.au

Professor Andrea Marshall
Gold Coast University Hospital
1 Hospital Boulevard
SOUTHPORT QLD 4215

Dear Professor Andrea Marshall

HREC Reference: HREC/2019/QGC/50128
Project title: ImprovinG Nutrition Intake after Trauma (IGNITe)

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 18 December 2022

The documents reviewed and approved include:

Document	Version	Date
Application	2	6 December 2019
Response to Request for Further Information		6 December 2019
Protocol	1.0	16 October 2019
<i>Participant Information and Consent Forms</i>		
PICF_Family member acceptability interviews	2.0	2 December 2019
PICF_Family consent to continue	2.0	2 December 2019
PICF_Health care professional acceptability interviews	2.0	2 December 2019
PICF_Patient Consent to Continue	2.0	2 December 2019

<i>Interview Guides</i>		
Family member demographics for interviews	1.0	16 October 2019
Healthcare professional demographics for interviews	1.0	16 October 2019
Interview Guide – Family Member	1.0	16 October 2019
Interview Guide – Patients	1.0	16 October 2019
<i>Worksheets</i>		
EQ-5D-5L Worksheet	1	1 October 2019
FSS-ICU Discharge Worksheet	1	1 October 2019
Hand Grip Dynamometry Worksheet	1	1 October 2019
Hand-Held Dynamometry Worksheet	1	1 October 2019
Katz ADL Worksheet	1	1 October 2019
MMT Worksheet	1	1 October 2019
SF-36 Full Domains Worksheet	1	1 October 2019
SPPB Worksheet	1	1 October 2019
Ultrasound Worksheet	1	1 October 2019
<i>Assessments</i>		
6 Minute Walk Test Worksheet_	1	1 October 2019
APACHE II Scoring Form		12 June 2019
Calorie_Protein_ ONS Count	1	16 October 2019
Clinical Frailty Scale	1	16 October 2019
Hospital Outcomes	1	16 October 2019
Mechanical Ventilation & RRT	1	16 October 2019
Nutrition Assessment	1	16 October 2019
Nutrition History	1	16 October 2019
Palliative Performance Status	1	16 October 2019
Patient Baseline with SOFA	1	16 October 2019
Patient Demographics	1	16 October 2019
SF-36 Physical Function Domain_ Version 1_1st October 2019	1	1 October 2019
SOFA with instruction	1	16 October 2019
Walking Impairment Questionnaire_Version1_1st October 2019	1	1 October 2019
<i>CVs</i>		
Professor Andrea Marshall	Gold Coast Hospital and Health Service	
Prof Martin Eduard Wullschleger	Gold Coast Hospital and Health Service	
Dr Shelley Roberts	Gold Coast Hospital and Health Service/Griffith University	
Ms Lisa Mahoney	Gold Coast Hospital and Health Service	
Ms Natalie Rose	Gold Coast Hospital and Health Service	
Dr Angelly Martinez	Gold Coast Hospital and Health Service	
Dr Bhavik Patel	Gold Coast Hospital and Health Service	
Ms Elizabeth Wake	Gold Coast Hospital and Health Service	
Prof Daren Heyland	Queen's University, Kingston, ON, Canada	

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. In accordance with the requirements of the *National Statement*, sections 2.3.9 - 2.3.10, the HREC **waived** the requirement for consent for the collection, use and/or disclosure of personal information in medical research or personal health information for the research project listed.
 - a. Please consider permissions under the *Hospital and Health Boards Act 2011* or *Public Health Act 2005* to enable access to confidential information for the purposes of research without consent. If you are unsure which permissions to use you should contact either the local Research Governance Officer at the site/s where the research will be conducted or the Health Innovation, Investment and Research Office, Office of the Director-General, Department of Health.
3. **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.
4. **Amendments to this project:**
 - a. **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).

5. 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



Vanessa Druett
Research Ethics and Governance Lead
On behalf of
Associate Professor Roselyn Rose'Meyer
A/Chair
Gold Coast Hospital and Health Service
Human Research Ethics Committee (EC00160)

Sites Approved

Site
Gold Coast Hospital and Health Service