



**Ref:** HREC/17/QCH/42 - 1139  
05.05 CG:jl  
NEAF - Approved  
**Telephone:** (07) 4226 5513  
**Email:** [Cairns\\_Ethics@health.qld.gov.au](mailto:Cairns_Ethics@health.qld.gov.au)

Far North Queensland  
Human Research Ethics Committee

1 June 2017

**Email:** [louise.cullen@health.qld.gov.au](mailto:louise.cullen@health.qld.gov.au)

Prof Louise Cullen  
Department of Emergency medicine  
Royal Brisbane & Women's Hospital

Dear Prof Cullen

**HREC Reference number: HREC/17/QCH/42 - 1139**

**Project title:** The impact of ImpACT: Validation of an accelerated diagnostic protocol for Aboriginal and Torres Strait Islander patients with suspected Acute Coronary Syndrome

Thank you for submitting the above project which was first considered by the FNQ HREC on 20 April 2017. Your response to the HREC's request for further information dated 11 May 2017 was received and reviewed out of formal session. I am pleased to advise that **ethical approval is granted** to your application.

You are reminded that this letter constitutes ethical approval only.

You must not commence this research project at *Queensland Health sites, utilize Queensland Health staff or Queensland Health resources* until separate authorisation from the Hospital and Health Service CE or Delegate of that site has been obtained.

**A copy of this approval letter must be submitted to the Research Governance Officer which govern the Queensland Health site/s listed in your approved NEAF.** This letter, accompanied with a completed Site Specific Assessment (SSA) Form, and all of your ethically approved documentation requires authorisation from the Chief Executive of the relevant Health Service.

Please contact: **Research Governance Officer – Margaret Grasso**  
Address: Level 7, William McCormack Place 2, 5B Sheridan Street, Cairns  
Email: [RGO\\_Cairns@health.qld.gov.au](mailto:RGO_Cairns@health.qld.gov.au)  
Phone: (07) 4226 5512

Please email Margaret Grasso regarding Part 2 of the Research Approval Process for any of your Queensland Health sites. These ladies can provide you with the Site Specific Assessment requirements in order for you to continue to progress your application.

This HREC (EC00157) 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)*,

NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice.

The ethically approved documents are:

<i>Document</i>	<i>Document Version</i>	<i>Document Date</i>
NEAF (AU/1/49DC216)	2.2	28 March 2017
Original Cover Letter	N/A	2 March 2017
Reply to HREC queries	N/A	11 May 2017
ImpACT protocol	2	11 May 2017
Master Patient Information Sheet	4	11 May 2017
HREC Exemption Letter RBWH HREC	N/A	27 June 2016
AusHSI email	N/A	8 December 2016
ImpACT Case Report Form/Accelerated Chest Pain Risk Evaluation (ACRE) Project	1	21 March 2017
ImpACT Adjudication Form/Accelerated Chest Pain Risk Evaluation (ACRE) Project	1	14 February 2017
ImpACT 30 day Follow up Questionnaire/ Accelerated Chest Pain Risk Evaluation (ACRE) Project *	1	27 March 2017
Master Consent Form/ Accelerated Chest Pain Risk Evaluation (ACRE) Project	2	27 March 2017
Master Consent to Release Information Form/ Accelerated Chest Pain Risk Evaluation (ACRE) Project	2	27 March 2017
Master Withdrawal of Consent Form/ Accelerated Chest Pain Risk Evaluation (ACRE) Project	2	20 March 2017
ImpACT Letter template to emergency Department from Cairns ED Medical Officer	<i>No version</i>	<i>No date</i>
ImpACT Patient Information Sheet/ Accelerated Chest Pain Risk Evaluation (ACRE) Project – Exercise Stress Test	<i>No version</i>	<i>No date</i>
ImpACT Poster	<i>No version</i>	<i>No date</i>
Letter of Support from Director of Aboriginal and/or Torres Strait Islander Health Unit, CHHHS, Venessa Curnow	N/A	7 February 2016
CV Prof Louise Cullen	<i>No version</i>	<i>No date</i>
CV Nicholas Graves	<i>No version</i>	<i>No date</i>
CV Adjunct Professor William Anthony Parsonage	<i>No version</i>	<i>No date</i>
CV Louise Anne McCormack	<i>No version</i>	February 2017
CV Gregory Starmer	<i>No version</i>	<i>No date</i>
CV Richard Stone	<i>No version</i>	<i>No date</i>
CV Katrina Starmer	<i>No version</i>	<i>No date</i>
CV Tileah Drahm-Butler	<i>No version</i>	<i>No date</i>
CV Tania Davis	<i>No version</i>	<i>No date</i>

CV Jaimi Greenslade	<i>No version</i>	<i>No date</i>
CV Sarah Ashover	<i>No version</i>	March 2017
CV Tanya Milburn	<i>No version</i>	<i>No date</i>
CV Karlie Proctor	<i>No version</i>	<i>No date</i>
CV Laura Catherine Foran	<i>No version</i>	<i>No date</i>

*\*the FNQ HREC noted that the 30 day Follow up Questionnaire document has a spelling error (questionnaire) in the document footer. For your information.*

### **Ethically Approved Queensland Health study sites:**

- Cairns Hospital

***(If you are a student researcher you are obliged to advise your Supervisor/s as to the current status of your research application.)***

Please note the following conditions of approval:

1. If relevant to your project, your attention is drawn to standards for clinical trials reporting as enunciated in the CONSORT statement (<http://www.consort-statement.org/?o=1001>) and a requirement by many journals for certain categories of clinical trials to be registered (see: <http://www.anzctr.org.au/Support/HowToAdd.aspx>).
2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
  - a. Unforeseen events that might affect continued ethical acceptability of the project. Serious Adverse Events must be notified to the Committee as soon as possible. In addition the Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.
3. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Major amendments should be reflected in a revised online NEAF (accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised NEAF, the cover letter and all relevant updated documents with tracked changes must also be submitted to the HREC coordinator as per standard HREC SOP. Further advice on submitting amendments is available from.

[http://www.health.qld.gov.au/cpic/documents/ethics/researcher\\_userguide.pdf](http://www.health.qld.gov.au/cpic/documents/ethics/researcher_userguide.pdf)
4. Amendments to the research project which only affect 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. Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the RGO.
6. Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted in hard copy to the HREC coordinator. 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.
7. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
8. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
9. The Health Service administration and the Human Research Ethics Committee 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 hospital premises or claiming any association with the hospital; or which the Committee has approved if conducted outside of Queensland Health however within the jurisdiction of the Committee (Cairns, Cape & Torres Hospital & Health Services).
10. If research is occurring in Aboriginal and Torres Strait Island Communities please ensure that you provide progress reports and feedback to relevant Aboriginal and Torres Strait Islander Groups in each area.

HREC approval is valid for **three years** from the date of this letter.

The HREC wishes you every success in your research.

Yours faithfully



Professor Christian Gericke

**Chair Far North Queensland Human Research Ethics Committee**  
Cairns and Hinterland, Torres and Cape Hospital and Health Service  
**Deputy Executive Director of Medical Services & Consultant Neurologist**  
Cairns and Hinterland Hospital and Health Service