

HREC/2019/QCH/52647 - 1354
Further information received – Study Approved
07.08 ES:jld
Telephone: (07) 4226 5513
Email: Cairns_Ethics@health.qld.gov.au



26 August 2019

Email: laura.foran@health.qld.gov.au

Dr Katrina Starmer
Cairns Hospital Emergency Department
Cairns Hospital

Dear Dr Starmer,

Review Reference: HREC/2019/QCH/52647 (Aug ver 2) – 1354

ERM Reference: 52647

Project Title: Prevalence of Coronary Artery Disease in Aboriginal and Torres Strait Islander people presenting to the Emergency Department with suspected acute Coronary Syndrome

Thank you for submitting the above research project for ethical and scientific review. This project was considered by the Far North Queensland Human Research Ethics Committee (FNQ HREC) (EC00157) as a new application on the 13 June 2019. Your response to FNQ HREC queries dated 22 August 2019 was received and reviewed out of formal session on 26 August 2019.

I am pleased to advise you that the above research project meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and **ethical approval for this research project has been granted** by FNQ HREC.

This letter constitutes ethical approval.

The nominated participant recruitment site for this project is:

- Cairns Hospital Emergency Department

Other sites:

- Cairns and Hinterland Hospital and Health Service – both Queensland Health and non-Queensland Health sites
- Torres and Cape Hospital and Health Service – both Queensland Health and non-Queensland Health sites

Inclusion of the Health Services listed above for Queensland Health and non-Queensland Health sites is for the purposes of follow up, where the participants cannot be contacted directly and where the participant has provided written consent and consent to release information forms. The participants nominated health service provider will be contacted to identify subsequent cardiac related presentations within 6 months of initial presentation.

Note: If additional sites are engaged or withdrawn prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to submit an amendment to the FNQ HREC via the ERM system.

HREC/2019/QCH/52647 - 1354
 Further information received – Study Approved
 07.08 ES:jld
Telephone: (07) 4226 5513
Email: Cairns_Ethics@health.qld.gov.au



Queensland
 Government
 Far North Queensland
 Human Research Ethics Committee

A HREC Only form of Indemnity is attached for your completion and return. This document must be signed by the study Sponsor and enables you to engage/commence with non-Queensland Health sites once the form has been executed by all parties.

This project cannot proceed at any Queensland Health site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

Please contact: Margaret Grasso, CHHS Research Governance Officer
 A: William McCormack Place, Level 7, 5B Sheridan Street, Cairns
 E: RGO_Cairns@health.qld.gov.au | T: (07) 4226 5512

and

Rosemary Schmidt, TCHHS Research Governance Officer
 A: Level 9, Citi link Building, Cnr Spence and Sheridan Street, Cairns
 E: Torres-Cape-Research-Governance@health.qld.gov.au | T: (07) 4226 5966

The documents reviewed include:

<i>Ethically approved documents</i>	<i>Version</i>	<i>Date</i>
HREA Form (HREC/2019/QCH/52647)	Aug ver 2	26 August 2019
Protocol	1.0	17 April 2019
Patient Information Sheet	2	1 August 2019
Consent Form	2	7 August 2019
Consent to Release information form	1	10 April 2019
6-month follow up checklist	1	10 April 2019
Withdrawal of Consent Form	1	7 August 2019
Research Patient Leaflet	1	14 March 2019
Adjudication Form	1	25 March 2019
Data Collection Form/Case Report Form	1	10 April 2019
<i>Documents noted</i>	<i>Version</i>	<i>Date</i>
Cover letter – original submission	N/A	12 April 2019
Reply to HREC queries	N/A	9 August 2019
Letter of support from Dr Mark Wenitong, Chair, Research Governance Committee on behalf of Mr Paul Stephenson CEO, Apunipima Cape York Health Council	N/A	12 August 2019
Email of support from Dr Richard Stone, Director of Emergency Medicine, Division of Integrated Medicine, Emergency, Child and Youth Services, Cairns and Hinterland Hospital and Health Service	N/A	12 June 2019
Letter of support from Dr Richard Stone, Director of Emergency Medicine, Division of Integrated Medicine, Emergency, Child and Youth Services, Cairns and Hinterland	N/A	24 May 2019



Hospital and Health Service		
Letter of support from Ms Joy Savage, Executive Director of the Aboriginal and Torres Strait Islander Health Directorate, Office of the Chief Executive, Cairns and Hinterland Hospital and Health Service	N/A	8 May 2019
Email of support from Mr Dru Locos, Director of Medical Imaging & Breast screen Services, Cairns and Hinterland Hospital and Health Service	N/A	24 May 2019
CV – Dr Katrina May Starmer	N/A	<i>Undated</i>

Ethical approval of this project from the Far North Queensland Human Research Ethics Committee is valid from the 26 August 2019 to 25 August 2024 subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the FNQ HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions are attached.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the FNQ HREC’s policy and procedures. These instructions are attached.
 - In accordance with Section 3.3.22 (b) of the National Statement the Coordinating Principal Investigator will report to FNQ HREC **annually** in the specified format, the first report being due on the **26 August 2020** and a final report is to be submitted on completion of the study along with any publications.
- The Coordinating Principal Investigator will notify the FNQ HREC if the project is discontinued before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify FNQ HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. These instructions are attached.
- The Coordinating Principal Investigator will notify the FNQ HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- A copy of this ethical approval letter together with completed Site-Specific Assessment (SSA) and any other requirements must be submitted by all site Principal Investigators to the Research Governance Office at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

HREC/2019/QCH/52647 - 1354
Further information received – Study Approved
07.08 ES:jld
Telephone: (07) 4226 5513
Email: Cairns_Ethics@health.qld.gov.au



Queensland
Government

Far North Queensland
Human Research Ethics Committee

Should you have any queries about the FNQ HREC's consideration of your project please contact the HREC Coordinator on 07 4226 5513 or via email Cairns_Ethics@health.qld.gov.au.

The FNQ HREC wishes you every success in your research.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'E. Strivens'.

Prof Edward Strivens
Acting Chair, Far North Queensland Human Research Ethics Committee
Cairns and Hinterland and Torres and Cape Hospital and Health Services

This HREC is registered with the NHMRC (EC00157), 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.