

Metro North

Hospital and Health Service

Royal Brisbane & Women's Hospital Human Research Ethics Committee

Ann-Maree Gordon

Coordinator

Telephone:

Enquiries to:

07 3646 5490

Facisimile:

07 3646 5849

File Ref:

HREC/17/QRBW/301

Email:

RBWH-Ethics@health.qld.gov.au

Dr David Fielding
Department of Thoracic Medicine
Level 3, Dr James Mayne Building
Royal Brisbane & Women's Hospital
Herston Old 4029

Dear Dr Fielding,

Re: Ref Nº: HREC/17/QRBW/301: Streamlining lung cancer diagnosis through genomic testing of cytology smears

Thank you for submitting the above research project for single ethical review. This project was considered by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (EC00172) at its meeting held on 12 June 2017. The research project meets the requirements of the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007).

I am pleased to advise that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

The nominated participating sites for this project are:

- Royal Brisbane & Women's Hospital
- Sunshine Coast University Hospital
- Gold Coast University Hospital

Note: If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the RBWH HREC. Notification of withdrawn sites should also be provided to the RBWH HREC in a timely fashion.

This letter constitutes ethical approval only. This project cannot proceed at any 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.

The approved documents include:

Document	Version	Date
Covering Letter		29 May 2017
Email notification of Principal Investigators at Gold Coast University Hospital and Sunshine Coast University Hospital		29 May 2017
Application: NEAF (Submission Code: AU/1/204E213)	2.2 (2014)	29 May 2017
Protocol		
TSANZSRS 2017 Abstract		
Curriculum Vitae of Dr Carl Michael Pahoff		
Curriculum Vitae of Dr Michael Putt		09 November 2015
Response to Request for Further Information		18 September 2017
Participant Information Sheet and Consent Form	2.0	18 September 2017

Approval of this project from the RBWH HREC is valid from **21.09.2017** to **21.09.2020** 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 RBWH 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 can be found at https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/default.asp.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the RBWH HREC policy and procedures. These instructions can be found at https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp.
- In accordance with Section 3.3.22 (b) of the National Statement the Coordinating Principal Investigator will report to the RBWH HREC annually in the specified format, the first report being due on **21.09.2018** and a final report is to be submitted on completion of the study. These instructions can be found at https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp.
- The Coordinating Principal Investigator will notify the RBWH HREC if the project is discontinued before the expected completion date, with reasons provided.

- The Coordinating Principal Investigator will notify the RBWH HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/default.asp.
- The Coordinating Principal Investigator will notify the RBWH 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.
- Should you have any queries about the RBWH HREC's consideration of your project
 please contact the HREC Coordinator on 07 3646 5490. The RBWH HREC's Terms of
 Reference, Standard Operating Procedures, membership and standard forms are available
 from https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/membership/default.asp.

The RBWH HREC wishes you every success in your research.

Yours sincerely,

Dr Allison Sutherland

A/Chairperson RBWH Human Research Ethics Committee

Metro North Hospital and Health Service

21.09.2017

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).* The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.