

**CHILDREN'S HEALTH QUEENSLAND
HOSPITAL AND HEALTH SERVICE
HUMAN RESEARCH ETHICS COMMITTEE**

Professor Alan Isles AM (Chair) 3069 7002
Mrs Amanda Smith (Co-ordinator) 3069 7002



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Queensland Children's Hospital Precinct
62 Graham Street, South Brisbane QLD 4101
Telephone (07) 3069 7002

10TH October 2019

Professor Claire Wainwright
Department of Respiratory & Sleep Medicine
c/ Centre for Children's Health Research
Level 7, 62 Graham Street
South Brisbane QLD 410

Dear Professor Wainwright,

HREC Reference number: HREC/19/QCHQ/58696

Project title: Finding the Optimal Regimen for *Mycobacterium abscessus* Treatment (FORMaT).

Many thanks for the submission of the above project for **paediatric** review. The Committee notes that this project has been reviewed and approved by The Prince Charles Hospital HREC for the adult component.

I am pleased to advise the proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and the Committee is happy to give approval. 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), and all subsequent updates, the Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice.

This project has **paediatric** Ethics approval for the following sites:

- Queensland Children's Hospital, Brisbane/Centre for Children's Health Research

Please note the HREC does not issue pre-determined approval periods. Ethical approval is ongoing, subject to the submission of an annual report on the anniversary of approval.

The documents reviewed and approved include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Cover Letter		19 June 2019
Application		11 July 2019
Protocol	1.3.1	7 August 2019
Participant Information Sheet and Consent Form Parent/Guardian consenting on behalf of participant (Child)	1.0	12 September 2019
Participant Information Sheet and Consent Form Parent/Guardian consenting on behalf of participant (Intervention Program)	1.0	2 September 2019
Participant Information Sheet and Consent Form Parent/Guardian consenting on behalf of participant (Sub-Studies)	1.0	18 September 2019
Participant Information Sheet and Consent Form Pregnancy Information Collection Child	1.0	18 September 2019
MBS/PBS Child Consent Form	1.0	6 August 2019
CFQ-R – Adolescents and Adults (Patients 14 years old and older)	3.0	2012
CFQ-R – Children ages 12 and 13 (Self report format)	3.0	2012
CFQ-R – Children Ages 6 to 11 (Interviewer Format)	3.0	2012

CFQ-R – Parents/Caregivers (Children Ages 6 to 13)	3.0	2012
The European Community Respiratory Health Survey II – Main Questionnaire		
PedsQL – Young Child Report (ages 5-7)	4.0	
PedsQL – Child Report (ages 8-12)	4.0	
PedsQL – Parent Report for Young Child (ages 5-7)	4.0	
PedsQL – Parent Report for Children (ages 8-12)	4.0	
RAND – Short Form-34	1.0	10 July 2019
Child Health Utility 9D		18 January 2008
Participant Wallet Card	1.0	7 July 2019
Radiation Safety Report		16 September 2019

Please note the following conditions of approval:

1. We require an annual progress report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report. Failure to comply with this requirement may result in suspension of the project by the HREC.
A comprehensive Final Report upon completion of the project. (In accordance with National Statement 5.5.3)
2. Please note if identifiable or potentially re-identifiable data for this research project is to be accessed without the written consent of the person to whom the data relates an application for disclosure of this data must be made under the *Public Health Act*. Further information regarding the *Public Health Act* is available via this link: http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp
3. Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
4. If the project does not proceed, the Committee must be informed as soon as possible. (In accordance with National Statement 5.5.6)
5. The Committee must be informed of any potential or realised problem with bioethical implications, if such occurs during the conduct of the research project.
6. Any serious adverse event (SAE) that arises in the context of this research, or involving a researcher conducting this research, must be reported to the Ethics Committee within 72 hours and reported to the sponsor (if applicable) within the stipulated time frame.

Serious Adverse Event Reports that are generated off-site may be (a) Serious Unexpected Adverse Reactions or (b) Serious Events which the Research Team believes cannot be related to the research intervention. The Research team must report incidents of (a) during multi-centre trials. Such are required to be submitted to the Chair of HREC on receipt by the researcher. A summary of the SAE reports is to accompany the submission. Information required includes; patient details (age & sex), adverse event, outcome and the likelihood of the event being related to the study drug/device/procedure.

With respect to all SAEs, the researcher must provide his or her opinion as to whether the SAE is directly related to the research intervention. A copy of the SAE Summary must be provided.

8. The HREC, authorising institution and/or their delegate/s may conduct an audit of the project at any time.

9. Ethical approval to undertake this research project is given on the understanding that you have an intention to publish your findings in a refereed journal or similar peer-reviewed forum. If you do not have this intention, it is an absolute requirement that you notify the Ethics Committee formally. In this latter instance, approval for this research is not given at this time; and will require further negotiation. Your work must be in accordance with the following:
- *National Statement on Ethical Conduct in Human Research:*
<https://www.nhmrc.gov.au/guidelines/publications/e72>
 - *Queensland Health Management Research Policy:*
http://www.health.qld.gov.au/ohmr/html/regu/resrch_mge_policy.asp
 - *Declaration of Helsinki:*
<http://www.wma.net/en/30publications/10policies/b3/17c.pdf>
 - *Guidelines under Section 95 of the Privacy Act 1995 and Guidelines approved under Section 95A of the Privacy Act 1995.*
http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp
 - *Queensland Health Privacy Guidelines IS42 & IS42A:*
<http://www.health.qld.gov.au/privacy/IS42A.asp>
10. Researchers should note, if not QLD Health employees, a Blue Card may be required for contact with children.
11. The Researcher must send the 'Notification of Commencement of Research Protocol' as soon as research begins. Status of the project will remain as 'Not Started' until this form is received.
12. In accordance with the National Statement (3.3.12), before beginning the clinical phase of the research, researchers should register clinical trials in a publicly accessible domain.

Should you have any queries about the HREC's consideration of your project please contact Mrs Amanda Smith (Co-ordinator) or Professor Alan Isles (Chairperson). 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

You are reminded that 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 HREC wishes you every success in your research.

Yours sincerely,



Professor Alan Isles AM
Chair
Children's Health Queensland
Hospital and Health Service
Human Research Ethics Committee

Cc: Ethics Committee Files

**Children's Health Queensland Hospital and Health Service Human
Research Ethics Committee (HREC)**

NOTIFICATION OF COMMENCEMENT OF RESEARCH PROTOCOL

HREC No: HREC/19/QCHQ/58686

PROTOCOL TITLE: Finding the Optimal Regimen for *Mycobacterium abscessus* Treatment (FORMaT).

PRINCIPAL INVESTIGATOR: Professor Claire Wainwright

This is to advise that the above research protocol commenced on:

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Signature:----- Date: -----/-----/-----

Please forward to CHQ HREC:
Amanda Smith, Co-ordinator HREC
Level 7, Centre for Children's Health Research
Queensland Children's Hospital Precinct
62 Graham Street, South Brisbane QLD 4101

