

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

Professor Alan Isles AM (Chair) 3069 7002  
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29<sup>th</sup> June 2020

Dr Adeline Lim  
Respiratory Fellow  
Department of Respiratory & Sleep Medicine  
Queensland Children's Hospital  
South Brisbane QLD 410

Dear Dr Lim,

**HREC Reference number: HREC/19/QCHQ/53788**

**Project title: Orkambi in patients with cystic fibrosis and severe liver disease.**

Many thanks for your submission of an amendment for the above project. This has now been reviewed and the Committee notes and approves this amendment. The documents reviewed and approved include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Amendment submission		1 June 2020
Protocol	2.0	22 May 2020
Parent/Guardian Information Statement	2.0	22 May 2020
Child Information Sheet	2.1	28 June 2020

The Children's Health Queensland HREC is constituted and operates in accordance with the National Health and Medical Research Council's "*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*".

A copy of this letter must be forwarded to any Research Governance Office that is impacted by this amendment. It should be noted that all requirements of the original approval still apply.

Yours sincerely,

A handwritten signature in blue ink that reads 'Isles'.

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

Cc: Ethics Committee Files