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

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23rd November 2021

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 letter received 20th November regarding 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:

Document	Version	Date
Cover Letter		8 November 2021
Protocol	3.0	8 November 2021
Parent/Guardian Information Statement	3.0	8 November 2021
Child Information Sheet	3.0	8 November 2021

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,

Professor Alan Isles AM

Chair

Children's Health Queensland Hospital and Health Service

Human Research Ethics Committee

Cc: Ethics Committee Files