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

Queensland Government

Level 7, Centre for Children's Health Research
Lady Cilento Children's Hospital Precinct
62 Graham Street, South Brisbane QLD 4101
Telephone (07) 3069 7002

8th August 2017

Dr Thuy Frakking
Research Development Unit
Executive Building 3
Caboolture Hospital
Caboolture, QLD 4510

Dear Dr Frakking,

HREC Reference number: HREC/17/QRCH/159
Project title: A randomised controlled study to evaluate an integrated care pathway for vulnerable children with chronic disease – connecting the dots in healthcare provision

Many thanks for your letter of the 3rd August together with response to queries for the above project. This has now been reviewed.

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 Ethics approval for the following sites:

- Gold Coast University Hospital
- Caboolture 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 HREC. Notification of withdrawn sites should also be provided to the HREC in a timely fashion.

The documents reviewed and approved include:

Document	*Version*	*Date*
Cover letter		13 July 2017
Application		
Child/Adolescent Information Sheet	1	12 July 2017
Parent/Guardian Consent form	2	16 June 2017
Protocol	1	22 June 2017
Response to Request for Further Information		
Parent Information Sheet	2	03 August 2017

Please note the following conditions of approval:

1. We require an annual progress report (or sooner if the project is completed) concerning the study. This must include progress to date or outcome in the case of completed research. Ethics approval is for 3 years from date of this letter. (In accordance with National Statement 5.5.3)

2. 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.

3. 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**

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. (This can be obtained from the Ethics Officer)

7. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Major amendments should be reflected in a revised online NEAF (accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised NEAF, the cover letter and all relevant updated documents with tracked changes must also be submitted to the HREC and the RGO as per standard HREC/RGO SOP.

8. The Ethics Committee may conduct a randomly identified audit of a proportion of research projects approved by the Committee. That audit process will look at such issues as;
   a. Security of Documents
   b. Consent Form Register
   c. Serious Adverse Events Register
   d. Withdrawal of Participants – who and why
   e. The de-identification of data

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 Act1995 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.

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/17/QRCH/159**

PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR:

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

/ /

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

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