ETHICS APPROVAL & GOVERNANCE AUTHORISATION

17 January 2023

Miss Jen Corda
Physiotherapy
The Royal Children's Hospital Melbourne

Dear Miss Corda,

Project Title: **Acceptability, feasibility and impacts of remote symptom monitoring and automated treatment plans in children with Cystic Fibrosis on highly effective modulators: a pilot randomised controlled trial**

HREC Reference Number: **91117/RCHM-2022**
RCH HREC Reference Number: **91117**

I am pleased to advise that the above project has received **ethical approval** from The Royal Children's Hospital Melbourne Human Research Ethics Committee (HREC).

The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

The project has also received **governance authorisation at the Melbourne Children's Campus** (incorporating The Royal Children's Hospital, Murdoch Children's Research Institute and the University of Melbourne Department of Paediatrics).

HREC Approval Date: 17 January 2023

Please note ongoing ethics approval is subject to the submission of a progress report on* **17 January *annually.*

Approved Documents:
The following documents have been reviewed and approved:

Document	Version	Date
Research Protocol	2.0	28 October 2022
Initial study information letter	1.0	27 October 2022
Screening questionnaire	1.0	27 October 2022
PICF – Families	3.0	23 November 2022
PICF – Child	3.0	23 November 2022
PICF – CF MDT	3.0	23 November 2022
Baseline demographic survey	1.0	27 October 2022
Patient onboarding information	1.0	27 October 2022
Baseline and Weekly Symptom survey	1.0	27 October 2022
Survey calculations to detect exacerbation	1.0	27 October 2022

baseline demographic data collection	1.0	27 October 2022
3, 6 and 12 month check in surveys	1.0	27 October 2022
Interview guide for parents	1.0	27 October 2022
Interview guide for CF MDT	1.0	27 October 2022
CF information Manual Pack	1.0	27 October 2022

Acknowledged Documents
The following documents have been noted:

Document	Version	Date
CFQ-R	1.0	27 October 2022
EQ-5D-Y	1.0	27 October 2022

Conditions of Ethics Approval:

- You are required to submit to the HREC:
    - 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, due within one month of the approval anniversary. 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.
- 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.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Safety monitoring and reporting in clinical trials involving therapeutic goods November 2016*.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves exposure of persons to ionising radiation, you must ensure that your research is carried out in accordance with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice for the 'Exposure of Humans to Ionizing Radiation for Research Purposes (2005)' (Radiation Protection series Publication No.8)
- The HREC, authorising institution and/or their delegate/s may conduct an audit of the project at any time.
- Comply with the following privacy of patient information statement:
    - Accessing identified patient information from health services other than your own for research purposes is not permitted. Precinct polices regarding appropriate access MUST be followed. Identified patient information must ONLY EVER be accessed after governance authorisation or quality assurance (QA) approval from the appropriate health service.

Yours sincerely

Margarete Kleinschmidt
Research Ethics and Governance Officer
Research Ethics and Governance
The Royal Children's Hospital Melbourne
Phone : (03) 9345 5044
Email : rch.ethics@rch.org.au
Web : www.rch.org.au