

10 April 2020

A/Prof Craig Jefferies
Starship Children's Health
2 Park Road, Grafton
Auckland 1023

Dear A/Prof Jefferies

Re:	Ethics ref:	20/NTA/12
	Study title:	Flash glucose monitoring in children with Type 1 diabetes to improve diabetes control: The FLASH-1 Study

I am pleased to advise that this application has been approved by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern A Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or <https://clinicaltrials.gov/>.
3. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.


Your next progress report is due by 9 April 2021.

Participant access to ACC

The Northern A Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'K O'Connor', with a long horizontal flourish extending to the right.

Kate O'Connor
Chairperson
Northern A Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

<i>Document</i>	<i>Version</i>	<i>Date</i>
PIS/CF: For participants who are 12 to 13 years old	1	07 January 2020
PIS/CF: For participants who are 7-11 years old	1	23 December 2019
Survey/questionnaire: Both child and parent questionnaires	1	23 December 2019
CV for CI	1	23 December 2019
PIS/CF: Participant information sheet and consent form for parents	1	07 January 2020
Evidence of scientific review: Peer review by Professor Fergus Cameron.	1.0	21 December 2019
Protocol: Protocol with questionnaires in the appendix	1	08 January 2020
Covering Letter	1	08 January 2020
Application		24 January 2020
Covering Letter: Cover letter with itemized responses	1	18 March 2020
Protocol: Study protocol - clean	2.0	18 March 2020
Protocol: Study protocol - tracked	2.0	18 March 2020
PIS/CF: PIS 4-7y	1.0	18 March 2020
PIS/CF: PISAF - 8-11 y - clean	2.0	18 March 2020
PIS/CF: PISAF - 8-11 - tracked	2.0	18 March 2020
PIS/CF: PISAF - 12-14 y - clean	2.0	18 March 2020
PIS/CF: PISAF - 12-14 y - tracked	2.0	18 March 2020
PIS/CF: PISCF - parents - clean	2.0	18 March 2020
PIS/CF: PISCF parents - tracked	2.0	18 March 2020
Survey/questionnaire: PedsQL - Young child	1.0	18 March 2020
Survey/questionnaire: PedsQL - Child self-report	1.0	18 March 2020
Survey/questionnaire: PedsQL - Child parent-proxy	1.0	18 March 2020
Survey/questionnaire: PedsQL - Toddler parent-proxy	2.0	18 March 2020
Survey/questionnaire: PedsQL - teen self-report	1.0	18 March 2020
Survey/questionnaire: PedsQL - Teen parent proxy	1.0	18 March 2020

Appendix B Statement of compliance and list of members

Statement of compliance

The Northern A Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Kate O'Connor	Lay (consumer/community perspectives)	14/12/2018	14/12/2021
Dr Karen Bartholomew	Non-lay (intervention studies)	18/07/2016	18/07/2022
Dr Sotera Catapang	Non-lay (observational studies)	11/02/2020	11/02/2023
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Ms Catherine Garvey	Lay (the law)	19/03/2019	19/03/2022
Professor Graham Mellsop	Non-lay (health/disability service provision)	11/02/2020	11/02/2023
Dr Michael Meyer	Non-lay (health/disability service provision)	11/02/2020	11/02/2023
Dr Kate Parker	Non-lay (observational studies)	11/02/2017	11/02/2023
Ms Rochelle Style	Lay (ethical/moral reasoning)	14/06/2017	14/06/2020

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

<http://www.ethics.health.govt.nz>