Health and Disability Ethics Committees
Ministry of Health
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23 June 2020

Dr Deborah Harris
PO Box 7625
Newtown, Wellington 6021

Dear Dr Harris

Re:	**Ethics ref:**	**20/CEN/47**
	Study title:	Pepi Splint Project - Intervention Proof of Concept Study

I am pleased to advise that this application has been *approved* by the Central Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.
The Committee noted a typographical error in the Participant Information Sheet brochure, please change the line, "your babies medical records" to "your baby's medical records".

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 Central 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 22 June 2021.

Participant access to ACC

The Central 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,

Mrs Helen Walker
Chairperson
Central Health and Disability Ethics Committee

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

Appendix A
Documents submitted

Document	*Version*	*Date*
Declined letter for previous application in respect of the same (or substantially similar) study: Letter	Version 1	20 December 2019
CVs for other Investigators: CV for Site Investigator	Version 1	30 July 2019
CVs for other Investigators: CV for Fiona Dineen	Version 1	30 July 2019
Evidence of CI indemnity	Version 1	30 July 2019
Evidence of scientific review: Peer Review	Version 1	27 September 2019
PIS/CF for persons interested in welfare of non-consenting participant: Parent information sheet	Version 2	01 March 2020
PIS/CF for persons interested in welfare of non-consenting participant: Consent form	Version 2	01 March 2020
Protocol: Pepi Splint Project protocol	Version 2	01 March 2020
Survey/questionnaire: Parent questionnaire	Version 2	01 March 2020
Conference poster	Version 1	29 November 2019
Newborn Intensive Care Poster	Version 2	01 March 2020
Adverse event form	Version 2	01 March 2020
Data Collection form	Version 2	01 March 2020
Letter of support	Version 1	06 November 2019
Confidential letter regarding Serious event	Version 1	01 November 2016
Covering Letter: Response letter	Version 1	09 March 2020
Covering Letter	Version 1	09 March 2020
CV for CI: CV Deborah Harris	Version 1	09 March 2020
Application		09 March 2020
PIS/CF for persons interested in welfare of non-consenting participant: PIS with changes	Version 3	26 May 2020
PIS/CF for persons interested in welfare of non-consenting participant: PIS: Clean version	Version 5	26 May 2020
PIS/CF for persons interested in welfare of non-consenting participant: Consent form with changes highlighted	Version 3	26 May 2020
PIS/CF: Consent form -Clean	Version 3	26 May 2020
Covering Letter: Cover letter, seeking full approval	Version 1	01 June 2020
Response to Request for Further Information		

Appendix B
Statement of compliance and list of members

Statement of compliance

The Central 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 00008712) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2018	01/07/2021
Ms Helen Davidson	Lay (ethical/moral reasoning)	06/12/2018	06/12/2021
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018
Dr Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Cordelia Thomas	Lay (the law)	20/05/2017	20/05/2020

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