Health and Disability Ethics Committees
Ministry of Health
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PO Box 5013
Wellington
6011
0800 4 ETHICS
hdecs@moh.govt.nz

15 February 2013

Dr Jo Hegarty
Newborn Services
Auckland City Hospital
2 Park Road
Auckland 1023

Dear Dr Hegarty

Re:	**Ethics ref:**	**13/NTA/8**
	Study title:	A randomised trial of oral dextrose gel for prevention of hypoglycaemia in at risk newborn babies.

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.

The main ethical issues considered by the Committee were as follows.

- The Committee discussed the design of the study, which could be conceptualised as two separate studies. The first part of the study would establish effective oral dose in 415 participants. Dr Hegarty noted that there was no evidence around effective dose, and explained how the research team had estimated these. The second part of the trial would involve more than 2000 participants.
- The researchers clarified that evidence of peer review from the HRC had not yet been obtained, as the review had not been completed. The study had already been reviewed and funded by CureKids. The Committee asked for evidence of HRC peer review to be forwarded when available.
- The Committee discussed whether a separate set of information should be provided to participants in the first part of the study. The researchers noted that the information was intended to cover both parts of the study, and that adapting it to the second part would involve only minor changes (eg, removing reference to continuous glucose monitoring). The Committee asked for a substantial protocol amendment to be submitted once the effective dose had been established. The researchers confirmed that the PISCF would also be revised and resubmitted at this stage. The Committee suggested that the PISCF for participants in the initial, dose-finding phase of the study could be more specifically tailored to this part.
- The Committee queried the standard treatment currently available for this condition. The researchers clarified that all participants would receive standard care, with closer monitoring than might otherwise be the case.
- The Committee asked that the PISCF be clear that only health information in the mothers' medical records that was "relevant to this pregnancy" would be accessed by the research team, and that specific consent be obtained to follow-up.

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 WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

3. Before the study commences at *a 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

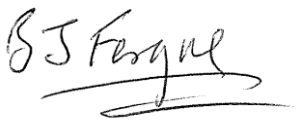
Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

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,



Dr Brian Fergus
Chairperson
Northern A Health and Disability Ethics Committee

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

18th August 2016

Women's & Children's Hospital

Research Secretariat
Level 2, Samuel Way Building
72 King William Road
Tel 08 8161 6390
Tel 08 8161 6521
www.wch.sa.gov.au

Ms P Ashwood
University Dept of Obstetrics and Gynaecology
WCHN

Dear Pat

Re: A randomised controlled trial comparing prophylactic oral dextrose gel with placebo in newborn babies at risk of neonatal hypoglycaemia. HREC/16/WCHN/86. Ethics expiry date: 31/08/2019.

Lead HREC for the above study for the following institutions/sites:

Women's and Children's Health Network

I refer to your letter dated 27th July 2016 in which you responded to matters raised by the Drug & Therapeutics Committee Clinical Trials Group at its meeting on 9th June 2016 and the WCHN Human Research Ethics Committee at its 22nd June 2016 meeting. I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

Specifically, the following documents have been noted/approved:

Document	*Version*	*Date*
Master Participant Information Sheet and Consent Form: Australian Master hPOD Information Sheet and Consent Form	2	22 July 2016
hPOD Case Report Form Booklet (Australia)	1	22 July 2016
Promotional Poster A	1	22 July 2016
Promotional Poster B	1	22 July 2016
Response to Request for Further Information: Response Letter		27 July 2016
Site Specific Participant Information Sheet: WCH hPOD Information Sheet	2	22 July 2016
Protocol: Main Protocol for Australian Sites	V 6	23 October 2015
Poster for Health Professionals	V1	25 May 2016
Questionnaire/s: 6 week Questionnaire	V5	27 March 2015
Medsafe Approval Letter		16 November 2015
Medsafe Application Form	V1	01 March 2013
Covering Letter	V1 - Submission	25 May 2016
Poster for Women	V1	25 May 2016
Drug data sheet: Dextrose Gel Information Sheet		01 May 2016
Protocol: Protocol with explanatory notes for WCH only	V 6.1	24 May 2016
NEAF Application: AU/1/7176213		27 May 2016

This letter constitutes advice on ethical consideration only. You must not commence this research project at a site until you have obtained separate research governance approval from the site concerned. A copy of this letter should be forwarded to all site investigators for submission to the relevant Research Governance Officer.

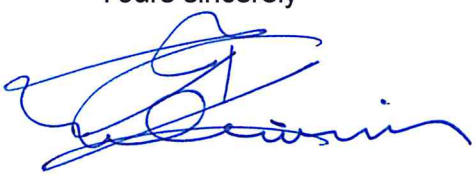
Government of South Australia
SA Health

At the WCHN, or any other SA Health site, separate authorisation from the Chief Executive or delegate of that site must be obtained through a Site Specific Assessment (SSA) request. For information on this process at the WCHN, please contact the WCHN Research Governance Officer, Ms Camilla Liddy (telephone 8161 6688, email camilla.liddy@health.sa.gov.au).

I remind you approval is given subject to:
- immediate notification of any serious or unexpected adverse events to participants;
- immediate notification of any unforeseen events that might affect continued ethical acceptability of the project;
- submission of any proposed changes to the original protocol. Changes must be approved by the Committee before they are implemented;
- immediate advice, giving reasons, if the protocol is discontinued before its completion;
- submission of an annual report on the progress of the study, and a final report when it is completed to the WCHN Research Governance Officer. It is your responsibility to provide these reports, without reminder. The proforma for the report may be found on the WCHN Research Governance and Ethics website.

Approval is given for three years only. If the study is more prolonged than this, an extension request should be submitted unless there are significant modifications, in which case a new submission may be required. Please note the expiry date in the title above and include it in any future communications.

Yours sincerely



TAMARA ZUTLEVICS (DR)
CHAIR
WCHN HUMAN RESEARCH ETHICS COMMITTEE