

11 July 2013

Ms Barbara Cormack
Nutrition Services
Level 8
Auckland City Hospital
Private bag 92024
Auckland 1023

Dear Ms Cormack

Re:	Ethics ref:	13/NTB/84
	Study title:	PROVIDE: The impact of Protein Intravenous Nutrition on Development in preterm babies. A randomised controlled trial of more intravenous protein in the first week of life

I am pleased to advise that this application has been approved by the Northern B 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 B 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 B 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 Raewyn Sporle
Chairperson
Northern B 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>
CV for CI: Barbara Cormack CV	1	31 May 2013
Evidence of scientific review: Gravida Funding response	1	10 May 2013
Covering Letter: Covering letter	1	14 June 2013
Evidence of scientific review: A+ Trust response letter	1	31 May 2013
PIS/CF: Consent form	1	14 June 2013
Protocol: ProVIDe Protocol	3.3	14 June 2013
Evidence of scientific review: Gravida Scholarship Response	1	10 May 2013
PIS/CF for persons interested in welfare of non-consenting participant: PIS	1	14 June 2013
Application		18 June 2013
Response to Request for Further Information: ProVIDE Consent Form V3	3	01 July 2013
Response to Request for Further Information: Revised ProVIDE Parent Information Sheet V6	6	01 July 2013

Appendix B Statement of compliance and list of members

Statement of compliance

The Northern B 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 00008715) 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 Raewyn Sporle	Lay (the law)	01/07/2012	01/07/2015
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2012	01/07/2014
Mrs Mary Anne Gill	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Mrs Kate O'Connor	Non-lay (other)	01/07/2012	01/07/2015
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr David Stephens	Lay (consumer/community perspectives)	01/07/2012	01/07/2014
Dr Paul Tanser	Non-lay (health/disability service provision)	01/07/2012	01/07/2014
Ms Kerin Thompson	Non-lay (intervention studies)	01/07/2012	01/07/2015

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