Health and Disability Ethics Committees
Ministry of Health
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0800 4 ETHICS
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12 April 2016

Dr Christine McIntosh
Kidz First Admin. Middlemore Hospital
Private Bag 93311
Otahuhu
Auckland 1640

Dear Dr McIntosh

Re:	**Ethics ref:**	**16/NTB/53**
	Study title:	Implementing a Safe Sleep Calculator into Primary Care to identify and address risk in infants more vulnerable to Sudden Unexpected Death in Infancy.

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-Expedited 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 clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.

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.

Your next progress report is due by 11 April 2017.

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,

Kate O'Connor
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

Document	*Version*	*Date*
Protocol: Project overview studies 1-6 with protocols, and scripts for qualitative interviews.	2	03 March 2016
PIS/CF: Participant information sheet and consent form Study 1	4	11 April 2016
PIS/CF: Participant information sheet and consent study 2	2	11 April 2016
PIS/CF: Participant information sheet Study 4	3	11 March 2016
CV for CI: CV Christine McIntosh	1	03 March 2016
CVs for other Investigators: CV Ed. Mitchell	1	03 March 2016
CVs for other Investigators: CV David Tipene-Leach	1	03 March 2016
Flyer for participants study 1 and 4	1	03 March 2016
Evidence of scientific review: Award of grant as evidence of scientific review	1	16 November 2015
Survey/questionnaire: Please see appendix for qualitative questions for studies 1 and 2.	2	03 March 2016
Head of Paediatrics Department approval	1	11 March 2016
PIS/CF: Participant Information Sheet Study 1 Version 4	4	11 April 2016
PIS/CF: Participant Information Sheet Study 2 Version 2	2	11 April 2016
PIS/CF: Participant Information Sheet Study 4 version 3	3	11 April 2016
Protocol: Project overview incl protocol studies 1-4	3	11 April 2016
Protocol: Protocol for obtaining verbal consent	1	11 April 2016
Confidentiality Agreement Transcriber - signed	1	11 April 2016
Covering Letter: Response to Ethics.	1	11 April 2016

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

Name	*Category*	*Appointed*	*Term Expires*
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018
Mrs Phyllis Huitema	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
Dr Nora Lynch	Non-lay (health/disability service provision)	24/07/2015	24/07/2018
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
Mrs Kate O'Connor	Lay (ethical/moral reasoning)	14/12/2015	14/12/2018
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2015	01/07/2018
Mrs Leesa Russell	Non-lay (intervention studies), Non-lay (observational studies)	14/12/2015	14/12/2018

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