

Health and Disability Ethics Committees
Ministry of Health
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15 August 2017

Ms Leith Pugmire 522 Kahuterawa Road RD2 Palmerston North 4472

Dear Ms Pugmire

Re: Ethics ref: 16/STH/186/AM01

Study title: Parenting from the start: Evaluating a preventative intervention to

improve infant attachment and family health

I am pleased to advise that this amendment has been <u>approved</u> by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

Note From Chair: Please supply an amended protocol (tracked changes version) incorporating the proposed change to inclusion criteria for our records.

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

Yours sincerely,

Ms Raewyn Idoine Chairperson

Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted

appendix B: statement of compliance and list of members

Appendix A Documents submitted and approved

Document	Version	Date
New recruitment poster	6	17 July 2017
Survey/questionnaire: New screening questionnaire	3	17 July 2017
PIS/CF: New information sheet & consent form - Group A (first baby, control)	3	17 July 2017
PIS/CF: New information sheet & consent form - Group B (first baby, intervention)	4	17 July 2017
PIS/CF: New information sheet & consent form - Group C (subsequent baby, control)	1	17 July 2017
PIS/CF: New information sheet & consent form - Group D (subsequent baby, intervention)	1	17 July 2017
Post Approval Form	AM01	20 July 2017

Appendix B Statement of compliance and list of members

Statement of compliance

The Southern 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 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	Category	Appointed	Term Expires
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
Dr Sarah Gunningham	Non-lay (intervention studies)	27/10/2015	27/10/2018
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Fiona McCrimmon	Lay (the law)	27/10/2015	27/10/2018
Dr Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
Dr Devonie Waaka	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Mathew Zacharias	Non-lay (health/disability service provision)	27/10/2015	27/10/2018

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