Research Office File No: (6091)

Project ID	2019/PID00733
Ethics Ref:	2019/ETH00672
Governance Ref:	NOT SUBMITTED

2 January 2020

Ms Lynn Tunchon
Child and Family Health Integrated
and Community Health
WSLHD

Dear Ms Tunchon

Project title: An effectiveness-implementation trial of the parenting Plus program for new parents

Thank you for your correspondence addressing the matters raised in the HREC's letter dated 13 June 2019 following single ethical review of the above project at its meeting held on 11 June 2019.

This HREC has been accredited by the NSW Department of Health as a lead HREC to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research and the CPMP/ICH Note for Guidance on Good Clinical Practice.
This proposal meets the requirements of the National Statement and I am pleased to advise that the HREC has now granted ethical approval of this research project to be conducted at:

- WSLHD – Coordinating Principal Investigator Ms Lynn Tunchon
  - Community Health Centres: Auburn / Doonside / Mt Druitt / Parramatta / Merrylands / The Hills
  - Community Migrant Resource Centre
  - Wiyanga House Parramatta Mission
  - Women's Health Clinic Westmead Hospital
- SLHD – Principal Investigator Ms Paula Caffrey
  - Early Childhood Centres: Alexandria Park / Balmain / Belmore / Campsie / Chiswick / Concord / Croydon / Earlwood / Five Dock / Forest Lodge / Glebe Homebush / Lakemba / Leichhardt / Marrickville / Punchbowl
- SWSLHD – Principal Investigator Ms Wendy Geddes
  - Early Childhood Centres: Ingleburn / Narellan

The following documentation has been reviewed and approved by the HREC:

- HREA, version 5, dated 13 November 2019
- Protocol, version 4 dated 13 November 2019
- Master PICF Participants version 3, dated 23 July 2019

- Master PICF Facilitators version 1, dated 13 May 2019
- Master Group Details, version 1, dated 13 May 2019
- Master Recruitment log version 1, dated 13 May 2019
- Master Reminder Text Message, version 1, dated 13 May 2019
- Master Pre Assessment Combined version 2, dated 25 June 2019
- Master Immediate Post Assessment Combined version 1, dated 13 May 2019
- Master 6 Month Post Assessment Combined version 1, dated 13 May 2019
- Master Observation checklist version 1, dated 13 May 2019
- Master weekly emails for enrolled participants version 1, dated 13 May 2019
- Master weekly email links to additional resources version 1, dated 13 May 2019
- Master Parenting Plus certification of completion, version 1, dated 13 May 2019
- Master Participant focus group qualitative interview schedule, version 2, dated 25 June 2019
- Master Facilitator focus group – qualitative interview schedule, version 1, dated 13 May 2019
- Master Parenting Plus Powerpoint slides, version 2, dated 18 December 2019
- Master online quizzes, version 1, dated 13 May 2019
- Master weekly online resources for behaviour change, version 1, dated 13 May 2019
- Master attendance log, version 1, dated 13 May 2019
- Master recruitment flyer, version 2, dated 23 July 2019

Please note the following conditions of approval:

- The Coordinating Chief Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.
- For clinical trials of implantable medical devices only – The Coordinating Chief Investigator will confirm to the HREC that a process has been established for tracking the participant, with consent, for the lifetime of the device and will immediately report any device incidents to the Therapeutic Goods Administration (TGA).
- The Coordinating Chief Investigator will immediately report any protocol deviation / violation, together with details of the procedure put in place to ensure the deviation / violation does not recur.
- The Coordinating Chief Investigator will provide to the HREC in the specific format via REGIS, proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project. .
- The Coordinating Chief Investigator must notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.
- The Coordinating Chief Investigator must provide an annual report to the HREC and a final report at completion of the study, in the specified format.
- HREC approval is valid for 5 years contingent upon submission of an annual report via REGIS.
- The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived including
    1. Discussion of relevant aspects of the project with investigators, at any time,
    2. Random inspection of research sites, data or consent documentation,
    3. Interview with research participants or other forms of feedback from them, and
    4. Request and review reports from independent agencies such as a Data Safety Monitoring Board.
- If your research project is an interventional trial, please ensure it is registered on one of the clinical trial registries, eg http://www.actr.org.au.

- It should be noted that compliance with the ethical guidelines is entirely the responsibility of the Coordinating Chief Investigator.

In all future correspondence concerning this study, please quote Research Office File number ***(6091).***
The HREC wishes you every success in your research.

Yours sincerely

Mrs Patricia Fa
Secretary
WSLHD Human Research Ethics Committee

cc: Research Governance Officer