

A facility of St Vincent's & Mater Health Sydney

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28 September 2016

Prof Gavin Andrews CRUfAD Level 4 O'Brien Centre Darlinghurst NSW 2010

Dear Gavin

SVH File Number: 16/046

Project Title: A randomised controlled trial comparing the clinical efficacy of internet-delivered cognitive behavioural therapy for perinatal anxiety and depression to wait-list control: Perinatal 'MUMentum' Program

Short Title: Perinatal 'MUMentum' Program HREC Reference Number: HREC/16/SVH/63

Thank you for submitting requests for amendments dated 8 September 20136 and 22 September 2016 to the above project.

This was considered by the St Vincent's Hospital HREC at its Executive meeting held on **27 September 2016.** St Vincent's Hospital HREC (EC00140) has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National Certification Scheme. 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. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the documents reviewed and approved at the meeting were:

- MUMentum RCT Protocol Version 4: 07 09 16
- PICF MUMentum RCT Study 1: Version 4 07 09 16
- PICF MUMentum RCT Study 2: Version 4_07 09 16
- World Health Organisation Quality of Life Assessment-Bref (WHOQOL-BREF)
- Karitane Parenting Confidence Scale (KPCS)
- Maternal Antenatal Attachment Scale (MAAS)
- Maternal Postnatal Attachment Scale (MPAS)
- MUMentum RCT Protocol Version 5: 22.09.16
- Experiences and Perceptions Questionnaire of the Postpartum program
- PICF for Study 3 (version 1) 22.09.16
- PICF_MUMentum RCT Study 1_Version 5: 22 09 16
- PICF_MUMentum RCT Study 2_Version 5: 22 09 16

You are reminded that this letter constitutes ongoing ETHICAL and SCIENTIFIC review only. For multi-site projects reviewed by the HREC after 1 July 2007 a copy of this letter must be forwarded to all Principal Investigators at every site approved by SVH HREC for submission to the relevant Research Governance Officer along with a copy of the approved documents prior to implementation of the amendment.

Please note that only an electronic copy of this letter will be provided, if you require the original signed letter please contact the Research Office and we will be happy to provide this.

Should you have any queries regarding this project please contact the Research Office, Tel: (02) 8382-4960, email SVHS.Research@svha.org.au. The HREC Terms of Reference, Standard Operating Procedures, National Statement on Ethical Conduct in Human Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice and

standard forms are available on the Research Office website found at: https://svhs.org.au/home/research-education/research-office

Yours sincerely,

Sarah Charlton

HREC Executive Officer

St Vincent's Hospital Research Office

Translational Research Centre, 97-105 Boundary Street

cc: Jessica Smith

TRIM REF: D/2016/87744