

St Vincent's Hospital (Melbourne) Limited ABN 22 052 110 755

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13 January 2014

Dr Gwyn Rees Centre for Eye Research Australia Locked Bag 8 East Melbourne VIC 8002

Dear Dr Rees,

HREC-A Protocol number: HREC-A 137/13

'Personalising Eye Consultations (PEC) to improve outcomes of diabetic retinopathy.'

The St Vincent's Hospital (Melbourne) Human Research Ethics Committee-A has reviewed and approved the aforementioned study.

**Approval Status: FINAL** 

Period of Approval: 13 January 2014 - 13 January 2018

Ethical approval is given in accordance with the research conforming to the *National Health* and *Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research (2007)*.

Ethical approval is given for this research project to be conducted at the following sites:

St Vincent's Hospital (Melbourne)

## **Approved documents**

The following documents have been reviewed and approved:

Document	Version	Date
National Ethics Application Form (NEAF)	2	17/12/2013
Victorian Specific Module (VSM)	1	12/11/2013
Research Protocol	1	18/11/2013
Participant Information and Consent Form (PICF) – Feasibility and acceptability of the Personalised Eye Consultation training program and study protocol	2	18/12/2013

Facilities
St Vincent's Hospital Melbourne
Caritas Christi Hospice
St George's Health Service
Prague House

Participant Information and Consent Form (PICF) – RCT	2	18/12/2013
PICF Withdrawal Forms	1	18/11/2013
PEC Consultation Manual	1	27/10/2013
Invitation Letter	1	18/11/2013
Visit Reminder Letter	1	18/11/2013
General Questionnaire and Psychological, Cognitive and Behavioural Questionnaires		
Participant Evaluation Questionnaires and Withdrawal Questionnaires	1	25/10/2013
Process Evaluation Questionnaire	1	25/10/2013
PEC Information for Participants and Optional Take Home Sheets	1	18/11/2013

St Vincent's HREC-A Protocol number: HREC-A 137/13 Please quote these numbers on all Correspondence

## Approval is subject to:

- The Principal Researcher is to ensure that all associate researchers are aware of the terms of approval and to ensure the project is conducted as specified in the application and in accordance with the National Statement on Ethical Conduct in Human Research (2007).
- Immediate notification to the Research Governance Unit of any serious adverse events on participants.
- Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
- Notification and reasons for ceasing the project prior to its expected date of completion;
- Notification of proposed amendments to the study;
- Submission of an annual report, due on the anniversary date of approval, for the duration of the study.
- Submission of reviewing HREC approval for any proposed modifications to the project;
- Submission of a final report and papers published on completion of project;
- Projects may be subject to an audit or any other form of monitoring by the Research Governance Unit at any time.

The HREC wishes you and your colleagues every success in your research.

Yours sincerely,

Ms Anita Arndt

Senior Administrative Officer and HREC-A Secretary

Research Governance Unit

St Vincent's Hospital (Melbourne)